Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 40 and 70

Public Workshop on the Regulation of Radioactive Devices

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The NRC will hold a public workshop in Rockville, Maryland to review the regulatory program for devices containing radioactive materials licensed under 10 CFR Parts 30, 31, 32, 40 and 70. Interested members of the public are welcome to attend the meeting, however, for efficient conduct of the workshop, participation will be in the format of a round table discussion among invited representatives of potentially affected parties. The NRC has prepared a workshop agenda. This and related documents are available for review prior to the workshop and interested parties are encouraged to review this information. The NRC will accept and consider written comments from interested parties on this regulatory issue.

DATES: The workshop will be held on January 18, 1996 from 9:00 am to 5:00 pm. The workshop will continue, if necessary, on January 19, 1996 from 9:00 am to 12 noon. Comments on this regulatory issue should be received no later than January 31, 1996.

ADDRESSES: The public workshop will be held in the NRC auditorium at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. Visitor parking around the NRC building is limited, however, the workshop site is adjacent to the White Flint station on the Metro Red Line. Written comments can be provided at the workshop or by January 31, 1996 to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of the agenda and related documents can be obtained from the NRC's Public Document Room, 2120 L Street NW, Washington DC 20037; Phone: 202–634–3273; Fax: 202–634–3343.

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Mail Stop O–15B18, U.S. Nuclear Regulatory Commission, Washington, DC 20555; Phone: 301–415–1642; Fax: 301–415–3200; INTERNET:FXC@NRC.GOV.

SUPPLEMENTARY INFORMATION: Inadequate control of radioactive devices by licensees has lead to radioactive materials being included in metal scrap intended for recycling (see J. Lubenau & J. Yusko, ''Radioactive materials in Recycled Metals,'' *Health Physics*, 68:4, April, 1995). Radioactive sources have been accidentally smelted in metal mills resulting in radioactive contamination of mills, metal products and mill byproducts. In the U.S., costs attributable to decontamination, waste disposal and temporary mill closures following a smelting of a radioactive source have been as much as $23,000,000 per event. There is a risk of radiation exposure to unsuspecting workers and members of the public. In 1990, the Commission determined that the problem needed to be addressed and directed a rulemaking to improve oversight of generally licensed devices. The proposed rule was published for public comment in 1991 (56 FR 67011, 26 December 1991). In 1993, however, finalization of the rule was deferred because of resource constraints. Instead, the Commission directed the staff to pursue alternatives. In 1995, the Commission approved formation of a joint Agreement State—Nuclear Regulatory Commission (NRC) Working Group to review the regulation of *all* devices containing licensed radioactive materials to assess the current regulatory program for these devices and provide recommendations to the Commission.

The Working Group held its initial meeting October 24–25, 1995, and a second meeting on December 19–20, 1995, in Rockville, Maryland. The Working Group members are Robert Free, Texas and Joel Lubenau, NRC, Co-chairs; Robin Haden, North Carolina, Martha Dibblee, Oregon; Rita Aldrich, New York (alternate); Lloyd Bolling, NRC and John Telford, NRC. James Yusko, Pennsylvania, is serving as liaison to the Working Group for the Conference of Radiation Control Program Directors. James Richardson, NRC Nuclear Safety Attache in Vienna, Austria is serving as liaison for the International Atomic Energy Agency. At its initial meeting, in addition to the Working Group members, 28 representatives of the metal recycling and steel manufacturing industries, devices vendors and users, health physics consultants and government agencies attended. Minutes of the first and second meetings of the Working Group and other background information are available for public inspection and copying for a fee at the NRC Public Document Room, under the file, ''Review Group—Radioactive Devices.''

The public workshop is intended to provide an opportunity for stakeholders to have an input into the Working Group assessment of the need for regulatory changes and development of recommendations, as needed, for regulatory options to improve controls of licensed devices and assure their proper disposal. A target date of May 1996 has been set for the Working Group to develop and finalize its recommendations.

For efficient conduct of the workshop, the meeting format will be a round table discussion among invited representatives from affected interests, e.g., the metal recycling industry and recycled metal consumers, device vendors and users, Federal and state regulators and citizen groups. The workshop will be open to the public, and the public will be provided opportunities throughout the workshop to comment on the issues presented for discussion.

If the Working Group recommends changes in NRC regulations and the Commission agrees, such changes would be proposed through a subsequent NRC public rulemaking process.

Dated at Rockville, Maryland, this 28th day of December 1995.

For the Nuclear Regulatory Commission.

Malcolm R. Knapp,

Deputy Director, Office of Nuclear Materials Safety and Safeguards.

[FR Doc. 96–108 Filed 1–3–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95P–0197]

RIN 0910–AA19

Food Labeling: Health Claims; Oats and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize the use, on food labels and in food labeling, of health claims on the association between oat products, i.e., oat bran and oatmeal, and reduced risk of coronary heart disease (CHD). FDA is proposing this action in response to a petition filed by the Quaker Oats Co. (the petitioner). The agency has tentatively concluded that, based on the totality of publicly available scientific evidence, diets high in oatmeal and oat bran and low in saturated fat and cholesterol may reduce the risk of CHD.

DATES: Written comments by April 3, 1996. The agency is proposing that any final rule that may issue based upon this proposal become effective upon its publication in the Federal Register.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments was that they confirmed FDA's authority to regulate health claims on food labels and in food labeling. As amended by the 1990 amendments, section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards contained in regulations adopted by FDA.

Under section 403(r)(3)(B)(i) of the act, the Secretary of Health and Human Services (and, by delegation, FDA) shall issue regulations authorizing such claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Sections 403(r)(3)(B)(ii) and (r)(3)(B)(iii) of the act describe the information that must be included in any claim authorized under the act. The act provides that the claim shall be an accurate representation of the significance of the substance in affecting the disease or health-related condition, and that it shall enable the public to comprehend the information and understand its significance in the context of the total daily diet. Finally, section 403(r)(4)(A)(i) of the act provides that any person may petition FDA to issue a regulation authorizing a health claim.

The 1990 amendments, in addition to amending the act, directed FDA to consider 10 substance-disease relationships as possible subjects of health claims. One of the 10 substance-disease relationships was the relationship between dietary fiber and cardiovascular disease (CVD) (58 FR 2552, January 6, 1993) (hereinafter referred to as the 1993 dietary fiber and CVD final rule).

B. FDA's Response

In the Federal Register of January 6, 1993 (58 FR 2478), FDA adopted a final rule that implemented the health claim provisions of the act (hereinafter referred to as the 1993 health claims final rule). In that final rule, FDA adopted § 101.14 (21 CFR 101.14), which sets out the circumstances in which a substance is eligible to be the subject of a health claim (§ 101.14(b)), adopts the standard in section 403(r)(3)(B)(i) of the act as the standard that the agency will apply in deciding whether to authorize a claim about a substance-disease relationship (§ 101.14(c)), sets forth general rules on how authorized claims are to be made in food labeling (§ 101.14(d)), and establishes limitations on the circumstances in which claims can be made (§ 101.14(e)). The agency also adopted § 101.70 (21 CFR 101.70), which establishes a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(d)). These regulations became effective on May 8, 1993.

In addition, FDA conducted an extensive review of the evidence on the 10 substance-disease relationships listed in the 1990 amendments. As a result of its review, FDA has authorized claims that relate to 8 of these 10 relationships. While the agency denied the use on food labeling of health claims relating dietary fiber to reduced risk of CVD (58 FR 2552), it authorized a health claim relating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain dietary fiber (particularly soluble fiber) to a reduced risk of CHD, the most common, most frequently reported, and most serious form of CVD.

In denying the dietary fiber and CVD health claim, the agency stated that a problem in determining whether there is a relationship between dietary fiber and heart disease is presented by the fact that dietary fiber is a diverse group of chemical substances that may be associated with different physiological functions (58 FR 2552 at 2572). Chemically and physiologically, cellulose, lignin, hemicellulose, pectin, and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogeneous mixtures of fibers) are not similar in composition. The agency also noted that it is very difficult to chemically analyze dietary fiber components, and that it is consequently hard to correlate the role of specific fiber components to health effects.

Based on its review of numerous authoritative documents, including Federal government reports and recent research on dietary fiber and CHD, and on its consideration of comments received in response to its ''Health Claims; Dietary Fiber and Cardiovascular Disease'' proposed rule (56 FR 60582, November 27, 1991) (hereinafter referred to as the 1991 dietary fiber and CVD proposal), FDA concluded that the publicly available scientific evidence supports an association between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products, foods that are low in saturated fat and cholesterol and that are good sources of dietary fiber, and reduced risk of heart disease (58 FR 2552 at 2572). The

agency further stated that, although the specific roles of the numerous potentially protective substances in such plant foods are not yet understood, populations with diets rich in these foods experience many health advantages, including lower rates of heart disease. The agency noted, however, that there was no scientific agreement as to whether the observed protective effects against heart disease are the result of a combination of nutrient components of the foods, including soluble fiber; of the other components of soluble fiber-rich diets (for example, potassium and magnesium); of the displacement of saturated fat and cholesterol from the diet; or of non-nutritive substances in these foods. For all these reasons, the agency stated that the fact that these foods contain dietary fiber, particularly soluble fiber, can serve as a useful marker for identifying those fruits, vegetables, and grain products that, when added to diets low in saturated fat and cholesterol, may help in reducing blood LDL-cholesterol levels (58 FR 2552 at 2572). Thus, the agency authorized a health claim in § 101.77 (21 CFR 101.77) on the association between diets low in saturated fat and cholesterol and high in vegetables, fruit, and grain products that contain soluble fiber and a reduced risk of heart disease.

In the 1993 dietary fiber and CVD final rule, in response to a comment regarding the apparent hypocholesterolemic properties of specific food fibers, e.g., oats, FDA agreed that the effectiveness of naturally occurring fibers in foods may be documented for specific food products (e.g., oat brans meeting specified parameters) (58 FR 2552 at 2567). Further, the agency stated that if manufacturers can document, through appropriate studies, that dietary consumption of the soluble fiber in their particular food has the effect of lowering low density lipoprotein cholesterol (LDL)-cholesterol, and has no adverse effects on other heart disease risk factors (e.g., high density lipoprotein (HDL)-cholesterol), they should petition for a health claim for their particular product.

The present rulemaking is in response to a manufacturer's health claim petition on the relationship between a specific fiber-containing food, oats, and heart disease.

II. Petition for Oat Products and Reduced Risk of CHD

A. Background

On March 22, 1995, the Quaker Oats Co. submitted a health claim petition to FDA requesting that the agency authorize a health claim on the relationship between consumption of oat products and the risk of CHD (Ref. 1). On June 29, 1995, the agency sent the petitioners a letter stating that it had completed its initial review of the petition, and that the petition would be filed in accordance with section 403(r)(4) of the act (Ref. 2). In this document, the agency will consider whether a health claim on this food-disease relationship is justified under the standard in section 403(r)(3)(B)(i) of the act and § 101.14(c) of FDA's regulations. The following is a review of the health claim petition.

B. Preliminary Requirements

1. The Substances Are Associated With a Disease for Which the U.S. Population Is at Risk

CHD remains a major public health problem and the number one cause of death in the United States. Despite the decline in deaths from CHD over the past 30 years, this disease is still exacting a tremendous toll in morbidity and mortality (Refs. 3 and 4). There are more than 500,000 deaths each year for which CHD is an underlying cause, and another 250,000 deaths for which CHD is a contributing cause. About 20 percent of adults (male and female; black and white) ages 20 to 74 years have blood total cholesterol (or serum cholesterol) levels in the ''high risk'' category (total cholesterol greater than (>) 240 milligrams (mg) per (/) deciliter (dL) and LDL-cholesterol greater than 160 mg/dL) (Ref. 47). Another 31 percent have ''borderline high'' cholesterol levels (total cholesterol between 200 and 239 mg/dL and LDL-cholesterol between 130 and 159 mg/dL) in combination with two or more risk factors.

CHD has a significant effect on health-care costs. In 1985, total direct costs related to CHD were estimated at $13 billion, and indirect costs from loss of productivity due to illness, disability, and premature deaths from this disease were an estimated $36 billion (Ref. 3).

Based on these facts, FDA concludes that, as required in § 101.14(b)(1), CHD is a disease for which the U.S. population is at risk.

2. The Substances Are Food

Oatmeal and oat bran are foods and are used as ingredients in other foods. These oat products contribute taste, aroma, or nutritive value that are retained when consumed at levels necessary to justify the petitioned claim.

Therefore, FDA tentatively concludes that these substances satisfy the preliminary requirements of § 101.14(b)(3)(i).

3. The Substances Are Safe

Oatmeal and oat bran are safe and lawful under the act. Both substances have a long history of use as food and food ingredients and are generally recognized as safe under § 170.30(d) (21 CFR 170.30(d)).

Thus, FDA tentatively concludes that the petitioner has satisfied the requirement of § 101.14(b)(3)(ii).

III. Review of Scientific Evidence

A. Basis for Evaluating the Relationship Between Oats and CHD

In the 1991 dietary fiber and CVD proposal, the agency set forth the basis of the relationship between dietary fiber and CVD (56 FR 60582 at 60583). In that document, the agency stated that there are many risk factors that contribute to the development of CVD, and specifically CHD, the most serious form of CVD and the leading cause of disability. The agency also stated that there is general agreement that elevated blood cholesterol levels are one of the major ''modifiable'' risk factors in the development of CVD and, more specifically, CHD. The Federal government and other reviews have concluded that there is substantial epidemiologic and clinical evidence that high blood levels of total cholesterol and LDL-cholesterol are a cause of atherosclerosis (inadequate circulation of blood to the heart due to narrowing of the arteries) and represent major contributors to CHD (56 FR 60727 at 60728, November 27, 1991; Refs. 3 through 6). Factors that decrease total cholesterol and LDL-cholesterol will also tend to decrease the risk of CHD. High intakes of saturated fat and, to a lesser degree, of dietary cholesterol are associated with elevated blood total and LDL-cholesterol levels (56 FR 60727 at 60728). Thus, it is generally accepted that total cholesterol and LDL-cholesterol levels can predict the risk of developing CHD, and that dietary factors affecting blood total cholesterol levels affect the risk of CHD (Refs. 3 through 6).

When considering the effect that the diet or components of the diet have on blood (or serum) lipids, it is also important to consider the effect that these factors may have on blood levels of HDL-cholesterol. Evidence from epidemiologic studies show that elevated levels of HDL-cholesterol are inversely related to the incidence of atherosclerosis and thus CHD (Ref. 3). HDL- cholesterol is involved in the regulation of cholesterol transport out of

cells and to the liver from which it is ultimately excreted (Refs. 3 and 48). Therefore, HDL-cholesterol has a protective effect in the body by helping to lower total cholesterol. Dietary factors that help to significantly lower total cholesterol should, themselves, not have an adverse affect on the level of HDL-cholesterol.

For these reasons, FDA limited its review of the relationship between oatmeal and oat bran and CHD to effects of these food components on blood lipid levels and on the risk of developing CHD. The agency based its evaluation of this relationship on changes in total blood and LDL-cholesterol from dietary intervention with oatmeal and oat bran and with oat- containing products. This focus is consistent with that used by the agency in response to the 1990 amendments in deciding on the dietary saturated fat and cholesterol and CHD health claim (§ 101.75) (56 FR 60727 and 58 FR 2739, January 6, 1993) and the fruits, vegetables, and grain products and CHD claim (§ 101.77) (56 FR 60582 and 58 FR 2552).

B. Review of Scientific Evidence

1. Evidence Considered in Reaching the Decision

The petitioner submitted scientific studies evaluating the relationship between oat bran and oatmeal, consumed as foods and as ingredients in foods, and serum lipid levels (Ref. 1). These studies were conducted between 1980 and 1995. The petition included a review of these studies and a summary of the evidence. Most of the studies that were published before 1993 had been reviewed by the agency in the proposed and final rules on dietary fiber and CVD (56 FR 60582 at 60596 and 58 FR 2552 at 2581). A review of the studies evaluating the effect of oat products on blood lipids submitted by the petitioner, including those previously reviewed by the agency, is provided in Table 1. In addition, in its review of the petition, the agency considered the conclusions of the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) (Ref. 7) relative to studies involving oats.

2. Criteria for Selection of Human Studies

The criteria that the agency used to select pertinent studies were that the studies: (1) Present data and adequate descriptions of the study design and methods; (2) be available in English; (3) include estimates, or enough information to estimate, soluble dietary fiber intakes; (4) include direct measurement of blood total cholesterol and other blood lipids related to CHD; and (5) be conducted in persons who represent the general U.S. population (adults with blood total cholesterol levels less than (<) 300 mg/dL).

In selecting human for review, the agency excluded studies that were published in abstract form because they lacked sufficient detail on study design and methodologies, and because they lacked necessary primary data. Studies using special population groups, such as insulin-dependent diabetics, individuals with very high serum cholesterol (mean greater than 300 mg/dL), children with hypercholesterolemia, and persons who had already experienced a myocardial infarction, were also generally not weighed heavily because of questions about their relevance to the general healthy U.S. population.

3. Criteria for Evaluating the Relationship Between Oat Products and CHD

FDA applied the same criteria in evaluating the relationship between oat products and CHD that it did in evaluating the relationship between dietary fiber and CVD in the 1991 dietary fiber and cardiovascular disease proposal (56 FR 60582 at 60587). The criteria that the agency used in evaluating these studies included: (1) Reliability and accuracy of the methods used in nutrient intake analysis, including measurements of total dietary soluble fiber and total dietary fiber; (2) available information on the soluble fiber or beta-glucan (β-glucan, the predominant soluble fiber in oats) content of the oat products and control food; (3) measurement of study endpoints (i.e., total cholesterol, LDL-cholesterol, and HDL-cholesterol); and (4) general study design characteristics. The characteristics of general study design included randomization of subjects, appropriateness of controls, selection criteria for subjects, attrition rates (including reasons for attrition), potential for misclassification of individuals with regard to dietary intakes, presence of recall bias and interviewer bias, recognition and control of confounding factors (for example, intake of saturated fat and other nutrients, monitoring body weight, and control of weight loss), appropriateness of statistical tests and comparisons, and statistical power of the studies. The agency considered whether the intervention studies that it evaluated had been of long enough duration to reasonably ensure stabilization of blood lipids (greater than or equal to 3 weeks duration). Finally, the agency considered it highly desirable if the available information on a study included information on the total dietary fiber and total dietary soluble fiber content of baseline, treatment, and control diets and on the nutrient intakes of the subjects during the course of the study.

As stated above, dietary saturated fat and cholesterol affect blood lipid levels (Refs. 4 through 6). Previous reviewers have generally concluded that, in persons with relatively higher baseline levels of blood cholesterol, responses to treatment tend to be of a larger magnitude than is seen in persons with more normal blood cholesterol levels (56 FR 60582 at 60587 and Refs. 4 through 6). To take into account these factors, FDA separately evaluated studies on mildly to moderately hypercholesterolemic individuals (persons with elevated blood total cholesterol levels of 200 to 300 mg/dL) and studies on normocholesterolemic individuals (persons with normal blood total cholesterol levels (< 200 mg/dL)). FDA also separately evaluated studies in which oat products' effects were evaluated as part of a ''typical'' American diet (approximately 37 percent of calories from fat, 13 percent of calories from saturated fat, and more than 300 mg of cholesterol daily) and studies in which the test protocols incorporated a Step I or similar (e.g., American Heart Association (AHA)) dietary regimen (less than 30 percent of calories from fat, less than 10 percent of calories from saturated fat, and less than 300 mg of cholesterol daily). Moreover, to ensure that results were not reflective of transient changes, such as failure of blood cholesterol levels to stabilize to the dramatic changes in dietary patterns that occur with the introduction of large amounts of test substances, FDA gave less weight to studies with treatment periods of less than 3 weeks than it gave to studies of longer duration.

C. Summary of Human Studies

FDA's review of the 37 human studies on oat bran and oatmeal and serum cholesterol (Refs. 8 through 32, 34 through 39, and 41 through 46) that were submitted with the petition is summarized in detail in Table 1. The results of a metaanalysis (Ref. 33) that included a number of the oat studies is discussed in section III.C.5. of this document.

1. Hypercholesterolemics: ''Typical'' or ''Usual'' Diets

Eight of the studies (Refs. 8, 12, 20, 21, 25, 35, 44, and 45) show a relationship between consumption of oat products and reduced serum

cholesterol in hypercholesterolemic subjects consuming a typical American diet. Anderson et al. (Ref. 8) in a metabolic ward study reported significantly lower total (12.8 percent) and LDL-cholesterol (12.1 percent) in male subjects consuming 110 grams (g) (7.6 g soluble fiber, 13.4 g total dietary soluble fiber) oat bran for 21 days (d). A wheat group, which consumed 40 g of wheat bran (1.3 g soluble fiber, 7.8 g total dietary soluble fiber), experienced nonsignificant decreases in total (4.4 percent) and LDL-cholesterol (5.5 percent). There was no significant change in HDL-cholesterol in either group. Both groups experienced a significant decrease in weight (1 kilogram (kg)) compared to their mean baseline weight values. There was no difference in weight loss between the oat and wheat groups.

Braaten et al. (Ref. 12) evaluated the effects on blood cholesterol levels of instant oat gum (7.2 g; 5.8 g β-glucan), an extract of oat bran comprised of almost entirely β-glucan soluble fiber plus some trace elements, or a placebo (maltodextrin) when mixed with a noncarbonated diet fruit drink (250 milliliters (mL)) and consumed twice a day at each main meal for 4 weeks by hypercholesterolemic subjects. Results showed significantly lower total cholesterol by 9.2 percent ($p<0.0001$) and LDL-cholesterol by 10 percent ($p<0.001$) in the oat gum group compared to baseline.

Hegsted et al. (Ref. 20) evaluated the hypocholesterolemic properties of rice bran and oat bran in hypercholesterolemic subjects. Using a cross-over design, subjects consumed treatment diets providing 100 g/d of rice bran and oat bran for 3-week periods each. A control diet, which consisted of the treatment diet but with wheat flour and no bran, was consumed for 2 weeks before each bran period. The results showed significant reductions in total cholesterol with both the rice and oat bran diets compared to the control diet ($p<0.001$). During the two oat test periods, serum cholesterol was reduced about 10 percent (phase 1) and 4 percent (phase 2) compared to serum cholesterol values during the control period. Oat bran intervention also resulted in significant reductions (about 13 percent in phase 1 and about 7 percent in phase 2) in LDL-cholesterol. Rice bran was as effective in lowering serum cholesterol as oat bran.

Kahn et al. (Ref. 21) evaluated the hypocholesterolemic properties of four oat bran muffins/d (80 g total daily oat bran) in hypercholesterolemic subjects randomized into immediate oat bran intervention and delayed oat bran intervention groups. The delayed oat bran intervention group served as the control group. After correcting for the time delay of the study, the results showed that oat bran dietary intervention significantly reduced total cholesterol by almost 8 percent ($p<0.02$), LDL-cholesterol by about 10 percent ($p<0.02$), and HDL-cholesterol by almost 1 percent ($p<0.03$) from baseline.

Kestin et al. (Ref. 25) reported decreased levels of total cholesterol (4.9 percent) and LDL-cholesterol (6.8 percent) in hypercholesterolemic subjects consuming 95 g/d (5.8 g soluble fiber) oat bran. These values were significantly lower than those observed in subjects consuming rice bran ($p<0.01$) and wheat bran ($p<0.001$). HDL-cholesterol increased in all groups. The oat bran was incorporated into bread and muffins.

Spiller et al. (Ref. 35) reported significantly lower total cholesterol (3.7 percent) and LDL-cholesterol (6.6 percent), and a nonsignificant increase in HDL-cholesterol (1 percent), in hypercholesterolemic subjects consuming 77 g/d (5 g soluble fiber) oat bran. Changes in total cholesterol were experienced within the first 14 days with no significant changes occurring between days 14 and 21 of the study. The oat bran was mixed with water and consumed before meals. The calories provided by the oat bran replaced about an equal amount of carbohydrate calories in the subjects' diets.

Whyte et al. (Ref. 45) reported decreases in total cholesterol of 3.1 percent ($p<0.01$) and LDL-cholesterol of 5.7 percent ($p<0.01$) compared to baseline values after hypercholesterolemic subjects consumed 123 g (10.3 g soluble fiber) oat bran/day for 4 weeks. The oat bran was consumed as a breakfast cereal. Consumption of total fat and saturated fat remained the same during the test period.

Van Horn et al. (Ref. 44) reported reductions in total cholesterol (about 6.2 percent) and LDL-cholesterol (9.2 percent) levels, compared to a control group, in subjects consuming 57 g of instant oats daily for 8 weeks. The control group experienced decreases in total cholesterol and LDL-cholesterol of 1.4 percent and 3.7 percent, respectively. The differences between the oat and control groups were significant ($p<0.05$). The authors reported greater reductions in total cholesterol in those individuals who had a baseline cholesterol level above the baseline median cholesterol level of 243 mg/dL. The authors also reported significantly different dietary intakes after 4 weeks of intervention for a number of nutrients in the oat group's diet compared to that of the control group. After 4 weeks of intervention, the oat group had higher intakes of soluble and total fiber and lower intakes of saturated fat and cholesterol. A metaanalysis conducted by Ripsin et al. (Ref. 33), which is discussed in section III.C.5. of this document, evidences that the changes in dietary fats and cholesterol intake in this study did not appear to be responsible for the drop in serum cholesterol levels, thus suggesting that oat bran and oatmeal were responsible for the observed effect.

Results of four studies (Refs. 18, 26, 34, and 38) were inconclusive regarding the relationship between oat bran or oatmeal consumption and reduced serum lipids. Gormley et al. (Ref. 18) reported no effect of oatmeal porridge on serum cholesterol or HDL-cholesterol in hypercholesterolemic men and normocholesterolemic women. The authors stated that dietary intakes were monitored, but the subjects' dietary intakes were not reported. The amount of total dietary fiber and soluble fiber in the total diet and oatmeal porridge were not provided. Insufficient dietary controls make the results of this study difficult to interpret.

Leadbetter et al. (Ref. 26) reported no significant effect of increasing intakes of β–glucan from oat bran on serum cholesterol in 40 hypercholesterolemic men and women. Subjects consumed 0, 30, 60, or 90 g oat bran/day for 1-month intervals. The authors stated that the New Zealand oats used in this study were lower in soluble fiber (3.7 to 4.2 percent β–glucan) than oat bran used in studies that showed a significant lowering of serum cholesterol with oat bran supplementation.

Saudia et al. (Ref. 34) reported no significant difference in serum cholesterol levels in hypercholesterolemic subjects consuming oat bran daily for 93 days. The subjects consumed 3 ounces (oz) (about 84 g) of oat bran daily with their usual diet for 3 months. The subjects' total dietary intake, including their intake of total and saturated fat and cholesterol, before and during the trial were not reported. The authors stated that the subjects may have changed their diets during the test period because the study took place over summer months and because of an increased awareness by the subjects of risk-reducing behavior and lifestyles. The study also lacked a control group, thus making the results of this study difficult to interpret.

Törrönen et al. (Ref. 38) showed small reductions in serum cholesterol, LDL-, and HDL-cholesterol in an oat bran

group compared to baseline, but these reductions were not statistically significant. An oat bran concentrate was prepared and incorporated into a loaf of bread (11.2 g β-glucan per loaf). A control bread was made with wheat flour. The use of oat bran concentrate in this study does not provide evidence for an effect of oat bran per se on serum cholesterol because the authors state that the method of concentrating and processing the oat bran and β-glucan may have affected the effectiveness of the β-glucan in lowering serum cholesterol. Animal studies by these authors confirmed that the method of producing the oat bran concentrate produced significantly weaker hypocholesterolemic responses than untreated oat bran or concentrates with higher viscosities.

One study (Ref. 32) showed equivocal results in reducing total cholesterol. Poulter and coworkers reported small but significant reductions in serum cholesterol and LDL-cholesterol in hypercholesterolemic subjects consuming 50 g of oat cereal compared to subjects consuming the same amount of cereal without oats. Subjects with baseline cholesterol values greater than 231 mg/dL experienced the most significant reduction in serum cholesterol. However, the results of this study are difficult to interpret because some subjects made changes in their diets after starting the trial. There was a significant reduction in total energy from fat compared to baseline intakes. Similarly, the ratio of polyunsaturated fat to saturated fat in the subjects' diet also fell significantly during the oat period.

2. Hypercholesterolemics: Low Fat Diets

Results of six studies (Refs. 11, 15, 23, 24, 39, and 43) showed a cholesterol reducing effect of oatmeal or oat bran in hypercholesterolemic subjects who consumed the oat products as part of a low fat diet. Beling et al. (Ref. 11) divided the subjects into 3 groups. Group 1 consumed their regular (not fat modified) diet. Groups 2 and 3 consumed an AHA fat modified diet. There were significantly lower total and LDL-cholesterol levels after 4 weeks in groups 2 and 3. In groups 2 and 3, total cholesterol decreased by 10 percent and 11.8 percent, and LDL-cholesterol decreased by 11.5 percent and 11.8 percent, respectively. From weeks 5 to 8, group 2 continued on the AHA diet, while group 3 consumed the AHA diet plus 56 g oat bran cereal/day. At the end of week 8, total cholesterol had decreased by 2.3 percent, 8.4 percent, and 12.2 percent from baseline levels for groups 1, 2, and 3, respectively. The mean total cholesterol level of the oat group was significantly different from the control group and the group that consumed only the AHA diet ($p<0.05$). At week 8, LDL-cholesterol levels were 10.1 percent below baseline for group 2 and 14.9 percent below baseline for group 3 ($p<0.05$). HDL-cholesterol decreased 1 percent, 3 percent, and 8 percent in groups 1, 2, and 3, respectively, at 8 weeks. The differences in HDL-cholesterol between the 3 groups were not significant. The differences in HDL-cholesterol in groups 2 and 3 were significantly different from the control ($p<.05$). Groups 2 and 3 experienced weight loss, but the differences between these groups were not significant.

Davidson et al. (Ref. 15) evaluated the hypocholesterolemic effects of increasing amounts of β-glucan from oat bran and oatmeal in hypercholesterolemic subjects consuming a Step 1 diet. The results showed that groups consuming diets containing 3 g/d or more of β-glucan experienced significant declines in blood total cholesterol (7 to 10 percent) and LDL-cholesterol (10 to 16 percent) compared to baseline. Blood total cholesterol levels of groups consuming diets containing 1 to 2.4 g daily of β-glucan did not differ significantly from baseline.

Turnbull and Leeds (Ref. 39) evaluated the effects of oats and wheat on total cholesterol in hypercholesterolemic subjects consuming a low fat diet. During a 1-month run-in period (baseline), the subjects consumed the low fat diet alone and experienced a 7.6 percent (not significant) reduction in total cholesterol. The subjects were then randomized to receive 150 g/d of oats or wheat while consuming the low fat diet for another month. At the end of the month, subjects crossed over to the other grain supplement. The results of this study showed that during the oat period, subjects experienced significant reductions in total cholesterol ($p<0.03$) and LDL-cholesterol ($p<0.002$) compared to baseline despite an increase in energy and total fat intake. There were no significant changes in total cholesterol and LDL-cholesterol when subjects consumed the wheat diet. HDL-cholesterol showed a nonsignificant increase from baseline during the oat period and no change during the wheat period.

In a large, controlled clinical trial, Van Horn et al. (Ref. 43) instructed moderately hypercholesterolemic subjects (mean total cholesterol of 208 mg/dL) on the AHA low fat diet. The subjects consumed the AHA diet alone for 6 weeks, during which time they experienced significantly reduced total cholesterol compared to baseline. The subjects were then randomized to one of 3 groups: two oat groups (2 oz of oat bran or oatmeal daily) or the control group (AHA diet only) for another 6 weeks. At the end of the intervention period, subjects consuming 56 g of oat bran and oatmeal had total cholesterol values 8 percent and 9.3 percent lower than baseline, respectively. The control group experienced a 4.5 percent reduction in serum cholesterol. At the end of the study, the differences in total cholesterol levels for all three groups compared to baseline levels were statistically significant ($p<0.05$), but there was no significant difference between the oat groups and the control. Both the oat bran and the oatmeal groups experienced a modest (3 percent) reduction in serum cholesterol beyond that achieved by the low fat diet alone.

The modest effect of oat bran and oatmeal on serum cholesterol in this study may have been affected by the subjects' cholesterol levels before dietary intervention. The subjects' mean cholesterol level was 208.4 mg/dL. After dietary intervention, the mean cholesterol levels were 201 mg/dL (control), 196.4 mg/dL (oat bran group), and 195.2 mg/dL (oatmeal group). Studies have shown that subjects with higher initial blood cholesterol levels usually experience the most reduction in total cholesterol from oat intervention (Refs. 6 and 33). Thus, because of the subjects' relatively low cholesterol levels at the initiation of the oats intervention period, the differences among the groups may have been minimized.

Keenan et al. (Ref. 23) reported variable responses in serum lipids depending on the order of feeding of the diets supplemented with 56 g of oat bran or wheat cereal during an 18-week double-blind study with crossover. Subjects consumed a Step 1 diet during the first period (6 weeks) and then were randomized to 1 of 3 groups. The control group consumed a Step 1 diet for another 12 weeks. The two test groups consumed wheat cereal or oat cereal for 6 weeks before crossover to the other test cereal for another 6 weeks. Interpretation of results was complicated by the fact that the control group showed an initial decline in blood cholesterol levels followed by a return to baseline at the end of the study. Only the oat groups maintained reduced serum cholesterol and LDL-cholesterol throughout the test periods. When compared to the control and wheat groups, these reductions were significant ($p<.01$).

Kelley et al. (Ref. 24) reported significantly reduced serum cholesterol ($p<0.04$) and LDL-cholesterol ($p<0.05$) at the end of 4 weeks in subjects who were participating in a program of supervised aerobic exercises. The subjects consumed about 94 g of oat bran daily as part of their usual low fat, low saturated fat diets. This study lacked an appropriate placebo control.

Six studies (Refs. 13, 16, 27, 28, 36, and 41) gave inconclusive results regarding the relationship between oat consumption and reduced serum lipids in hypercholesterolemic subjects consuming low fat diets. In a study by Bremer et al. (Ref. 13), subjects consumed either oat or wheat bread (about 8 slices/day) in place of other carbohydrate foods as part of their AHA phase II diet (total fat 25 to 30 percent of energy, saturated fat <8 percent of energy, polyunsaturated fat 5 to 10 percent of energy, cholesterol <250 mg/day). Subjects had a mean intake of 44.6 g/day of oat bran (range of 34.2 to 68.4 g/day). The study showed no significant differences in total serum cholesterol or LDL-cholesterol between the period in which the subjects consumed oat bread and the period in which they consumed wheat bread. However, the lack of an observed effect on serum cholesterol from oat bran could be attributable to the lower soluble fiber content of the New Zealand oat bran used in this study compared to oat bran used in other studies.

Demark-Wahnefried et al. (Ref. 16) evaluated the hypocholesterolemic properties of oat bran in hypercholesterolemic subjects following one of four dietary protocols for 12 weeks: Step 1 diet alone, Step 1 diet plus added soluble fiber from 50 g of oat bran, regular diet plus 50 g of oat bran, and regular diet plus 42 g of processed oat bran. The results of this study showed significant reductions ($p<0.05$) in serum cholesterol in all diet groups. The serum cholesterol levels of groups consuming diets containing the higher soluble fiber (approximately 4 g added soluble fiber daily) did not differ from groups on a dietary regimen modified only in fat and cholesterol content. Variable weight loss was reported among the groups, and dietary changes in all groups confound the results of this study.

In a study by Lepre and Crane (Ref. 27), subjects received a prescribed low fat diet for 8 weeks before being randomly assigned to either the oat or wheat group. Subjects consumed 2 oat bran muffins (60 g of oat bran, 3.2 g soluble fiber) or 2 wheat bran muffins (60 g wheat bran) daily for 8 weeks. At the end of the first 8-week test period, subjects crossed over to the other test group for another 8 weeks. The results showed small, nonsignificant reductions in serum cholesterol (2.2 percent) and LDL-cholesterol (3.1 percent) and a nonsignificant increase in HDL-cholesterol (3.0 percent) during the oat bran period compared to diet only period. During the wheat bran period, there was a nonsignificant increase in total cholesterol, LDL-cholesterol, and the ratio of LDL- to HDL-cholesterol (LDL:HDL) and a nonsignificant decrease in HDL-cholesterol. The results of this study were confounded because subjects made significant dietary changes during the diet only and the oat bran periods. The subjects were aware of their hyperlipidemias and were already on a low fat diet before the start of this study. They also knew in advance which days they were required to record their dietary intake. The intakes of dietary cholesterol and saturated fat were significantly less, and dietary fiber intake was significantly more, during the oat bran period compared to the diet only period. The results of this study, therefore, are inconclusive for an effect of oat bran on serum cholesterol.

Mackay and Ball (Ref. 28) evaluated the hypocholesterolemic properties of 55 g each of low-fiber and high-fiber oat bran (New Zealand cultivars) and of beans in hypercholesterolemic subjects consuming a moderately low fat diet. The oat bran used in this study was specially formulated to provide specific amounts of β-glucan. The low-fiber oat bran provided 1.9 g β-glucan, and the high-fiber oat bran provided about 3 g β-glucan. The results of this study showed no significant changes in serum cholesterol or LDL-cholesterol from any of the test substances. HDL-cholesterol, however, increased in all groups compared to baseline values, and these increases were statistically significant ($p<0.05$). The energy intake on the high-fiber oat bran diet was significantly higher than that of the low-fat diet alone; however, there was no reported change in body weights. This study lacked a placebo control which makes the study difficult to interpret. Also, the source of this oat bran, a New Zealand cultivar, may have contributed to the lack of a hypocholesterolemic response to oat bran in this study (see Refs. 13 and 26).

Stewart et al. (Ref. 36) reported no significant differences in serum cholesterol, LDL-, or HDL-cholesterol in subjects consuming an oat-free, low fat diet or a low fat diet with 50 g/d of oat bran for 6 weeks each. However, the subjects' compliance with the required dietary protocol in this study was poor. The authors reported a wide variability among the subjects' diets at baseline as well as a variability in the intake of oat bran. Moreover, both processed and unprocessed New Zealand oat brans were used in this study. As stated in the previous paragraph, the type of oat bran cultivar used, and the method of processing the oat bran, may have affected the results of this study.

Uusitupa et al. (Ref. 41) evaluated the hypocholesterolemic effects of a β-glucan-enriched oat bran and regular wheat bran in hypercholesterolemic subjects consuming an AHA Step 1 diet. Baseline serum cholesterol values were determined during a 4-week run-in period when the subjects consumed the AHA Step 1 diet with no bran. The subjects were then randomized into two groups to receive the β-glucan-enriched oat bran or regular wheat bran for an 8-week test period. The brans were provided in sachets (62 g/sachet), and the subjects instructed to increase their daily consumption of bran in a step-wise approach until they consumed the entire contents of the sachet or until they reached the highest tolerable amount. The mean intake of oat bran during the test period was 50 g. At the end of 4 weeks of bran intervention, there was a significant reduction in serum cholesterol in the oat bran group compared to baseline. By the end of 8 weeks, however, the differences were no longer significant. There was no change in LDL-cholesterol in the oat bran group after 4 weeks, but a small, nonsignificant reduction (about 3 percent) after 8 weeks. There was a small, nonsignificant increase in serum cholesterol in the wheat bran group. The results of this study were difficult to interpret because subjects did not adhere to the reduced fat diet and failed to consume the required amount of bran.

Two studies (Refs. 10 and 46) showed equivocal results in reducing total cholesterol. Bartram et al. (Ref. 10) evaluated the effect of oat bran muesli cereal on serum cholesterol in 13 men and women who had been on a low cholesterol diet for 6 months. The subjects consumed 60 g of oat muesli (made with lowfat milk and 120 g of bananas, grapes, and apples) for 3 weeks. The results of this study showed a significant reduction in serum cholesterol (8–10 percent) ($p<0.01$) and LDL-cholesterol ($p<0.05$) during the oat cereal period. However, the results are difficult to interpret because the fruits consumed with the muesli cereal may have contributed to the observed reduction in serum cholesterol.

Zhang et al. (Ref. 46) compared the hypocholesterolemic properties of oat

bran (118 g) with wheat flour using a crossover design. The subjects consumed one of the test substances as part of a low fiber base diet for 3 weeks before crossover to the other test substance. During the oat period, serum cholesterol was significantly lower than during the wheat flour period. The results of this study are difficult to interpret because all subjects had ileostomies (i.e., an opening from the ileum through the abdominal wall, permitting drainage of the contents of the small intestine) and the mechanism by which oat bran lowers serum lipids in this group may not apply to the general population.

3. Normocholesterolemics: ''Typical'' or ''Usual'' Diets

The results of two studies (Refs. 17 and 29) support a cholesterol lowering effect of oat bran or oatmeal in subjects with normal serum cholesterol values. A third study (Ref. 14) showed evidence of the cholesterol-lowering effects of oat bran postprandially.

Gold and Davidson (Ref. 17) reported a significant ($p<0.05$) reduction in total cholesterol (5.3 percent) and LDL-cholesterol (8.7 percent) compared to baseline measures in normocholesterolemic subjects consuming 2 oat bran muffins/d for 4 weeks. The oat bran muffins provided a total of 34 g oat bran. There were no data given on the subjects' dietary intake before or during the test period.

Marlett et al. (Ref. 29) studied the mechanism of serum cholesterol reduction by oat bran using a single isotope to determine bile acid kinetics. During the first month, normo-cholesterolemic subjects consumed a low fiber control diet provided in a metabolic unit. During the second month, this same diet was supplemented with 100 g of oat bran. The results showed significantly lowered serum cholesterol compared to baseline values during both periods. Serum cholesterol on the low fiber diet was reduced 14 percent ($p<0.01$) and on the oat bran diet 22 percent ($p<0.01$) compared to baseline values. Serum cholesterol during the high fiber period was also significantly lower than that of the low fiber period (an additional decrease of 9 percent).

Cara et al. (Ref. 14) evaluated the effects of oat bran and other high fiber-containing foods on postprandial lipemia in 6 normocholesterolemic men. The subjects consumed, on separate days, a low fiber (control) meal or a high fiber test meal enriched with 10 g of oat bran, rice bran, wheat fiber, or wheat germ. The results of this study showed that the oat bran test meal produced the greatest reduction in serum cholesterol compared to the other fibers tested. The differences between serum cholesterol levels in the oat bran test and those in the control test remained significant ($p<0.05$) 7 hours postprandial. The results of this study support a significant short term effect on serum cholesterol, but they do not address long term effectiveness of oat bran in maintaining reduced serum cholesterol levels.

The results of one study (Ref. 31) was inconclusive for an effect of oatmeal on serum cholesterol in normo-cholesterolemic subjects. O'Kell and Duston (Ref. 31) reported no significant differences in serum cholesterol and HDL-cholesterol in subjects consuming 1/2 to 3/4-cup of oatmeal daily for a series of 3-month test periods over the course of a year. After each 3-month oatmeal period, the subjects consumed their usual diets without oatmeal for 3 months. The results of this study were difficult to interpret because the subjects' dietary intakes before and during the study were not reported, and subject compliance was not adequately addressed.

One study (Ref. 37) showed equivocal results in reducing total cholesterol. Swain et al. evaluated the hypocholesterolemic effects of oat bran and wheat bran in a group of young females with normal serum cholesterol (mean total cholesterol of 185 mg/dL) using a double-blind, cross-over study design. The subjects consumed an average of 87 g oat bran and 93 g wheat bran/day during each 6-week test period. The authors reported statistically significant reductions from baseline levels in total cholesterol ($p<0.05$) and LDL-cholesterol ($p<0.05$) in both bran test periods. The differences between the oat bran and wheat bran groups were not significant. The results of this study are difficult to interpret because of dietary changes during the oat bran period. The subjects significantly increased their intake of total calories from fat and saturated fat compared to the wheat period. Mean body weight was unchanged over the short test period suggesting that there was a substitution effect with the diet. Young premenopausal women with low serum cholesterol levels do not represent a population at risk for CHD. Therefore, the benefits of oat bran may not be reflected in this group.

4. Normocholesterolemics: Low Fat Diets

One study (Ref. 42) reported significantly lower total cholesterol, compared to a control group, after 4-weeks of oat intervention in subjects with normal to mildly elevated total cholesterol. The oat group consumed a Phase II AHA diet (low fat, low saturated fat, low cholesterol) plus 56 g of oatmeal daily compared to a control group that consumed only the Phase II diet. Over the next 4 weeks, however, serum cholesterol levels increased slightly in the oat group and decreased slightly in the control group. After 8 weeks, serum cholesterol was reduced 3.1 percent in the oat group and 1.4 percent in the control group. There were no significant differences in total serum cholesterol levels between the groups. Subgroup analysis of the data showed greater reductions in serum cholesterol among those subjects in the oat group who had the highest baseline cholesterol levels. The results of this study suggest a modest benefit of oatmeal in lowering serum cholesterol in subjects with normal cholesterol levels.

One survey (Ref. 19) showed equivocal results for an effect of oat bran or oatmeal on serum cholesterol. He et al. (Ref. 19) evaluated the relationship between the intakes of oats and buckwheat and serum cholesterol in a population of Chinese by conducting a survey of their dietary habits. This particular population group consumed a high energy, low fat, and high fiber diet, and had active working lifestyles. The results of this study showed that the groups consuming greater than 25 g of oats a day had significantly lower serum cholesterol than those who ate less than 25 g of oats a day or no oats. All baseline serum cholesterol values, however, were under 160 mg/dL. The results of this study were difficult to interpret because this population group is one whose diets and lifestyles do not reflect that of the general American population. The results of this study are also confounded because of the questionable assessment of dietary intake of oat bran and oatmeal and the absence of any controls.

5. Other Studies

Evidence for the cholesterol-lowering effect of soluble fiber from oatmeal and oat bran was evaluated using a metaanalysis (Ref. 33). In this study, after pooling the raw data from 13 studies (Refs. 11, 15 through 17, 23, 25, 30, 37, 39, 40, and 42 through 44) that reported on the effect of consumption of oatmeal and oat bran on total cholesterol, a modest reduction (average decrease of 5 to 6 mg/dL) on blood total cholesterol levels was found.

To assess whether other dietary factors, i.e., substitution of oats for dietary fats and cholesterol, might have been responsible for the drop in blood

total cholesterol levels, Ripsin and coworkers used the experimentally derived, predictive equation of Keys to see whether dietary changes in fat components of the test diets could account for the observed decreases in serum cholesterol (Ref. 33). The results of their analysis showed that reduction in fat and cholesterol intake attributable to substituting oat bran or oatmeal for these food components did not account for all of the blood cholesterol reduction observed. Oat bran and oatmeal apparently had some effect beyond that of simply replacing fat and cholesterol in the diet. The authors concluded, therefore, that incorporation of oat products into diets causes a modest decrease in average blood cholesterol.

The authors also suggested that there was a dose-response relationship between the amount of soluble fiber from oat bran or oatmeal and the reduction in blood cholesterol levels, with intakes of soluble fiber from oats above 3 g/day showing more effect than lower intakes. They stated that there is significant evidence of an interaction between dose and initial cholesterol levels. The trials that used subjects with initial serum cholesterol levels of 229 mg/dL or higher demonstrated fivefold greater reductions in total cholesterol with 3 g/d or more of soluble fiber from oat bran or oatmeal than trials whose subjects had lower initial cholesterol levels. Additionally, the authors noted that other components in oats may play a role in the observed cholesterol reduction and suggested the need for long-term clinical trials (6 months or more) with multiple doses to verify their conclusions from the metaanalysis.

LSRO, in its 1987 report entitled ''Physiological Effects and Health Consequences of Dietary Fiber,'' stated that oat bran has been shown to exert a substantial cholesterol-lowering effect in patients with hypercholesterolemia (Ref. 7). It noted that the effects of oat bran are not as pronounced in subjects with normal serum cholesterol as they are in subjects with elevated serum lipid levels.

6. Summary

Of the 37 studies that FDA reviewed, 4 studies (Refs. 9, 14, 22, and 30) had short test periods, ranging from 7 hours to 18 days and, thus, did not meet the agency's criteria for selecting pertinent studies with respect to study duration (i.e., intervention test period of no less than 3 weeks).

Seventeen studies (Refs. 8, 11, 12, 15, 17, 20, 21, 23, 24, 25, 29, 35, 39, 42 through 45) demonstrated a positive effect of oat bran or oatmeal on total and LDL-cholesterol. The majority of these studies showed statistically significant reductions in total and LDL-cholesterol in hypercholesterolemic subjects consuming either a typical American diet (Refs. 8, 12, 20, 21, 25, 35, 44, and 45) or a low fat diet (Refs. 11, 15, 23, 24, 39, 42, and 43). The results of three studies showed a statistically significant effect of oat bran or oatmeal in subjects with normal serum cholesterol consuming either a typical American diet (Refs. 17 and 29) or a low fat diet (Ref. 42). The amount of oat bran or oatmeal consumed daily to lower total and LDL-cholesterol in the above studies ranged from 34 g (2.5 g soluble fiber) (Ref. 17) to 123 g (10.3 g soluble fiber) (Ref. 45). In those studies that evaluated HDL-cholesterol responses to oat intervention, three reported a slight, nonsignificant decrease in HDL-cholesterol (Refs. 8, 11, and 21); four reported no change (Refs. 12, 20, 23, and 35); and five reported a slight increase in HDL- cholesterol as a result of oat intervention (Refs. 24, 25, 39, 42, and 45).

Five studies (Refs. 10, 19, 32, 37, and 46) showed equivocal results in reducing serum cholesterol. The results by Bartram et al. (Ref. 10) were difficult to interpret because fruits were included in the oat bran cereal. The soluble fiber of the fruit may have had an independent effect on serum lipid levels. The questionable assessment of dietary intake and the lack of temporal sequence in an uncontrolled, cross-sectional survey conducted by He et al. (Ref. 19) make the beneficial results of this study difficult to interpret. In addition, the population group used in this study (i.e., Chinese farmers and migrants) do not reflect the general population in the United States. The agency also questioned the appropriateness of the population groups used in two other studies (Refs. 37 and 46). Zhang et al. (Ref. 46) showed significant reductions in total cholesterol in subjects who had ileostomies. The mechanism by which oat bran or oatmeal help lower serum lipids in this population may not reflect the general population in the United States. Swain and coworkers (Ref. 37) evaluated the cholesterol-lowering properties of oat bran and wheat in a group of young pre-menopausal women with low serum cholesterol levels, a group who does not represent a population at risk for CHD. Dietary changes were reported during the oat period which also make interpretation of the results difficult.

Significant dietary changes during the oat intervention period made it difficult to interpret the results of another study (Ref. 32). Poulter et al. (Ref. 32) reported significant reductions in total and LDL-cholesterol in subjects consuming 56 g of oat cereal. There were no significant changes in total and LDL-cholesterol when the subjects consumed their usual (control) cereal. However, an analysis of the nutrient data revealed a significant reduction in total energy from fat and in the ratio of polyunsaturated to saturated fat (P:S) during the oat period.

In the 11 studies in which no effect on serum lipid levels were found (Refs. 13, 16, 18, 26 through 28, 31, 34, 36, 38, and 41), a number of reasons were advanced for the lack of a positive finding. A lack of compliance and changes in dietary intakes by the subjects plagued a number of these studies (Refs. 18, 27, 31, 34, and 41). The source of the oat cultivars allegedly contributed to the lack of an effect of oat bran or oatmeal on serum lipids in four others (Refs. 13, 26, 28, and 36). The authors of these studies noted that New Zealand oat cultivars tend to have lower levels of soluble fiber than oat cultivars used in studies showing cholesterol-lowering properties.

The processing of oats allegedly caused a loss of effectiveness in another study (Ref. 38). Törrönen and coworkers found that wet milling Finnish oats to produce an oat bran concentrate negatively affected the hypocholesterolemic properties of oat β-glucan.

The results of the study by Demark-Wahnefried et al. (Ref. 16) suffered from a lack of statistical power to detect changes between groups, variable weight loss among the groups, and significant dietary changes during the course of the study.

IV. Decision To Propose a Health Claim Relating Oat Products to Reduction in Risk of CHD

The petition set out the conclusions reached by the Federal government and other recognized scientific bodies, as well as those reached in review articles and in pertinent human studies published since 1987. FDA reviewed this information as well as those studies that evaluated the effects on serum cholesterol and LDL-cholesterol levels from dietary intervention with oat bran or oatmeal in subjects with normal to elevated serum cholesterol levels.

FDA tentatively concludes that, based on the totality of publicly available scientific evidence, there is significant scientific agreement to support the relationship between consumption of oat bran or oatmeal as foods, or as ingredients in foods, and the risk of CHD. The strongest evidence for the effect of oat bran or oatmeal on the risk of CHD is provided by studies that

measured the effect of dietary oat consumption on the two major risk factors for CHD, total and LDL-cholesterol. FDA is aware of five studies of that effect in which problems associated with subject compliance and weight loss were avoided and in which appropriate controls were used (Refs. 12, 25, 29, 39, and 45). All of these studies showed a significant relationship between oat consumption and lowered serum total and LDL-cholesterol levels and no adverse effect on other CHD risk factors, such as significantly lowering HDL-cholesterol. The daily oat intake ranged from an estimated 70 g oat bran (Ref. 12) to 150 g oat bran (Ref. 39). Four of these studies (Refs. 12, 25, 39, and 45) were conducted in subjects with mild to moderately elevated levels of serum cholesterol. One study (Ref. 29) used subjects with normal serum cholesterol levels.

Braaten et al. (Ref. 12) showed that when subjects consumed an amount of purified oat gum (containing 80 percent β-glucan) equivalent to consuming 70 g oat bran daily, total and LDL-cholesterol were significantly reduced, and HDL-cholesterol remained unchanged. The oat gum was consumed with a typical American diet.

Kestin et al. (Ref. 25) showed significant reductions in total and LDL-cholesterol, compared to blood lipid levels during wheat and rice bran periods, in subjects who consumed 95 g oat bran/day for 4 weeks (Ref. 25). HDL-cholesterol showed slight, nonsignificant increases compared to baseline in all diet periods. The subjects consumed the test foods as part of their usual diet.

Subjects with moderate hypercholesterolemia showed significant reductions in total and LDL-cholesterol after they consumed 150 g oats/day for 4 weeks compared to baseline lipid levels (Ref. 39). These same subjects experienced small increases in total and LDL-cholesterol (not significant) after consuming wheat products. Blood levels of HDL-cholesterol increased slightly (not significant) during the oat period but remained the same during the wheat period. All subjects consumed a low fat diet in this study.

Whyte et al. (Ref. 45) reported significant reductions in total and LDL-cholesterol in subjects who consumed 123 g oat bran/day for 4 weeks as part of their usual diets. The subjects experienced a slight increase in total cholesterol and no change in LDL-cholesterol after consuming wheat bran. HDL-cholesterol increased slightly (not significant) during both bran periods.

In a study designed to assess the mechanism by which oat bran lowers total cholesterol, Marlett et al. (Ref. 29) reported significant reductions in total cholesterol in the period in which subjects consumed oat bran compared to a wheat control period. The subjects consumed 100 g oat bran/day for 4 weeks during the high fiber period and wheat gluten during the low fiber, control period, with their usual diets.

The results of 12 other studies (Refs. 8, 11, 15, 17, 20, 21, 23, 24, 35, and 42 through 44) also support the relationship between oat consumption and reduction in total and LDL-cholesterol. Six studies (Refs. 8, 17, 20, 21, 35, and 44) showed the benefits of oat intervention in reducing serum total and LDL-cholesterol in subjects consuming a typical American diet. HDL-cholesterol showed no significant change in four of these studies (Refs. 8, 20, 21, and 35) and a significant reduction in one study (Ref. 21). The amount of oat bran or oatmeal consumed in these studies ranged from 34 g/day (Ref. 17) to 110 g/d (Ref. 8).

Three studies (Refs. 15, 23, and 24) showed a significant effect of oat bran or oatmeal on total and LDL-cholesterol that was beyond that of a Step 1 diet alone. The results of the three other studies (Refs. 11, 42, and 43) showed lower, nonsignificant, total and LDL-cholesterol in subjects who consumed oat bran or oatmeal compared to the group who consumed the Step 1 or Step 2 diets alone. In two of these studies (Refs. 42 and 43), the subjects' lipid values after a run-in period on the low fat diet ranged from a mean of 193 to 197 mg/dL. The lack of significant difference between the diet only and the oat groups in these studies may be overshadowed by the effect of the diet alone on subjects who had initially low total and LDL-cholesterol levels. There were no significant changes in HDL-cholesterol from the consumption of a low fat diet plus oats. The range of oat intake in these studies ranged from 35 g (Ref. 43) to 100 g/day (Ref. 24).

Two studies (Ref. 20 and 23) used wheat as a placebo control. The results of these studies showed significantly lower total and LDL-cholesterol in subjects who consumed oat bran compared to those who consumed wheat.

A metaanalysis (Ref. 33) using pooled, raw data from a number of oat studies (Refs. 11, 15 through 17, 23, 25, 30, 37, 39, 40, and 42 through 44) found that an intake of 3 g soluble fiber (used as a marker for oat bran and oatmeal) or more produced modest reductions (average decrease of 5 to 6 mg/dL) of serum total cholesterol levels. The decrease in total cholesterol was largest in those trials with subjects that initially had high total cholesterol levels.

As stated in section III.A. of this document, Federal government and other reviews have concluded that there is substantial epidemiologic and clinical evidence that high blood levels of total cholesterol and LDL-cholesterol represent major contributors to CHD (56 FR 60727 at 60728, and Refs. 3 through 5). Dietary factors that decrease total cholesterol and LDL-cholesterol will affect the risk of CHD (Refs. 3 through 6). Based on the scientific evidence presented in the petition, the agency tentatively concludes that there is significant scientific evidence to show that oat bran and oatmeal will help reduce serum lipids, and that such reductions may reduce the risk of CHD. In the majority of clinical studies evaluating oat products, total and LDL-cholesterol fractions were shown to be the most affected by oat intervention. Regular consumption of oat bran or oatmeal, in an amount to provide 3 g or more of oat β-glucan soluble fiber, resulted in reduced total and LDL-cholesterol levels in subjects with normal and elevated serum cholesterol levels.

Changes in HDL-cholesterol levels as a result of oat intervention were generally absent or not significant (Refs. 8, 11 through 13, 18, 20, 23 through 28, 32, 35 through 39, 41, 42, and 45). A tendency toward an increase in HDL-cholesterol was shown in nine studies (Refs. 13, 24, 25, 27, 28, 32, 39, 42, and 45); no change was shown in nine studies (Refs. 8, 12, 18, 20, 23, 24, 35, 36, and 41); and a nonsignificant decrease in HDL-cholesterol was shown in three studies (Ref. 11, 26, and 38). Although HDL-cholesterol was reduced 0.9 percent ($p<0.03$) in the study by Kahn et al. (Ref. 21), the HDL:LDL and HDL:total cholesterol ratios were improved, compared to baseline, because of significant reductions in total cholesterol (8 percent) and LDL-cholesterol (10 percent).

Oat bran and oatmeal were tested in a variety of food forms but produced fairly consistent results, showing that the way in which these foods are consumed does not alter their effect on serum lipids. They were consumed as hot and cold cereals or used in a variety of other foods, such as muffins, breads, shakes, and entrees.

The eleven studies that did not show reduced total and LDL-cholesterol from the consumption of oat bran or oatmeal (Refs. 13, 16, 18, 26 through 28, 31, 34, 36, 38, and 41) do not detract from the agency's tentative conclusion about this relationship or that the claim is valid.

The lack of result in five of these studies (Refs. 13, 26, 28, 36, and 38) was apparently attributed to the oat source, i.e., New Zealand cultivars, or to the method of processing oat bran. The results of the remaining six studies were associated with a lack of subject compliance and significant changes in dietary intake during the test periods, or to problems in study design, i.e., a lack of statistical power to detect changes between groups.

Given all of this evidence, the agency is proposing a health claim on the relationship between oat bran and oatmeal and reduced risk of CHD.

V. Description and Rationale for Components of Health Claim

A. Relationship Between Oatmeal and Oat Bran and CHD and the Significance of the Relationship

Proposed § 101.81(a) describes the relationship between diets high in oat bran or oatmeal and the risk of CHD. In proposed § 101.81(a)(1), the agency recounts that CHD is the most common and serious form of CVD, and that CHD refers to diseases of the heart muscle and supporting blood vessels. The regulation also notes that high blood total and LDL-cholesterol levels are associated with increased risk of developing CHD. The regulation identifies the levels of total cholesterol and LDL-cholesterol that would put an individual at high risk of developing CHD and those serum lipid levels that are associated with borderline high risk. The intent is to provide consumers with information to help them understand the seriousness of CHD.

In proposed § 101.81(a)(2), the agency recounts that populations with a low incidence of CHD tend to have low blood total and LDL-cholesterol levels. It states that these populations also tend to have dietary patterns that are low in total fat, saturated fat, and cholesterol and high in fruits, vegetables, and grain products, such as oatmeal and oat bran. This information is consistent with that provided in the authorized health claim for fruits, vegetables, and grain products and CHD (§ 101.77). The agency tentatively finds that this information provides a basis for a better understanding of the numerous factors that contribute to the risk of CHD and the relationship between oat bran and oatmeal and a low fat diet.

Proposed § 101.81(a)(3) describes the relationship between oat bran and oatmeal, foods low in saturated fat and cholesterol, and reduction in the CHD risk factors. The paragraph states that several studies have shown that diets high in oatmeal or oat bran are associated with reduced blood lipid levels. This information encapsulates the scientific evidence about how oatmeal and oat bran can contribute to reduction in heart disease risk factors.

Proposed § 101.81(b) describes the significance of the diet-disease relationship. In proposed § 101.81(b)(1), the agency recounts that CHD remains a major public health concern in the United States because the disease accounts for more deaths than any other disease or group of diseases. The claim states that early management of modifiable risk factors for CHD is a major public health goal that can assist in reducing the risk of CHD. This information is consistent with the evidence that lowering blood total and LDL-cholesterol levels reduces the risk of CHD (56 FR 60727, 58 FR 2739, and Refs. 3 through 6 and 47).

In proposed § 101.81(b)(2), the significance of the relationship between oatmeal and oat bran and CHD risk factors in context of the total diet is discussed. The agency recounts that many Americans' intakes of saturated fat and cholesterol exceed recommended levels, and it summarizes public health recommendations for the diet (56 FR 60727 at 60738 and § 101.75(b)(3)). This paragraph also states that scientific evidence demonstrates that diets high in oatmeal and oat bran and low in saturated fat and cholesterol are associated with reduced blood lipids. FDA tentatively concludes that the latter statement is scientifically valid based on the evidence that it has reviewed on this nutrient-disease relationship.

B. Nature of the Claim

In § 101.81(c)(1) (21 CFR 101.81(c)(1)), FDA is proposing to require that all of the general requirements for health claims set out in § 101.14 be met. This provision is consistent with the provisions of the other specific health claim regulations in part 101, subpart E, of the Code of Federal Regulations (CFR) (21 CFR part 101, subpart E).

In § 101.81(c)(2)(i), FDA is proposing to authorize a health claim on the relationship between diets high in oat bran or oatmeal and the risk of CHD. The agency is proposing to do so based on its review of the scientific evidence on this nutrient-disease relationship which shows that diets that are high in oat bran or oatmeal help to reduce total and LDL-cholesterol levels in individuals with normal to elevated blood total cholesterol (Refs. 8, 11, 12, 15, 17, 20, 21, 23 through 25, 29, 35, 39, 44, and 45). This result is significant for the risk of heart disease because elevated levels of total and LDL-cholesterol are associated with increased risk of CHD (Refs. 3 through 6).

In § 101.81(c)(2)(i)(A), the agency is proposing to require, consistent with other health claims, that the relationship be qualified with the terms ''may'' or ''might.'' These terms are used to make clear that not all persons can necessarily expect to benefit from these dietary changes (56 FR 60727 at 60740 and 58 FR 2552 at 2573).

In § 101.81(c)(2)(i)(B), the agency is proposing to require, consistent with other authorized health claims, that the terms ''coronary heart disease'' or ''heart disease'' be used in specifying the disease. These terms are commonly used in dietary guidance materials, and therefore they should be readily understandable to the consumer (56 FR 60727 at 60740 and 58 FR 2552 at 2573).

In § 101.81(c)(2)(i)(C)(*1*), the agency is proposing that the claim describe the relationship between diets high in oatmeal or oat bran and risk for CHD. Based on its review of the scientific evidence submitted with the petition, the agency tentatively concludes that there is significant scientific agreement that diets high in oat bran or oatmeal may help to reduce blood total and LDL-cholesterol levels, the major modifiable risk factors for CHD (Refs. 12, 17, 20, 21, 25, 29, 35, 44, and 45).

The petitioner stated in its petition that there is significant scientific evidence to show that the effect of oats on lowering serum lipids is independent of a diet low in saturated fat and cholesterol. In light of this evidence, the petitioner argued that any health claim that is authorized need not refer to such a diet. The petitioner explained that important public health policy objectives, as well as FDA's statutory mandate to authorize health claims supported by significant scientific agreement, mandate that FDA issue a regulation that requires only that claims describe the relationship between oat products and reduced risk of CHD (Ref. 1, p. 68).

The agency acknowledges that there were a number of studies that showed that high intakes of oat bran and oatmeal lowered blood total and LDL-cholesterol in subjects that otherwise consumed a typical American diet (Refs. 12, 17, 20, 21, 25, 29, 35, 44, and 45). However, as stated in section V.A. of this document, CHD is a major public health concern in the United States, and that the totality of the scientific evidence provides strong and consistent support that diets high in saturated fat and cholesterol are associated with elevated levels of blood total and LDL-cholesterol, and thus CHD (56 FR 60727

at 60737). Dietary estimates for American adults show that the average saturated fat intakes of American adults are about 13 percent of calories, total fat intakes are about 37 percent of calories, and average cholesterol intakes range from 300 to over 400 mg daily for adult men and women (56 FR 60727 at 60738). The current intakes of saturated fat and total fat are thus well in excess of recommended goals of less than 10 percent and 30 percent of calories. Dietary guidelines from both government and private-recognized scientific bodies conclude that the majority of the American population would benefit from decreased consumption of dietary saturated fat and cholesterol (Refs. 3 through 6).

The results of several studies showed that while daily consumption of oat bran or oatmeal lowered total cholesterol and LDL-cholesterol, the effects of dietary intake of oat bran or oatmeal were particularly evident when the diets were low in saturated fat and cholesterol (Refs. 11, 15, 24, 39, and 43). Thus, the agency tentatively finds that it will be more helpful to Americans' efforts to maintain healthy dietary practices if the effect of oats on serum lipids is described in context of a healthy diet. This information is extremely important to a full understanding of the significance of the claim.

The agency tentatively finds that for the public to understand fully, in the context of the total daily diet, the significance of consumption of oat bran and oatmeal on the risk of CHD (see section 403(r)(3)(B)(iii) of the act), information about the total diet needs to be included as part of the claim. Therefore, in § 101.81(c)(2)(i)(C)(*2*), the agency is proposing to require that the claim include the fact that the effect of dietary consumption of oatmeal or oat bran on the risk of CHD is particularly evident when these foods are consumed as part of a diet that is low in saturated fat and cholesterol. Based on its review of the scientific evidence submitted with the petition, the agency tentatively concludes that there is significant scientific agreement that diets high in oat bran or oatmeal and low in saturated fat and cholesterol are associated with reduced blood total and LDL-cholesterol levels (Refs. 11, 15, 23, 24, 39, 42, and 43).

FDA is proposing to require that this dietary information be included as part of the full health claim to ensure that people understand the significance of the information in the claim. A diet low in saturated fat and cholesterol is important because if intake of these dietary components are not controlled, then there is a significant question as to whether high fiber diets will have their full effect on blood total and LDL-cholesterol levels, and thus on the risk of heart disease. However, based on information supplied by the petitioner, FDA tentatively concludes that a claim that diets high in oat bran or oatmeal may reduce the risk of heart disease is truthful, not misleading, and scientifically valid without this additional information. Therefore, FDA tentatively finds that it is appropriate to require that a label that bears an oat bran or oatmeal health claim disclose the fact that a diet should be high in oat bran and oatmeal and low in saturated fat and cholesterol, but that it is not necessary to require that the latter dietary information be disclosed in immediate proximity of the oat bran or oatmeal claim each time the claim appears on the label or in labeling (see the discussion of § 101.81(c)(2)(ii) below). FDA is proposing to require only that the full statement of the claim disclose the fact that the effect of the dietary intake of oat bran or oatmeal is particularly evident when the diet is low in saturated fat and cholesterol.

Proposed § 101.81(c)(2)(i)(D), consistent with other authorized health claims, requires that the claim not attribute any degree of risk reduction of CHD to consumption of oat products. None of the studies that the agency reviewed provide a basis for determining the percent reduction in risk of CHD likely from consuming diets high in oat products.

The agency considered proposing to require that the claim state that the development of CHD depends on many factors. This statement has been required in the two authorized heart disease health claims (§§ 101.75 and 101.77) (although the agency has recently proposed to delete this requirement in a document that published in the Federal Register of December 21, 1995 (60 FR 66206) (hereinafter referred to as the 1995 proposal). The petitioner requested that the statement regarding the multifactorial nature of CHD be listed under optional requirements for the health claim (Ref. 1, p. 68). The petitioner stated that based on an ever increasing background of health information made available through various media, consumers already understand that foods are not drugs, and that health enhancement depends not only on consumption of a particular food but also on other dietary practices, exercise, heredity, lifestyle, and a host of other factors. The petitioner did not provide any data to support this observation. The petition stated that the ''depends on many factors'' language makes the health claim cumbersome, unnecessarily long, and detracts from its central and critical consumer message. The petition stated that using the required statement ''may help'' (i.e., ''may help reduce the risk of heart disease'') more simply, directly, and succinctly indicates to consumers that oatmeal and oat bran are not magic bullets, and that other factors are associated with CHD risk.

The agency agrees with the petitioner that the requirement that the claim use the term ''may'' or ''might'' to relate the ability of oat bran or oatmeal to reduce the risk of heart disease is intended to reflect the multifactorial nature of the disease. In response to comments on the scientific standard proposed for health claims, the agency stated in the 1993 health claims final rule (58 FR 2478 at 2505):

> * * * Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term ''may'' with respect to the potential to reduce the risk of disease. * * *

The agency notes that FDA has been asked in a petition from the National Food Processors Association (NFPA) (Docket No. 94P–0390) to reevaluate the required elements of the health claim and to consider a number of options including the option of using an abbreviated health claim and eliminating the multifactorial element of the health claim requirements. In the 1995 proposal, the agency initiated rulemaking that, in part, proposed to eliminate or make optional some of the required elements. More specifically, the agency proposed to make optional the statement ''a disease caused by many factors'' (see section IV.E. of the 1995 proposal), and to permit the use of certain abbreviated health claims on the label or labeling of a product (see section IV.C. of the 1995 proposal) (60 FR 66206). In this proposed rule on oat bran and oatmeal and CHD, the agency is proposing to make the phrase ''depends on many factors'' optional information. In place of the requirement for stating the multifactorial nature of

the disease, the agency is proposing § 101.81(c)(2)(i)(E) to require that the claim not imply that the consumption of oat bran and oatmeal is the only recognized means of achieving a reduced risk of CHD. Thus, the agency tentatively concludes that the concept of the multifactorial nature of CHD will be preserved without adding additional words to the claim. The agency requests comment on whether consumers will be misled to believe that reduction of risk will be achieved if the multifactorial nature of CHD is not stated on the claim. This proposed rule would also permit use of a shortened version of the claim in conjunction with the full claim (see section IV.C. of the 1995 proposal).

C. Presentation of the Claim

In proposed § 101.81(c)(2)(ii), the agency is providing for how the health claim is to be presented on the label or labeling. This paragraph states that all of the elements listed in § 101.81(c)(2)(i) must be included in one presentation of the claim on the label or labeling. As discussed in sections V.A. and B. of this document, the scientific evidence provides strong and consistent support that diets high in saturated fat and cholesterol are associated with elevated levels of blood total and LDL-cholesterol, the major modifiable risk factors for CHD. Because the typical American diet tends to be high in saturated fat and cholesterol, dietary guidelines recommend that Americans modify their intakes of food that contain significant levels of saturated fat and cholesterol. From a public health standpoint, it is important for the public to comprehend the significance of the relationship between diets high in oat bran or oatmeal and CHD risk in context of a diet low in saturated fat and cholesterol. This relationship is supported by significant scientific evidence as discussed above.

However, the 1995 proposal permits a short, simple statement of certain health claims that is truthful, not misleading, and scientifically valid, which may be used on the principal display panel, as long as the full claim appears on the particular label or in the particular labeling in which the short statement appears, and there is a referral statement from the shortened to the full claim (60 FR 66206). In recognition of this fact, FDA is providing in proposed § 101.81(c)(2)(ii) that if a full statement of the claim appears on a label or in a piece of labeling, other presentations of the claim may appear on the label or in labeling that do not include the information required in proposed § 101.81(c)(2)(i)(C)(*2*) so long as there is a referral statement to the full statement of the claim in immediate proximity with the shortened statement. FDA has explained above the basis for its tentative conclusion that the shortened claim need not include the information in paragraph (c)(2)(i)(C)(*2*) regarding the importance of low saturated fat and cholesterol diet.

The referral statement that FDA is proposing accompany the shortened claim is consistent with that provided for in the general requirements for nutrient content claims (§ 101.13) and health claims (§ 101.14(d)(2)(iv)). This referral statement is short and thus consistent with the use of an abbreviated claim. It is important, however, because the agency tentatively finds that it is essential that the consumer be directed to the full claim. Specifically drawing the consumer's attention to the full claim will help to ensure that he or she is able to comprehend the information that is being presented in the context of the total daily diet.

In its 1993 health claims final rule, the agency stated that it did not believe that it is appropriate to use abbreviated health claims as referral statements (58 FR 2478 at 2512). The agency was concerned that an abbreviated claim would not include facts that are material in light of the representation that is made and that are necessary to understand the claim in the context of the daily diet. The agency was concerned that confusion is possible whenever the full health claim information appears in a location different from that of the reference statement and is especially likely to occur when a multiplicity of labeling is associated with a product.

The agency has tentatively concluded that this proposed rule addresses these concerns. It is providing for an abbreviated statement that reflects the facts that are material under section 201(n) of the act (21 U.S.C. 321(n)) and that are necessary to ensure that the claim is scientifically valid. It is also providing for an accompanying referral statement to additional information that is necessary for a full understanding of the claim. The agency is concerned, however, about the possibility that consumers may not read the complete claim, and thus that they will not have all of the facts necessary to fully understand the significance of the claim being made and to comprehend the claim in the context of the daily diet. For this reason, the agency is asking for data to demonstrate that permitting a shortened claim in this manner will not significantly decrease the likelihood that consumers will read the full claim so long as it appears prominently on the label or in the piece of labeling.

In new § 101.81 (c)(2)(ii)(A) and (c)(2)(ii)(B), the agency is proposing, consistent with requirements for nutrient content claims in § 101.13 (g)(1) and (g)(2), requirements for the typesize and location of the referral statement.

FDA has long held that accompanying information should be in a size reasonably related to that of the information that it modifies. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. Section 403(r)(2)(B) of the act requires that a referral statement for nutrient content claims appear prominently, although it does not specify specific requirements such as to typesize or style. For nutrient content claims, FDA established type size requirements for referral and disclosure statements related to the area of the surface bearing the principal display panel rather than to the type size used for the nutrient content claim. The proportionality between the size of the referral statement and the size of the label ensures that the referral statement is presented with appropriate prominence. However, when the claim is less than twice what the minimum size of the referral statement would be given the size of the label and § 101.105(i) (21 CFR 101.105(i)) the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. This approach to the type size requirement for the referral statement provides flexibility to firms in utilizing label space but still ensures adequate prominence for this statement. Because health claim referral statements are used similarly to those that accompany nutrient content claims and are likely to appear on the principal display panel, the agency tentatively concludes that a health claim referral statement should have the same type size requirements as those for nutrient content claims. Therefore, the agency tentatively concludes that the requirements for the referral statement set forth in § 101.105 (c)(2)(ii)(A) and (c)(2)(ii)(B) are appropriate when a shortened health claim is used and is including them in this proposed rule.

D. Nature of the Food

Proposed § 101.81(c)(2)(iii)(A) requires that the food bearing the health claim contain 13 g of oat bran or 20 g

oatmeal, and that the oat bran or oatmeal contain, without fortification, at least 1.0 g of β-glucan soluble fiber. The paragraph states that oat β-glucan be determined by the Association of Official Analytical Chemists (AOAC) official method (i.e., method 992.28), per reference amount customarily consumed (RACC).

The requirement that the food contain oat bran or oatmeal is consistent with the scientific evidence that shows that oat bran or oatmeal, when consumed as a food or as an ingredient in food, helps to lower total and LDL-cholesterol.

The agency is not proposing to permit a claim for oat gums or oat fibers, substances that may be manufactured by different methods and are not well defined chemically or physically. These substances, like all food fibers, are a complex matrix and factors, such as the fermentability; particle size; molecular weight; chemical structure; water holding capacity; nonfiber components; net charge; viscosity; and cation-exchange capacity, binding, and chelation, may affect their physiological properties (Ref. 7).

The effects of processing on the physiological properties of oat bran were evidenced in three studies. In a study by Törrönen et al. (Ref. 38), a specially processed oat bran concentrate incorporated into bread to provide 11.2 g/d β-glucan showed no effect on lowering serum lipids in a controlled study with hypercholesterolemic subjects. Two other studies testing a specially processed oat fiber source providing 3.3 g/d β-glucan soluble fiber (Ref. 35) and oat gum providing 5.8 g/d β-glucan soluble fiber (Ref. 12) showed significant reductions in blood total and LDL-cholesterol levels. The latter two studies showing a cholesterol-lowering response did not adequately characterize the material being tested to permit their (oat fiber source and oat gum) inclusion in the regulations, however. If manufacturers can document, through appropriate studies, that dietary consumption of a well-characterized oat product, e.g., purified extracts of oat gum or modified oat fiber isolates, has the effect of lowering total and LDL-cholesterol levels, and has no adverse effects on other heart disease risk factors (e.g., HDL-cholesterol), they should submit that information in comments or petition FDA to amend § 101.81 to cover the substance.

Because the subject of this health claim petition is the effect of oatmeal or oat bran on the risk of CHD, it is appropriate to consider the levels of oat bran and of oatmeal intake that have been shown to have significant effects on the levels of serum total and LDL-cholesterol in establishing qualifying levels for foods to bear an oatmeal or oat bran and CHD health claim. In the clinical studies that showed that consumption of oatmeal or oat bran lowered total and LDL-cholesterol, daily consumption ranged from 35 g (Ref. 43) to 84 g (Ref. 15) of oat bran and 34 g (Ref. 17) to 150 g (Ref. 39) of oatmeal. Based on values provided in the petition, 35 g of oatmeal would provide about 1.75 g of β-glucan soluble fiber, and 34 g of oat bran would provide about 2.5 g of β-glucan soluble fiber (Ref. 1, p. 66). The higher the daily intake of oatmeal and oat bran, the higher the intake of β-glucan soluble fiber and the better the response in lowering serum lipids. This observation is supported by the metaanalysis of oat products by Ripsin et al. (Ref. 33) and is consistent with the agency's comments on the Davidson et al. study (Ref. 15) in the preamble to the 1993 dietary fiber and CVD final rule (58 FR 2552 at 2568):

> * * *[B]ased on the results of this study, an intake of soluble fiber (in this case, β-glucan from oats) of about 3 g per day or more was beneficial in that it resulted in a significant lowering of serum cholesterol in persons consuming a low-fat diet.

An intake of 3 g of β-glucan soluble fiber is equivalent to approximately 60 g of oatmeal or 40 g of oat bran (dry weight) (Ref. 1, p. 67), the approximate midpoints of the consumption ranges of oat bran and oatmeal that had an effect on blood lipids. The petitioner suggested that 40 g of oat bran, 60 g of oatmeal, and 3 g β-glucan soluble fiber be considered as the standard for determining the qualifying levels of oat bran and oatmeal for this health claim. Applying a regression analysis to the results of Davidson et al. (Ref. 15), and using β-glucan soluble fiber as a marker for oat bran and oatmeal, the petitioner determined that 3 g β-glucan would be required to achieve a 5 percent reduction in serum cholesterol (Ref. 1, p. 22–27). The petition stated that a 5 percent reduction in serum cholesterol is a desirable goal because that is the level that was achieved as a result of a dietary fat and cholesterol focused intervention in the Multiple Risk Factor Intervention Trial (MRFIT) and Lipid Research Council (LRC) clinical trials (Refs. 1 and 40).

The petitioner stated that while current research may not demonstrate that β-glucan is the only component of oats that affects blood lipids, it does suggest that it is an excellent marker for cholesterol reduction potential (Ref. 1, p. 64). The petitioner stated that the amount of β-glucan also serves as a marker for the content of oat bran and oatmeal in foods. Using 40 g of oat bran, 60 g of oatmeal, and 3 g β-glucan as the qualifying amounts for a CHD claim, the petitioner suggested that a single serving of an oat-containing product (i.e., 1 RACC) should provide ⅓ of this amount (based on 3 servings a day). Thus, an oat bran-containing product would have to contain at least 13 g oat bran (⅓ × 40 g) that provides 1 g β-glucan (⅓ × 3 g) soluble fiber per RACC. An oatmeal-containing product would have to contain no less than 20 g oatmeal (⅓ × 60) that provides 1 g β-glucan soluble fiber. The petitioner stated that this approach is reasonable because it would permit a wide variety of low fat, oat-containing products, e.g., muffins, cereals, and breads, to qualify for this health claim. The petitioner provided several examples of meals, developed on the basis of U.S. Dietary Guidelines, that demonstrated how 40 g of oat bran and 60 g of oatmeal, providing 3 g of β-glucan soluble fiber, could be incorporated into a diet that is consistent with dietary guidelines (Ref. 1, pp. 43–54).

The agency agrees that, based on Davidson et al. (Ref. 15), the metaanalysis (Ref. 33), and other studies that reported the amount of β-glucan soluble fiber in oat products, 3 or more grams of oat β-glucan soluble fiber were associated with significant reductions in serum cholesterol. The agency also agrees that not all oat bran or oatmeal-containing products that might otherwise qualify for this claim contain that amount per RACC of oat product. Based on nutrient composition data presented in the petition (Ref. 1, pp. 38–39), only oat bran hot and cold cereals contain 3 g β-glucan soluble fiber would qualify for this proposed health claim. Thus, limiting eligibility for the claim to products with 3 g β-glucan soluble fiber would have the unintended effect of eliminating a number of low fat, oat-containing products, e.g., oatmeal cereals, oatmeal waffles, oat bran muffins, and oatmeal breads, from bearing an oatmeal or oat bran and CHD health claim.

The petition states that the most common oat food forms are oat bran and oatmeal consumed as hot cereals (Ref. 1, p.33). The mean daily dietary intake by oat consumers of oatmeal and oat bran hot cereals is 43.3 g (dry weight basis) and the median intake is 40.1 g (Ref. 1, p. 33). The petition states that the 90th and 95th percentiles of intake are 71.3 and 84.2 g (dry weight basis) per day, respectively. Therefore, it is reasonable to assume that a person could consume a total of, or more than, 40 g oat bran, 60 g oatmeal, or a combination of the

two that provides 3 g β-glucan soluble fiber if the oat products are consumed over the course of a day.

The agency has generally made the assumption that a daily food consumption pattern includes three meals and a snack (see 58 FR 2302 at 2379, January 6, 1993). Therefore, one approach to determining the qualifying levels of oat bran, oatmeal, and oat β-glucan soluble fiber for a CHD health claim is to divide the effective levels of these substances by four eating occasions per day. Using this approach, an oat bran product would have to provide at least 10 g of oat bran and 0.75 g β-glucan soluble fiber, and an oatmeal product would have to provide at least 15 g of oatmeal and 0.75 g β-glucan soluble fiber per RACC in order to qualify to bear an oat and CHD health claim. However, considering that the mean daily dietary intake of oatmeal and oat bran is 43 g, and that that amount is consumed mostly in the form of hot cereal, and considering the nature of this food, it is not expected that people will consume oat-containing products 4 times a day. The agency is persuaded by the petitioner's argument that oat products can reasonably be expected to be consumed 3 times a day, being incorporated into a variety of products. Thus, an oat bran-containing product would have to provide no less than 13 g oat bran and 1 g β-glucan soluble fiber per RACC, and an oatmeal-containing product would have to provide no less than 20 g oatmeal and 1 g β-glucan soluble fiber. Therefore, the agency tentatively finds that use of 13 g oat bran and 20 g oatmeal that provide 1 g β-glucan soluble fiber as the qualifying criteria for this proposed rule is appropriate and is proposing these levels in this document.

The proposed qualifying requirement of 1 g β-glucan soluble fiber per RACC of oat bran or oatmeal-containing product is higher than the amount of soluble fiber that is required for a food to qualify to bear the fruits, vegetables, and grain products and CHD health claim (§ 101.77). Under § 101.77(c)(ii)(C), a food need only contain, without fortification, 0.6 g soluble fiber per RACC. In the preamble to the 1993 dietary fiber and CVD final rule, the agency explained that the 0.6 g of soluble fiber was based in part on the recommendation by the LSRO expert panel that 25 percent of the recommended daily intake of fiber be soluble fiber (58 FR 2552 at 2573 and 2574). The agency also stated that the 0.6 g soluble fiber is consistent with the definition of a ''good source'' of a nutrient (i.e., 10 percent of the daily reference value (DRV)). The agency explained that the 10 percent level is deemed useful and appropriate because very few foods could naturally meet the requirement for a ''high'' source of soluble fiber. The current dietary guidance recommendations of five or more servings of fruits and vegetables and six or more servings of grain products daily, if followed, would likely result in intakes of soluble fiber close to or exceeding the recommended daily intake of 6 g (58 FR 2552 at 2574). Thus, the 0.6 g of soluble fiber was intended to allow a number of fruits, vegetables, and grain products to qualify. The agency stated that without this alternate level very few fruits, vegetables, and grain products would qualify for the health claim (58 FR 2552 at 2574).

Based on the scientific evidence reviewed in this document, higher daily intakes of oat bran and oatmeal (about 40 g and 60 g, respectively) that provided 3 g/d or more of β-glucan soluble fiber were associated with significant cholesterol-lowering benefits (Refs. 15 and 33). As discussed above, it is reasonable to assume that oat bran and oatmeal would likely not be consumed in more than three eating occasions per day. Therefore, the agency tentatively finds that the proposed criterion that the oat bran or oatmeal provide 1 g β-glucan soluble fiber per RACC is appropriate for this health claim. The agency is asking for comments on this tentative determination.

In § 101.81(c)(2)(iii)(B), the agency is proposing, consistent with other authorized heart disease health claims, that foods bearing the health claim meet requirements for ''low saturated fat,'' ''low cholesterol,'' and ''low fat.'' In the preamble to the final rule on fruits, vegetables, and grain products and heart disease (§ 101.77, 58 FR 2552 at 2572), the agency stated that populations with diets rich in these low saturated fat and low cholesterol foods experience many health advantages, including lower rates of heart disease. In the preamble to the proposed rule on dietary lipids and heart disease (56 FR 60727 at 60739), the agency stated that while total fat is not directly linked to increased risk of CHD, it may have significant indirect effects. Foods that are low in total fat facilitate reductions in intakes of saturated fat and cholesterol to recommended levels. Therefore, the agency tentatively concludes that proposed § 101.81(c)(2)(iii)(B) sets forth an appropriate requirement for food to be eligible to bear the oatmeal and oat bran/CHD claim.

E. Optional Information

FDA is proposing in § 101.81(d)(1) that the claim may state that the development of heart disease depends on many factors and, consistent with authorized CHD health claims, may list the risk factors for heart disease that are listed in §§ 101.75(d)(1) and 101.77(d)(1). The agency is also proposing, in response to the petition, that the claim may provide additional information about the benefits of exercise and body weight management. This additional information can provide a context that is useful for an understanding of the relationship between oat bran and oatmeal and heart disease, but manufacturers should be cautioned that it should not be presented in a way that is misleading to the consumer.

In proposed § 101.81(d)(2), consistent with §§ 101.75(d)(2) and 101.77(d)(2), FDA is providing that the claim may state that the relationship between a diet high in oat bran or oatmeal and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total cholesterol'' and ''LDL-cholesterol.'' The relationship between oat bran or oatmeal and reduced blood total cholesterol and LDL-cholesterol is supported by the scientific evidence presented in this proposal.

In § 101.81(d)(3), the agency is proposing that, consistent with §§ 101.75(d)(3) and 101.77(d)(3), the claim may include information from § 101.81(a) and (b). These paragraphs summarize information regarding the relationship between diets high in oat bran or oatmeal and the risk of CHD and about the significance of that relationship. This information helps to convey the seriousness of CHD and the role that a diet high in oat bran and oatmeal can play to help reduce the risk of CHD.

In § 101.81(d)(4), the agency is proposing that the claim may state that oat bran or oatmeal are good sources of dietary fiber, particularly soluble fiber. In referring to the fiber components the claim may use the terms ''fiber,'' ''dietary fiber,'' and ''soluble fiber.'' If the term ''soluble fiber'' is used in the claim, the declaration of soluble fiber content is required. This proposed provision is consistent with § 101.9(c)(6)(i)(A), which states that the declaration of soluble fiber on the nutrition label is voluntary, except that when a claim is made on the label or in labeling about soluble fiber, label declaration is required.

The agency is proposing that the claim may include any of the optional information authorized to be included

in §§ 101.75(d)(5), (d)(6), and (d)(7) and 101.77(d)(5), (d)(6), and (d)(7). The health claim may state that diets high in oat bran or oatmeal and low in saturated fat and cholesterol are part of a dietary pattern that is consistent with dietary guidelines for Americans. The claim may state that individuals with elevated serum lipids should consult their physicians for medical advice and treatment and may include information on the prevalence of CHD in the United States. The intent of this information is to provide consumers with information that will help them understand the seriousness of CHD in the United States and to help them understand that diets high in oat bran or oatmeal are consistent with dietary guidelines.

In proposed § 101.81(d)(8), in response to the petition, the claim may provide information about the amount of food, such as bowls, servings or slices, to be consumed daily. This information may give the consumer a better perspective on how much oat bran and oatmeal is needed to help lower serum cholesterol levels.

F. Model Health Claims

In proposed § 101.81(e), FDA is providing model health claims to illustrate the requirements of new § 101.81. FDA emphasizes that these model health claims are illustrative only. These model claims illustrate the required, and some of the optional, elements of the proposed rule. If the agency authorizes a claim about the relationship between oat products and CHD, manufacturers will be free to design their own claim so long as it is consistent with § 101.81(c).

In § 101.81(e)(1), the model claim illustrates all of the required elements of the proposed health claim. The claim states ''Diets high in [oat bran or oatmeal] and low in saturated fat and cholesterol may reduce the risk of heart disease.''

In § 101.81(e)(2), the model claims provide examples of a shortened claim with the required referral statement.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

This proposed rule will not result in significant costs to industry. Some oat manufacturers are currently using FDA's approved health claim regarding the benefits of fruits, vegetables, and grain products. This proposed health claim will allow them to specifically highlight the benefits of oat bran and oatmeal. Consumers will benefit from the additional information regarding the relationship of oat products and CHD.

VIII. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements; thus there is no ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is seeking comment on whether this proposed rule to permit health claims on the association between oat products (i.e., oat bran and oatmeal) and reduced risk of CHD imposes any paperwork burden.

IX. Effective Date

FDA is proposing to make these regulations effective upon publication in the Federal Register of a final rule based upon this proposal.

X. Comments

Interested persons may, on or before April 3, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. New § 101.81 is added to subpart E to read as follows:

§ 101.81 Health claims: Oat products and risk of coronary heart disease.

(a) *Relationship between diets high in oatmeal and oat bran and the risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing CHD. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease.

(2) Populations with a low incidence of coronary heart disease tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat, and cholesterol but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as oatmeal and oat bran.

(3) Oat bran and oatmeal are low in saturated fat and cholesterol and a good source of soluble fiber. Scientific evidence demonstrates that diets high in these oat products are associated with reduced blood total and LDL-cholesterol levels.

(b) *Significance of the relationship between diets high in oatmeal and oat bran and the risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing the risk of coronary heart disease. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets high in oat bran and oatmeal and low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets high in oatmeal or oat bran with reduced risk of coronary heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that oatmeal or oat bran ''may'' or ''might'' reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the following terms: ''heart disease'' or ''coronary heart disease.''

(C) The claim states that:

(*1*) Diets high in oatmeal or oat bran may reduce the risk of coronary heart disease; and

(*2*) The effect of dietary intake of oatmeal or oat bran on the risk of coronary heart disease is particularly evident when these foods are consumed as part of a diet that is low in saturated fat and cholesterol.

(D) The claim does not attribute any degree of risk reduction for coronary heart disease to diets high in oat bran or oatmeal and low in saturated fat and cholesterol.

(E) The claim does not imply that consumption of oat bran or oatmeal is the only recognized means of achieving a reduced risk of coronary heart disease.

(ii) *Presentation of the claim.* All of the elements listed in paragraph (c)(2)(i) of this section must be included in one presentation of the claim displayed prominently on the label or in the labeling on which the claim appears. Other presentations of the claim on that label or labeling, including on the principal display panel, need not include the information in paragraph (c)(2)(i)(C)(*2*) of this section provided that, displayed prominently and in immediate proximity to a shortened statement of the claim, the following referral statement is used: ''See _____ for more information'' with the blank filled in with the identity of the panel on which is presented the statement of the claim that includes all of the elements in paragraph (c)(2)(i) of this section.

(A) The referral statement ''See [appropriate panel] for more information'' shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than 2 times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(B) The referral statement shall be immediately adjacent to any presentation of the health claim that does not include all of the elements in paragraph (c)(2)(i) of this section, and there may be no intervening material between the claim and the referral statement. If the abbreviated health claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the full health claim, where it may be omitted.

(iii) *Nature of the food.* (A) The food shall contain no less than 20 g oatmeal or 13 g oat bran that provides, without fortification, at least 1 g of β-glucan soluble fiber per reference amount customarily consumed. Beta-glucan will be determined by method No. 992.28 from the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th ed. (1993), which is

incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC;

(B) The food shall meet the nutrient content requirements in § 101.62 for a ''low saturated fat,'' ''low cholesterol,'' and ''low fat'' food.

(d) *Optional information*. (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of oat bran and oatmeal and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total- and LDL-cholesterol.''

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between oat bran or oatmeal and coronary heart disease and the significance of the relationship.

(4) The claim may state that oat bran and oatmeal are good sources of dietary fiber, particularly soluble fiber. In referring to the oat fiber component, the claim may use the terms ''fiber,'' ''dietary fiber,'' or ''soluble fiber.'' If the claim uses the term soluble fiber, the total soluble fiber content shall be declared in the nutrition information panel, consistent with § 101.9(c)(6)(i)(A).

(5) The claim may state that a diet low in saturated fat and cholesterol and high oatmeal or oat bran is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or ''Nutrition and Your Health: Dietary Guidelines for Americans,'' USDA and DHHS, GPO;

(8) The claim may provide information about the amounts of oat-containing food, e.g., bowls, servings, slices, to be consumed in a day.

(e) *Model health claim*. The following model health claims may be used in food labeling to describe the relationship between oat bran and oatmeal and reduced risk of heart disease:

(1) The following is an example of a full claim: Diets high in [oat bran/oatmeal] and low in saturated fat and cholesterol may reduce the risk of heart disease.

(2) The following are examples of a shortened claim:

(A) [Front panel] Diets high in [oat bran or oatmeal] may reduce the risk of heart disease

See [side/back] panel for more information

(B) [Front panel] Eating [oat bran or oatmeal] daily may reduce heart disease risk

See [side/back] panel for more information

Dated: December 22, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

Note: The following tables will not appear in the Code of Federal Regulations.

BILLING CODE 4160–01–P

Table 1. Oats and Coronary Heart Disease

Study	Study Design, Subjects	Methods	Results	Comments
Anderson et al., 1991 (Ref. 8)	Clinical study, randomized, controlled, metabolic ward study 21 men*, ages 38-73 years (yrs); hypercholesterolemic (TC: 190 to 347 mg/dL). Body mass indices less than 28.7; no medication for hypercholesterolemia. 1 subject failed to complete study. *14 men had hypertension, CHD, or CVD	Subjects (Ss) consumed "typical" American diet for 7 d as a baseline control (C), then randomized to OB (110 g OB/d) or WB (40 g WB/d) diets for 21 d; C and treatment diet identical in energy content, and nutrients, differing only in SF (OB) and insoluble fiber (WB). Baseline diet: 41% of E from fat, 16% protein, 43% from carbohydrate, 450 mg CHOL, 14 g/d TDF, 3 g/d SF. Brans were incorporated into muffins and cereals. TDF / SF (bran) / TSF (diet) g/d Baseline diet 14 / 5.6 OB 34 / 7.4 / 13.4 WB 34 / 1.3 / 7.8	TC % / LDL % / HDL % OB ↓12.8* / ↓12.1* / ↓7.4 WB ↓4.4 / ↓5.5 / ↓3.1 *significant from baseline There was no change in the LDL-HDL ratio in OB group. No effect on HDL in either group.	Authors state the purpose of their study is to compare the effects of SF (from OB) and insoluble fiber (from WB) keeping TDF constant. Significant weight loss in both groups (about 1 kg from control values). The weight loss in the OB group was not significantly different to the weight loss in the WB group.
Anderson et al., 1990 (Ref. 9)	Clinical study, randomized, self-controlled, cross-over on metabolic ward 12 men; 46-70 yrs old; hypercholesterolemic (TC 210-326 mg/dL); body mass indices of less than 30; 5 subjects had evidence of CVD	Ss, randomized into 2 groups, consumed typical "American" diet for 2 weeks (wks) in addition to test or control cereal followed by cross-over to other cereal for 2 wks. Base diet provided 41% E as fat; 20% E as protein; 43% E as carbohydrate; 355 mg CHOL. One group started with addition of 56 g OB cereal to the diet; the other consumed 56 g of cornflakes (control). TDF / TSF OB cereal 21 g / 7.4 g Cornflakes 15 g / 4.5 g	OB diet: ↓ TC 5.4% (signif.) compared to the corn flakes diet. LDL was lowered by 8.5%, and HDL was not significantly lowered.	The intake of carbohydrates, protein, fat and cholesterol were nearly identical in the two groups. Total dietary fiber varied between the two diets. No change in body weight. Short duration of test (2 wks) is a major limitation with this study.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Bartram et al., 1992 (Ref. 10)	Clinical study, self-controlled 13 adults (4 male, 9 female), ages 21- 59 years, with hyperlipidemia type IIa (mean TC 284.9 mg/dL); all within desirable weight range.	All Ss had been on low CHOL diet for 6 months (mo). Individual dietary instruction given every 2 mo before the study. Serum lipids were measured 4 times during 3-wk baseline period. Dietary intake assessed by 3-d records. Each morning for 3 wks, Ss consumed OB cereal muesli (60 g OB cereals) made with 250 mL low-fat milk and 120 g soft fruits (bananas, grapes, apples) in the metabolic ward; otherwise Ss were free living but kept dietary records. Serum CHOL was measured weekly during test period and for 2 followup wks when Ss consumed pre-study diets without oat bran muesli. Comparison between study periods and baseline made by nonparametric Friedman's block test.	Dietary intakes: Energy (E), Cal/d: Pre 2230, Test 2133, Post 2316 Fat(% E): 33.7, 32.6, 42.2 Sat fat (% E): 9.1, 9.7, 14.0 Dietary CHOL, mg/d: 268, 244, 336 TDF, g/d: 21.9, 42.4, 22.0 Serum lipids: mean mg/dL Base: TC 284.9, LDL 194.9, HDL 64.1 Cereal Week 1: 253.6*, 182.6*, 58.7 Week 2: 260.9*, 173.3+, 60.2 Week 3: 257.1*, 174.5+, 57.5* Post Week 1: 263.2, 181.8, 58.7+ Week 2: 262.0, 179.1+, 57.9* * p<0.01; + p<0.05 -- p values are compared to baseline values	Authors reported no significant changes in Ss' body weight. Ss said to be on low fat diet but actual fat intake reported at >30% E and Sat Fat > 9%. Results of this study are confounded because the muesli cereal contained other sources (fruits) of dietary fiber and SF which can affect serum TC. The amount of SF from OB was not reported and the amount of total SF in daily diet was not reported. Although serum TC values remained elevated, Ss experienced a ↓ in TC of about 8 to 10%. No significant changes to HDL-TC until the 3d test week. No significant changes to HDL:LDL.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Beling et al., 1989 (Ref. 11)	Clinical trial, randomized, controlled 351 men and women, ages 20-60, hypercholesterolemic (TC between 200 and 300 mg/dL); not greater than 50% above ideal body weight. 433 enrolled; 351 completed; attrition rates for groups 1,2, & 3 were 17%, 15%, and 24%, respectively. Major reason for attrition was inability to attend classes.	This was an 8-wk study with 3 groups: Group 1: no dietary change Group 2: American Heart Association (AHA) Step I diet, which was introduced during the first 4 wks of the study and continued for 8 wks. Group 3: Step I diet for wks 1-4, followed by the addition of 2 oz (56 g) oat cereal for wks 5-8. Oatcor™, a concentrated OB cereal, was provided in 2 packets (1 oz each) to be consumed as a snack or cereal. The OB provided 10.6 g TDF/d; 4 g β-glucans. Group % E - Sat Fat: Base, Tx; % E - Fat: Base, Tx 1: 12, 10-11, 38, 34-36 2: 11, 6, 34, 23 3: 12, 7, 37, 25-26 TDF: baseline 9-12 g; Test: group 1 12-14 g; group 2 18-19 g; group 3 15-16 g. Sample size calculations based on a null hypothesis of no difference in TC between groups at end of 8 wks with a 5% chance of failing to reject this hypothesis and 90% chance of detecting at least 15 mg/dL CHOL reduction.	TC, mg/dL % = % change from baseline Group Base 4 wks % 8 wks % 1 238.7 233.9 2↓ 233.2 2↓ 2 242.9 218.5+ 10↓ 222.4* 8.4↓ 3 242.3 213.9+ 11.8↓ 212.5* 12.2↓ LDL-CHOL, mg/dL % = % change from baseline Base 4 wks % 8 wks % 1 165.6 161.0 3↓ 157.6 5↓ 2 165.7 147.4+ 11.5↓ 149.7* 10.1↓ 3 167.2 147.8+ 11.8↓ 142.5* 14.9↓ + p<0.05 compared with C * p<0.05 compared with C and other treatment group HDL % change from baseline Group 4 wks 8 wks 1 ↓ 1 ↓ 1 2 ↓ 6 ↓ 3 3 ↓ 8 ↓ 8	Variable weight loss by treatment: group 1: 2 lbs; group 2: 4 lbs, and group 3: 6 lbs. There was no significant difference in weight loss between groups 2 and 3. There was no data on SF in diets. Not everyone responded similarly; both positive and negative responders and variation in magnitude of effect within treatment groups. Oatcor group maintained about 12% reduction in TC and 15% reduction in LDL-CHOL at 8 wks. AHA group experienced a slight increase in TC and LDL to a final reduction of 8.4% for TC and 10.1% for LDL. Results of this study suggest a modest CHOL-lowering effect of oats beyond that of a low fat diet.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Braaten et al., 1994 (Ref. 12)	Clinical study, randomized, placebo controlled, crossover 19 adults (9 males, 10 females), ages 44-64 years, hypercholesterolemic (TC 220 to 308 mg/dL), free living, all with stable body mass	Study design: 1 to 3-wk pretest period, two 4-wk test periods with a 3 to 4 wk wash-out period between oat gum (OG) and placebo (P) test periods, and a 3-wk washout following the OG period when the OG was tested in the second 4-wk period. Ss randomized to OG or P groups. Test substance: purified OG (80% β glucan) blended with maltodextrin which was mixed with a noncarbonated diet drink or water. Each packet of OG contained 3.6 g OG, 2.9 g β-glucan, and 5.4 g maltodextrin. Ss consumed 2 packets a day with their regular meals. This was equivalent to a daily intake of 70 g OB. Ss were asked not to consume any oat products with diets. Placebo: 5.4 g packets maltodextrin. Ss consumed 2 packets daily with meals. 3-day food diary was kept. Analysis of variance (ANOVA) used to examine blood lipid and body weight data. Repeated measures ANOVA used with subject, treatment, week of treatment, and treatment X week interaction.	No significant differences in nutrient intake among various phases of study. Pre Test / OG / P / Wash out E, Cal: 2175 / 2072 / 2065 / 1967 Fat, % E: 31.0 / 31.3 / 30.6 / 30.7 Fat, g: 79.1 / 76.2 / 72.5 / 70.9 CHOL, mg: 220 / 187 / 214 / 193 Fiber, g: 21.6 / 18.7* / 19.2 / 18.1 *Does not include additional 5.8 g/d β-glucan fiber. TC / LDL / HDL (mg/dL) Oat gum Week 0: 261.8 / 178.6 / 49.9 Week 4: 237.8* / 160.9* / 49.1 * p<0.0001 compared to baseline HDL remained unchanged throughout study; no significant correlations between body weight or nutrient intake and blood lipid levels, or changes in these, during OG phase.	A well-controlled study. Results suggests that the OG used in this study lowers TC. Total dietary SF and CHOL were not reported. TC and LDL decreased 9% (p<0.0001) and 10% (p<0.001), respectively, during the 4-week gum phase. TC and LDL returned towards pre-treatment levels during wash-out period at end of study further supporting a true effect of OG. Authors reported that based on individual one-tailed 95% confidence intervals for LDL, 5 Ss were nonresponders and 14 were responders (LDL ↓ from baseline approximately 13%).

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Bremer et al., 1991 (Ref. 13)	Clinical study, randomized, single-blind, cross-over 12 hyperlipidemic men and women, mean age 53 yrs, mean TC 298 mg/dL, free living	Ss were stabilized on phase II AHA diet for 3 mo prior to study. Base diet: fat 25-30% E; Sat Fat <8%; PUFA 5-10%; mono-unsat. fat >10%; CHOL <250 mg/d; fiber >20 g/1000 Cal. Two-wk run-in with the addition of bread to the diet prior to test. Ss randomized to oat or wheat group for 4 wks, followed by 2-wk washout, then cross-over to other diet. Bread added to diet in place of other carbohydrate foods. Mean intake oat bread and wheat bread 7.8 slices/d. Dietary assessment by food records and bread charts. bread: TDF, g% — Oat bread 5.2, Wheat 6.1; IF, g% — Oat bread 4.0, Wheat 5.2; SF, g% — Oat bread 1.2, Wheat 0.9 OB intake: 34.2-68.4 g/d TDF intake: Oat period - 32.2 g; Wheat period - 34.1 g	At beginning of first study period, there was no significant difference between TC, LDL, and HDL between groups. At end of 4 wks, no significant difference between lipid parameters. TC, mg/dL: OB Wk 0 286, Wk 4 274, % change 4.1↓; WB Wk 0 297, Wk 4 286, 3.9↓ LDL, mg/dL: OB Wk 0 216.5, Wk 4 204.9, % Change 5.4↓; WB Wk 0 228.1, Wk 4 212.7, 6.8↓ HDL, mg/dL: OB Wk 0 37.5, Wk 4 41.1, % Change 10.3↑; WB Wk 0 40.2, Wk 4 43.7, 8.7↑ Mean body weights did not change during the oat period but decreased significantly during the wheat period.	Ss had very high mean TC values. At end of study, TC remained very high. There was no measure of dietary soluble fiber. Subjects increased consumption of PUFA and decreased intake of Sat Fat (all nonsignificant) during test period. Investigators accounted for ↑ in fat consumption as due to use of PUFA margarine with bread. Oat bran bread was no better than wheat bran bread on lowering serum TC when Ss were on AHA diet. Authors suggest the full lipid-lowering potential of the AHA diet had already been achieved prior to the bran intervention. They also noted that New Zealand oat bran may not be the same as oat brans used in other studies (difference may be in the SF portion of the oats). WB cannot be considered a placebo because Ss experienced decreased TC and LDL while consuming the wheat bread.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Cara et al., 1992 (Ref. 14)	Clinical study, randomized, double blind, self controlled; study to evaluate effects of dietary fibers on postprandial lipemia 6 males, ages 22-41 yrs, normocholesterolemic (TC 158.6 - 200.7 mg/dL), with stable body weights	Ss instructed not to deviate from regular habits and to avoid excess alcohol consumption and exercise. Their basal diets were monitored through a 7-d food recall. Ss consumed typical western diet: 2815 Cal/d; protein - 108 g; carbohydrates - 295 g/d; 134 g fat; dietary CHOL 492 mg/d; and low to moderate dietary fiber (range 15-24 g/d). Ss ingested on separate days a low-fiber test meal: protein, 12.7%; carbohydrate, 37.9%; fat, 49.4%; TDF, 2.8 g. On high fiber days, the low fiber test meal was enriched with 10 g TDF as oat bran, rice bran, or wheat fiber or 4.2 g as wheat germ. The fiber sources were ground fine and incorporated into tomato sauce. Soluble fiber: OB, 5.14 g; rice bran, 1.16 g; wheat fiber, 2 g; wheat germ, 0.50 g. The control low-fiber meal and the 4 test meals were presented in random order. The interval between two meals was 7-15 d. Ss ingested meals within 20 minutes (min), then blood samples were collected every 0.5 hour (hr) for 5 hr and then 6 and 7 hr later. ANOVA and Student's t-test used to compare baseline and test values.	Serum TC dropped rapidly and significantly after ingestion of the C meal and maintained a low constant value (-5.8 to -8.5 mg/dL) from 1.5 to 6 hours. 7 hr after the meal CHOL values increased to baseline. With the exception of rice bran, other fibers suppressed serum TC below that from C meal and remained significantly less ($p<0.05$) than baseline after 7 hours. The OB meal produced the greatest change in TC (maximum decrease of 15.5 mg/dL after 4 hr) compared to baseline and the C. The difference from baseline values averaged -84.5 mg/dL.	With C diet, serum TC ↓ to a maximum of -8.5 mg/dL within 2 hr, then ↑ gradually over the next 5 hr. OB produced a continuous ↓ in serum TC over 4 1/2 hr before beginning a gradual ↑. Results of this study support a significant short-term effect on lowering serum TC by OB; however, the results do not address long term effects of OB.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Davidson et al., 1991 (Ref. 15)	Clinical trial, randomized, single-blinded, controlled. 156 men and women (ages 30-65 yrs), 148 completed this study; free living hypercholesterolemic (230-319 mg/dL) with multiple risk factors. Data from only 140 were used, 8 dropped because of lack of compliance. Dropouts: placebo (3), OB-56 (2); OM-28(1); OM-84(1), and OB-84(1).	NCEP Step 1 diet given 8 wks before randomization to test diet and during the test period. 6 wks of intervention with OM or OB in 28 g, 56 g, or 84 g servings. 28 g farina as a control. After intervention, 6 wks of followup with no supplementation. Step 1 diet: fat: <30% E Sat Fat: <10% E Groups — TDF — TSF OM 28 g — 16 — 6 OB 28 g — 17 — 6 OM 56 g — 14 — 5 OB 56 g — 20 — 7 OM 84 g — 19 — 7 OB 84 g — 22 — 7 Farina 28 g — 15 — 0 4-d food records at baseline, wks 3, 6, and 12.	Group — g — β Glu — % TC — % LDL 1. OM 28 — 1.2 — 3.9↓ — 5.8↓ 2. OB 28 — 2.0 — 2.7↓ — 4.7↓ 3. OM 56 — 2.4 — 2.7↓ — 3.5↓ 4. OB 56 — 3.6 — 9.5↓* — 15.9↓* 5. OM 84 — 4.0 — 7.1↓* — 10.1↓* 6. OB 84 — 6.0 — 6.9↓* — 11.5↓* 7. FA 28 — 0.0 — 0.6↓ — 0.6↓ FA=farina Glu=glucan * Only these changes are significantly different from baseline. The groups showed a decrease in total- and LDL-CHOL at the higher levels of oat intake.	Lacked control group for each level of oats consumed. Body weights were stable. The wash-out period is not a true control, but considered with evidence from the intervention period, TC was reduced at higher β-glucan intakes. 3 g/d or more is beneficial with a low fat diet.
Demark-Wahnefried et al., 1990 (Ref. 16)	Clinical study, randomized 81 men and women, ages 20-65 yrs, hypercholesterolemic (mean of 271 mg/dL), free-living: 13 dropped out.	12 wks of intervention on OB or processed OB cereal. Individuals given OB supplements, OB cereal, and a recipe book for fat-modified diets. One group consumed regular diet and did not get recipes. 50 g OB/d (estimated 3.7 g SF) as add-on to test group. 50 g OB and 42.5 g processed cereal had same amount β-glucan. Diets: Group 1: low fat, low CHOL Group 2: low fat, low CHOL plus 50 g OB Group 3: Regular diet plus 50 g OB Group 4: Regular diet plus 42.5 g processed OB	Although there was a significant ↓ in TC with all groups, there was no significant difference in the final serum TC between any of the four groups. The low fat, low cholesterol C group had the most marked ↓ in TC (↓17%) from baseline. C group 1: TC ↓ 17% group 2: ↓ 13.1% group 3: ↓ 12.3% group 4: ↓ 10.1%	Drop out rate is very high (16%). The study size is small; power to detect changes between groups is limited. Variable weight loss among groups with the group consuming low fat diet plus OB experiencing the greatest weight loss (4-5%) and group 4 (processed OB) experienced the least (0-0.1%). E intake decreased in all groups from -10% to -28%. % changes from baseline in Sat Fat ranged from 22% for regular OB group to 51% for low fat, low CHOL OB group. Results of CHOL-lowering effect of low fat diet was not further enhanced by the addition of OB.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Gold and Davidson, 1988 (Ref. 17)	Clinical study, double blind 72 male and female medical students; 25-37 yrs old; free-living; TC - mean 178 mg/dL	This was a 4-wk intervention study. Ss consumed 2 muffins/d that contained test fibers (muffins were provided) along with their regular diet. 3-d food records were submitted. Ss randomized into 3 groups and received muffins made with either OB, WB, or a wheat/OB combination. SF and DF from muffins: (per muffin) Total Bran / SF* / DF (grams) O: 17.0 / 2.5 / 5.0 oat/wheat: 5.5/8.3 / 0.9 / 5.3 WB: 11.3 / 0.33 / 5.5 *estimated Intake of oat bran per day about 34 g.	OB: TC ↓5%* and LDL ↓9%* *significant from baseline, $p<0.05$ SF from combined oat/wheat and wheat: TC no change; LDL no significant decrease.	No assessment of the dietary intake before or during the test period. No data on total dietary fiber or total SF intakes in baseline and treatment diets.
Gormley et al., 1978 (Ref. 18)	Clinical study, randomized 58 males: hypercholesterolemic (TC about 240 mg/dL) 10 females: normocholesterolemic (TC about 190 mg/dL); mostly between ages 30-50, except 5 who were less than 30 and 2 who were over 50. 6 smoked cigarettes, 5 smoked cigars, 3 were pipe smokers. Free living	All Ss ate 43 g cornflakes daily for 20 days. Blood samples were taken and based on the values, Ss were paired on the basis of similar TC levels into 2 groups. Ss in each pair were randomly assigned to be in the C group (cornflakes) or the test group (oatmeal porridge). C group consumed 43 g cornflakes daily and the test group - 43 g oatmeal. No other dietary restrictions given. Ss consumed cereals for 1 1/2 months. Weekly dietary log maintained to show cereals were consumed. Paired t-test used to assess significance.	Results showed no effect of oatmeal porridge on TC and HDL.	Authors state that dietary intakes were monitored but nothing is reported in this study. Amounts of total dietary fiber, oatmeal total- and soluble fibers consumed were not reported. LDL was not reported. Authors do not account for the influence of smoking and other lifestyle habits on the results. Results of this study are hard to interpret. There is insufficient dietary control.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
He et al., 1995 (Ref. 19)	Survey 857 Chinese people (ages 15-77 yrs) (included farmers and migrants; people with almost no leisure time activity): at time of survey only 65 (15%) consumed oats and were included in this part of the survey. Normo-cholesterolemics	Age, sex, race, education level, smoking, medical history, and intakes of oats and buckwheat were obtained by local physicians. A 24-hr recall, administered on 3 consecutive days, was also used to get specific information on the diet. Authors stated that agreement between the estimates obtained by interview and 24-hr recall was moderate, with a correlation coefficient of 0.41 ($p<0.001$) for oats and 0.61 ($p<0.001$) for buckwheat. Ss divided into groups based on average daily intake of oats and buckwheat. Blood samples were taken in morning after 14-hr fast. Serum TC, HDL, and triglycerides were measured. 100 g oats: 10.2 TDF; 3.9 SF Differences in cardiovascular disease (CVD) risk factors and dietary nutrients among the oats and buckwheat intake groups were examined by ANOVA.	Dietary Intakes[1] Groups Oats 1 2 3 4 g/d: 0 <25 25-90 >90 E, Cal/d 3134 3233 3464 3120 Dietary Fat, % of E 24 24 16 12 P:S 1.37[2,5] 1.29[2,5] 2.14[3,4] 2.08[3,4] CHOL, mg/d 214[2,5] 186[2,5] 86[2,5] 186[2,5] Lipids Group mg/dL 1 2 3 4 TC 156[2,5] 154[2,5] 33[3,4] 139[3,4] LDL 71.4[5] 68.7[5] 59.4[3,4] 67.9 HDL 15.1 15.1 15.5 13.9 HDL:CHOL 0.39 0.30 0.40 0.36 [1] mean values [2] $p<0.05$, signif. from group 4 [3] $p<0.05$, signif. from group 1 [4] $p<0.05$, signif. from group 2 [5] $p<0.05$, signif. from group 3	Authors report that groups consuming ≥ 25 grams of oats per day had significantly lower TC than those who did not consume oats. Authors state that TDF and SF from oats were significantly and independently associated with lower TC concentrations. The overall effect of oats was more pronounced in group with higher initial TC concentration. This population group consumes a low fat and high fiber diet. Dietary intake of oats and buckwheat were not accurately assessed. This is a large population-based cross-sectional study with no controls. The lack of temporal sequence in a cross-sectional survey and the questionable assessment of dietary intake of oats makes support of a beneficial effect of oats on serum CHOL by this study trivial.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Hegsted et al., 1993 (Ref. 20)	Clinical study, randomized, cross-over, double blinded, controlled diets 11 subjects (10 males, 1 female), ages 19-57, with mild hypercholesterolemia (mean TC 233 mg/dL); free living subjects	10-wk study. Test diets contained 100 g/d stabilized rice bran (RB) (heat stabilized to inactivate lipase enzymes in the bran) or OB. Test periods: 3 wks each. Bran was used in muffins, cookies, crackers, breads and other foods. Ss consumed C diet containing wheat for 2 wks prior to phase 1 and between phases 1 and 2 (before cross-over). Control diets: C RB OB E, Cal/d 2746 2551 2608 Fat, % E 36 37 36 Sat fat, % 27.6 28.4 28.8 Dietary CHOL, mg 300 300 300 Fibers: RB OB Fat, % 21.9 9.6 Carbohydrate, % 47.2 57.1 Fiber, insol % 21.9 9.1 sol % 2.6 8.0 β glucan, % - 3.8 Comparison between RB and OB effects on CHOL were analyzed as a cross-over design. Changes between the C diet and bran diets were evaluated as a split plot design. Paired t-test used to test differences between means.	C Phase 1 C Phase 2 mg/dL TC OB 220.8 198.8* 224.7 214.6+ RB 234.7 210.8* 216.5 207.7+ LDL OB 160.6 139.0* 167.5 154.8+ RB 179.9 154.8* 151.0 140.9+ HDL OB 48.0 46.1** 37.9 39.1 RB 39.1 37.1** 48.0 47.2 * signif. different from previous diet by p<0.001 ** signif. different from previous diet by p<0.01 + signif. different from previous diet by p<0.05	During the first OB phase, TC ↓ 10% and in phase 2, it ↓ 5% (all signif.). LDL ↓ about 13% during phase 1 of OB and about 7% during phase 2 (all signif.). During phase 1, HDL ↓ significantly, but ↑ to 3.1% in phase 2. Small number of subjects.
Kahn et al., 1990 (Ref. 21)	Clinical study, randomized, controlled 16 men and women, age 51-54 yr, hypercholesterolemic (215-314 mg/dL); some were diabetic. Free living	One group began immediate intervention on OB for 3 wks; the other group was the untreated control for 3 wks, after which they started the intervention diet for 3 wks. This was followed by a 6-wk washout period during which blood samples were taken. Test Ss consumed 80 g/d OB (estimated 5 g SF), added to the diet as OB muffins (4/d). Each muffin provided 112 Cal and 20 g OB. Ss' usual diets were not assessed.	All groups, including the control group, had ↓ TC but there was no significant change in serum TC values when the immediate intervention test group was compared to the delayed intervention group (serving as a C). When the results were combined, the oat group showed a significant ↓ in TC by 8% (p<.02), LDL by 10% (p<.02), and HDL 0.9 % (p<.03) from baseline.	No dietary assessment before or during test. Subjects experienced some weight loss. The study design should have been modified to overcome the problem of time delay in comparing the groups. After correcting for the delay, results of this study show that OB significantly reduced TC.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Kashtan et al., 1992 (Ref. 22)	Clinical study, randomized, metabolically controlled, parallel, double-blind 44 men and women (31 men and 14 women), mean age of 61.3 yrs. Mean TC for group 1: 207 mg/dL; group 2: 227 mg/dL.	Ss randomly assigned to either the OB group or the WB (control) group. Ss consumed the bran products twice a day for 2 wks. All food was prepared and delivered to the Ss. E content of diet was one of 4 amounts: 1,600, 2,000, 2,400, and 2,800 Cal. Ss were fed the amount closest to their requirements based on the Lipid Research Clinic tables. Base diet: 37% E from fat; 16% protein; 47% carbohydrate; TDF 24 to 25 g/d. OB consumed as cereals: dry wt OB 88.4 g, estimated 5.5 g SF/d. WB consumed as Cream of Wheat: 73 g/d	Before / After mg/dL TC WB 207 198** OB 227* 203** LDL WB 129 125** OB 150* 131** * Significantly different from WB ** Significantly different from baseline	OB group experienced a TC decrease of 24.9 points (10.7%) from baseline ($p<0.001$); LDL decreased 18.7 points (12.5%) from baseline ($p<0.001$). HDL decreased 10% from baseline but the difference was not significant. Short term study (14 d) is a limitation.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Keenan et al., 1991 (Ref. 23)	Clinical trial, randomized, controlled, double blind with crossover 145 men and women, ages 20-70; free living; hypercholesterolemic (207-267 mg/dL). 15% dropout after randomization.	Study designed with 3 periods (6 wks each): period 1: step 1 diet (C); periods 2 & 3: test periods. Test products were provided. 3 groups: C, wheat, and oat. The C group consumed step 1 diet for entire study period. 2 groups randomized to consume oats or wheat during period 2, followed by cross-over after 6 wks to other diet (period 3). 4-d food records were collected in wk 5 of each period; baseline dietary intake taken by self-administered food frequency questionnaire. Step 1 diet: Fat, % E: <30%; Sat Fat, % E: <10%; CHOL: 240 mg/d Test products: 2 oz OB cereal and 2 oz of ready-to-eat wheat cereal. OB: (3 g SF/d); mean intake SF during OB period was 8 g. Wheat cereal: (1 g SF/d); mean intake SF during wheat period was 6 g. Group and period effect for lipids assessed using a 3(group) X 4(phase) repeated ANOVA.	TC and LDL decreased in all groups on step 1 diet (↓2.5-4%). Oat-wheat group had a further ↓ in TC of 2% (NS) on oat cereal, followed by a 6% ↑ in TC on wheat cereal. The wheat-oat group had a nonsignif. change in TC on wheat and a 3% ↓ on oats. The C group had significant ↑ in TC back to baseline during test periods. Women under 50 found resistant to OB intervention. TC, mg/dL Group / Base / End Step 1 / Period 1 / Period 2 Diet 238 228 236 242 W-O 237 231 231 225 O-W 239 229 224 239 LDL, mg/dL Group / Base / End Step 1 / Period 1 / Period 2 Diet 165 156 162 166 W-O 164 159 158 152 O-W 162 155 148 160 Lipid responses during cereal periods complicated by an order or period effect, which overlays the treatment effect.	Placebo was needed for diet only group. Control group initially dropped TC and then returned to baseline making it difficult to use as a control. A significant order or period effect was observed which overlaid the treatment results. Both the diet only and wheat group showed a tendency for TC and LDL to return to baseline. The oat groups maintained their original diet period improvement in lipids. Post hoc analysis demonstrated evidence of additional significant reductions in TC and LDL in the oat group when compared with diet only and wheat groups ($p<.01$). There was no significant change in HDL in any group.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Kelley et al., 1994 (Ref. 24)	Clinical study, self controlled, unblinded 13 Ss (7 men and 6 postmenopausal women), ages 50-84 yrs; all with fasting TC > 200 mg/dL. All Ss had been in a supervised program of exercise for at least 3 mo; free living	4 wk study. Ss continued their exercise program (40-60 minutes at 65% to 75% of maximum capacity) during the study. Ss consumed their usual low fat diet (without oats) for 2 wks prior to study. During baseline (last 3 d of 2d wk), Ss kept food records. Ss instructed to consume 100 g OB (7.1 g SF)/d for 4 wks. Oats were used in recipes and baked products. Total E and fat intakes were to remain stable. Ss recorded oat intake during 4-wk period. Dietary and plasma data analyzed by one way ANOVA with repeated measures. Fisher's least significant difference test used for post-hoc testing.	Daily Nutrient Intakes Base / Wk 2 / Wk 4 / Sig. E: 1,762 / 1,870 / 1,827 / NS Fat, % E: 24.2 / 24.8 / 25.5 / NS Sat Fat, % E: 6.5 / 6.9 / 6.4 / NS CHOL, mg: 166 / 179 / 232 / NS Fiber, g: 21.3 / 25.6 / 22.6 / NS Base / Wk 2 / Wk 4 / Sig. (mg/dL) TC: 226.2 / 212.3 / 207.7 / p<0.04 Change: 6.1%↓ / 8.2%↓ LDL: 155.2 / 140.5 / 139.7 / p<0.05 Change: 9.4%↓ / 9.9%↓ HDH: 46.4 / 47.6 / 46.8 / NS Change: 2.5%↑ / 1%↓	Study lacked an adequate placebo control. Authors reported mean daily intake of OB by 10 of 13 Ss was 94.07 g. Mean body weight was maintained in 11 of 13 Ss. Reduction in LDL significantly correlated with baseline LDL (p<0.04). Results suggest a benefit from OB intake beyond that of a low fat, low CHOL diet.
Kestin et al., 1990 (Ref. 25)	Clinical study, randomized, double blind, controlled with cross-over. 24 men, 29-61 yrs, mild to moderate hypercholesterolemia (186-293 mg/dL)	3-wk control period prior to test; 4 wks on each of 3 test diets; no washout. Test foods (OB, WB, rice bran (RB)) were provided as bread and muffins; control - low fiber white bread. Test foods were added to individual's normal diet. Test fibers: OB: 95 g/d; 5.8 g SF/d Rice bran: 60 g/d; 2.9 g SF/d WB: 35 g/d; 2.6 g SF/d Base diet: % fat cal: 31-37 % SFA cal: 12-13 CHOL: 250-300 mg/d TDF: Baseline: 11.2 g/day Test diet: 21 g/day SF: OB diet: 10.3 g/day RB diet: 7.2 g/day WB diet: 6.8 g/day Baseline: 5.7 g/day	TC / LDL / HDL (mg/dL) Baseline: 245.2 / 175.9 / 40.6 OB: 233.2 / 163.9 / 41.8 WB: 247.1* / 175.6* / 42.1 RB: 242.5+ / 173.6+ / 42.5 * Signif. from OB, p<0.001 + Signif. from OB, p<0.01	The amounts of SF and insoluble fiber in the three test diets were varied while total fiber was held constant. The OB diet had higher SF than the rice, wheat or baseline diets. OB lowered TC ↓ 5% and LDL 6.8% compared to baseline (significance to baseline not reported).

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Leadbetter et al., 1991 (Ref. 26)	Clinical study, randomized, not blinded. 4 x 4 Latin square with 3 levels of oat intake and a control. 40 men and women, ages 25-64 (TC 250-348 mg/dL), free-living	Ss randomized into one of 4 sequences: 0, 30, 60, or 90 g/d OB added to Ss' usual diet. Each period was 1 mo long. No washout between periods. OB was provided in weighed sachets and detailed advice and recipes were provided. 5-d food records were kept prior to study and single-day records were kept during study periods. Beta-glucan content of oat bran was 3.7-4.2%. Base diets (excluding OB): Group: 0 g, 30 g, 60 g, 90 g E: 1854, 1947, 2017, 2017 % Fat: 36.6, 34.7, 33.5, 34.8 % Sat Fat: 13.5, 13.0, 13.4, 14.0 Fiber, g: 27, 23, 26, 24 Starch, g: 64, 86, 93, 99	No significant effect of OB at any dose on TC or LDL; no dose-related trend and no correlation between bran dose and change in TC conc. OB Intake, g/d 0, 30, 60, 90 TC, mg/dL: 278, 284, 279, 273 LDL, mg/dL: 184.5, 179.8, 187.5, 177.1 HDL, mg/dL: 60.3, 57.2, 57.6, 54.9	Authors state that OB used in this study (New Zealand) may be lower in SF content than the OB used in studies showing ↓ TC with OB supplementation. Dietary CHOL intake not reported. No body weight data provided.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Lepre and Crane, 1992 (Ref. 27)	Clinical study, randomized, double blind, placebo controlled, cross-over 37 Ss (16 men, 21 women), mean age 51.9 yrs, TC 212-300 mg/dL, Ss already on low CHOL, low Sat Fat diet.	24-wk study: Ss received prescribed diet for 8 wks, then were randomly assigned to receive 2 muffins/d containing 60 g OB (4.6 g TDF and 1.6 g SF each) or WB (5.2 g TDF and 0.7 g SF each) for 8 wks. At end of 8 wks, Ss crossed over to other kind of muffin for another 8 wks. Diet during study contained less than 30% of total E as fat, less than 10% as sat fat, less than 300 mg dietary CHOL, and 21-27 g of TDF. Muffins were consumed with meals. Energy intake was adjusted to maintain body weight during first 8-wk (diet only) period. During muffin period, diets adjusted for energy, fat, and fiber content of muffins. Differences between periods in serum measures analyzed by repeated measures ANOVA followed by pairwise comparisons using 2-tailed t-test.	30 Ss completed study. Nutrient content test diets: Baseline / OB / WB E, Cal/d: 1434 / 1483 / 1546* Fat, % of E: 25.8 / 26.3 / 25.3 Sat Fat, % E: 8.4** / 7.4 / 6.9 CHOL, mg: 200+ / 169++ / 153 Fiber, g: 21.6# / 26.0 / 26.8 * p<0.001 compared to baseline ** p<0.01 and p<0.001 compared to OB and WB, respectively + p<0.05 compared to OB, p<0.001 compared to WB ++ p<0.05 compared to WB # p<0.001 compared to OB and WB Serum measures at end of test periods: Baseline / OB / WB TC, mg/dL: 264.8 / 259.0 / 266.3 LDL, mg/dL: 186.0 / 180.3 / 191.1* HDL, mg/dL: 51.3 / 52.9 / 50.9 LDL/HDL: 3.83 / 3.68 / 4.01** * p<0.01; ** p<0.001 (comparison of OB to WB periods)	WB cannot be considered a placebo because it caused ↑ in TC and LDL. Authors reported no signif. changes in Ss' body weights during test period. Signif. differences were reported between diet only phase and the test periods in dietary CHOL, sat fat, and dietary fiber. During the OB period, Ss consumed signif. less (p<0.01) sat fat and dietary cholesterol (p<0.05) compared to the diet only period. Dietary fiber was significantly less (p<0.001) during the diet only period. OB produced a nonsignif. ↓ in TC (2.2%), LDL (3.1%), LDL/HDL (3.9%) and a nonsignif. ↑ in HDL (3.0%) compared to baseline (diet only) measures. During WB period, there was a nonsignif. ↑ in TC, LDL, and LDL/HDL, and a nonsignif. ↓ in HDL. Authors reported that, using the Keys equation, a ↓ of 4.63 mg/dL in serum TC CHOL was expected based on the dietary intake in the OB period compared to diet only period. Authors state that the observed ↓ of 5.8 mg/dL in TC is likely due to the ↓ intake of dietary sat fat and not to the OB.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Mackay and Ball, 1992 (Ref. 28)	Clinical study, randomized, crossover 39 adults (22 males. 17 females), ages 28-66 years, hypercholesterolemic (mean TC 265 mg/dL), free living	Study consisted of 4-wk run-in period followed by 3 test periods of 6 wks each. During run-in, Ss consumed moderately low-fat diet (28-32% of E from fat and less than 10% E from sat fat). Ss divided into 2 groups based on TC (above or below 262.6 mg/dL) and randomized to one of 6 possible combinations of the order of the diets. Test substances in diets: 55 g low-fiber OB (LFOB) (3.5% β-glucan), 55 g high-fiber OB (HFOB) (5.4% β-glucan), or 80 g cooked beans (SF same as high fiber OB). Other high SF-containing foods were not allowed during test periods. Three-day dietary records kept during run-in and test periods. Statistical methods: one-way ANOVA using repeated measures to assess between stages and between diets. Paired t-tests were used to establish trends between plasma lipids at wks 3 and 4 of run-in and wks 5 and 6 of each diet. Repeated measures analysis using SPSS-X MANOVA used to test difference between order of diets, the difference between diets, and the interaction of both variables.	Nutrient intake: run-in / HFOB / Beans / LFOB E, Cal/d 1664 / 1876* / 1710 / 1817 % of E Fat 29 / 30 / 28 / 28 Sat fat 10 / 10 / 9 / 10 CHOL, mg 188 / 215 / 161 / 192 TDF, g 24 / 28* / 29* / 27 * signif. different (p<0.05) compared to run-in Serum Lipids: mg/dL / run-in / HFOB / Beans / LFOB TC 242.0 / 241.2 / 240.1 / 240.1 LDL 161.7 / 162.1 / 161.7 / 159.8 HDL 44.4 / 49.4* / 49.0* / 49.4* LDL/HDL 3.76 / 3.43* / 3.51* / 3.4* * signif. different (p<0.05) compared to run-in	There was no placebo control. Authors reported that the order of consumption made no significant difference on results. The interaction of order of diet was not significant for TC or LDL, but was significantly different for HDL whether the run-in was excluded or included. No change to TC or LDL from OB in this study. HDL ↑ significantly which improved the LDL/HDL ratio. This study does not support a beneficial effect of OB on TC. Results observed in this study may be related to the type of cultivar used (New Zealand source of oats) and the method for analyzing for SF.
Marlett et al., 1992 (Ref. 29)	Clinical study, metabolically controlled, single isotope used to determine bile acid kinetics 9 men, ages 20-28 yrs, normocholesterolemic (mean TC of 177 mg/dL)	A 2-mo study: period 1 was a low fiber C period and period 2, a high fiber period with OB. Base diets: Energy - 2,770, 3,000, 3,300, and 3,600 Cal/d with 35% fat, 15% protein, and 50% carbohydrate. Foods were consumed in a metabolic unit except an evening snack which could be taken home. OB: 100 g (16.1% TDF, 38% β-glucan, 46% SF) Wheat gluten: an amount comparable to protein in OB was included in low fiber foods.	SF intake: Low fiber period, 4 g High fiber period, 10.3 g Pre Study / Low fiber Period / High fiber Period mg/dL TC 177 / 152* / 138** * p<0.01 Signif. lower than prestudy period ** p<0.01 Signif. lower than low fiber period Total daily fecal bile acid excretion more than doubled when OB was incorporated into the metabolic diet.	There was no change in body weights. Small sample size. Authors state that the results of the bile acid study showed 2 mechanisms by which oat bran lowers TC: through increased bile acid synthesis and decreased bile acid adsorption. The lowered TC in the C group was in response to the lower fat diet given the Ss. Authors report prestudy fat intake at 40 to 45% of E.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
O'Brien et al., 1985 (Ref. 30)	Clinical study, randomized, controlled 45 adults (30 males, 15 females), mean age of 57±2 yr, hyper-cholesterolemic (TC >250 mg/dL), free living.	Pre test period - 3 d: Ss consumed a low CHOL diet of unprocessed foods (<10% E from fat, 13% protein, and remainder carbohydrate from whole wheat grains and bread, beans, fresh vegetables and fruits). TDF = 35-40 g/1000 Cal and <25 mg CHOL. Test period - 18 d: Ss divided into 3 groups: OB group (50 g/d OB: 15.2 g TDF, 7.6 g SF); WB group (50 g/d WB: 23 g TDF, 1.8 g SF); C group - diet only, no bran. The brans were provided in packets daily and the Ss instructed to add the bran to each of their 3 main meals. All variables analyzed using Hotelling's multivariate analysis and t-test comparison. Total CHOL data analyzed using univariate and multivariate analysis to test for significance between group differences.	TC / HDL / CHOL/HDL / Wt mg/dL / kg OB pre 276.0 / 43.0 / 6.8 / 82.4 test* 195.4 / 37.5 / 5.4 / 78.0 WB pre 272.9 / 44.0 / 7.0 / 88.2 test 203.0 / 40.8 / 5.1 / 84.2 C pre 290.1 / 56.2 / 5.3 / 77.3 test 214.0 / 45.3 / 5.0 / 74.4 * All test values significantly different from pre values, except the CHOL/HDL for the C group. No signif. difference between the groups. Significant loss of weight in all groups but differences among groups were not significant.	Short test period is a limitation. The diet high in fruits, vegetables, and grain products and low in fat and dietary CHOL was effective in lowering serum TC significantly. This diet, for all groups, was probably already high in SF. The addition of OB produced an additional ↓ in TC (about 3%) but the effect was not statistically significant. TC: ↓ 29% in OB group, ↓ 26% in WB group, and ↓ 26% in C group. Results also show HDL significantly lowered: ↓ 11 in OB group, ↓7% in WB group, and ↓ 19% in C group.
O'Kell and Duston, 1988 (Ref. 31)	Clinical study, randomized, self controlled 45 adults (21 males and 24 females), normal to moderately high cholesterol (TC from >180 to <211 mg/dL during non-OM mo), free living	Ss randomly divided to 2 groups. Ss instructed to include OM (women - 1/2 cup dry and men - 2/3 cup) in their usual diet for 5 of 7 d. Ss in OM group consumed oats for 3 mo followed by 3 mo with OM no more than once per wk. There were two 3-mo OM periods and two 3-mo non OM periods. When group 1 was consuming OM, group 2 was not. Repeated measures ANOVA used on data.	TC, mg/dL: Period: OM / Non-OM Group 1 189-213 / 175-194 Group 2 176-193 / 193-211 No signif. differences between OM and non-OM periods and no signif. differences in HDL values between periods.	Dietary intakes were not reported. TDF and SF were not reported. Authors state that the Ss' diets did not change during the study and no signif. change in body weights. LDL not reported. Results of this study suggests that an intake of 1/2-2/3 cup OM may not be beneficial in lowering TC in individuals with normal to moderately elevated TC values.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Poulter et al., 1993 (Ref. 32)	Clinical study, randomized, cross-over Ss recruited from hypertension clinic (n=44), their spouses (n=7), and hospital staff and their relatives (n=13); all cereal eaters. 74 participated, 59 (17 males, 42 females) completed study. Mean age range 52-59 yrs, TC 231 mg/dL, free living	Retrospective 48-hr recall used to assess baseline diets. Ss in oat group asked to consume 50 g oat cereal (4.5 g TDF, 2.6 g SF) daily for 4 wks. All Ss told not to change lifestyle or diets. Second group served as C and ate their usual cereal (without oats). Diet diaries were kept for last 2 days of 4-wk period. After 4 wks, Ss crossed over to other cereal type for another 4 wks. No washout Student's two-tailed t-test used to compare data.	Mean daily intake oats 56 g (2.24 g SF) Dietary intake: Baseln: Group 1 / 2; Fat, % 35.2 / 37.1; P:S 0.5 / 0.7; TDF, g 15.7 / 17.0 Usual Cereal: Group 1 / 2; Fat, % 32.1 / 31.9; P:S 0.5 / 0.7; TDF, g 17.5 / 18.7 Oat Cereal: Group 1 / 2; Fat, % 30.9 / 35.8; P:S 0.4 / 0.5; TDF, g 17.3 / 17.7 mg/dL TC: Baseln 231.6*; Usual Cereal 232.0; Oat Cereal 226.6*; % Diff 2.23 LDL: Baseln 151.3; Usual Cereal 145.9; Oat Cereal 139.0**; % Diff 4.55 HDL: Baseln 56.4; Usual Cereal 59.8; Oat Cereal 58.3; % Diff 2.69 LDL/HDL: Baseln 2.9; Usual Cereal 2.6; Oat Cereal 2.5; % Diff 8.8 * $p<0.04$ compared to value after usual cereal ** $p<0.05$ compared to value after usual cereal	C group permitted to consume any cereal as long as it didn't contain oats. No change in weights were reported. Small but significant ↓ in TC and LDL with oat cereal. Authors reported significant reductions in TC and LDL in 32 Ss with baseline TC of >231 mg/dL. There was a nonsignif. ↓ in HDL, so there was no improvement in the LDL/HDL ratio. Authors reported that 11 Ss reported making changes in their diets after starting the trial. Combined in-trial data compared with baseline nutrient intake data revealed a signif. reduction in total E consumed from fat ($p<0.05$). The P:S ratio fell significantly during oats consumption ($p<0.001$).
Saudia et al., 1992 (Ref. 34)	Prospective intervention study, unblinded, not controlled, not randomized 20 adults (11 males, 9 females), age range of 21-60 yrs, TC > 200 mg/dL	Ss completed dietary survey sheet to identify food groups and daily consumption of each. Ss were to consume their regular diets. All Ss consumed 3 oz (84 g) OB/d for 3 mo. TC was measured at the end of each month. Total study time = 93 d. A dietary intake sheet was completed at the end of the study. Repeated measures ANOVA	Results showed no signif. difference in TC levels over the 3 consecutive time periods using repeated measures ANOVA. ANOVA for polynomial trends revealed a signif. difference in TC levels over time ($p<0.007$). TC ↓ first month (day 31, mean of 239.4 mg/dL), but levels gradually returned to baseline (mean of 254.4) over next 2 mo (day 62, mean of 242.1 and day 93, mean of 250.7 mg/dL).	Actual data not given. Lacks a control group. Not a well controlled study. Diets not reported. Dietary intake not adequately assessed. Authors consider the possibility that Ss may have changed their diets for a period considering the clinical trial took place over summer months and the increased awareness of risk-reducing behavior and a healthy lifestyle.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Spiller et al., 1991 (Ref. 35)	Clinical study, randomized, cross-over 13 male and females, ages 62 ± 3.0 years, TC 204-276 mg/dL, free living.	3-d food record kept during 1-wk baseline period and during 3d wk of treatment. Each treatment dose was preweighed in pouches; 3-wk supply given to Ss at start of each test period. Both fibers were mixed with water or other fluid and consumed before each meal. Ss remained on usual diet whether it was fat modified or not. Test periods: 21 d then cross-over to other fiber for 21 d. Blood lipid values made on days 14 and 21 during treatment period and on days 14 and 16 after treatment stopped. Fiber sources: guar gum: 15 g/d providing 11 g/d dietary fiber and 10 g/d SF; oat fiber source: 77 g/d providing 11 g/d dietary fiber and 5 g/d SF, 3.3 g β-glucan.	TC / LDL / HDL (mg/dL) Baseline: 244 / 152 / 62 Guar day 14: 217 / 124 / 63 Guar day 21: 219* / 126* / 63 OB day 14: 235 / 142 / 62 OB day 21: 236* / 143* / 62 * Significant from baseline Oats: 3.7% ↓ TC 6.6% ↓ LDL	Study needs a low SF control. Changes in TC for both treatment groups took place within 14 d with no significant changes taking place between days 14 and 21. Limitations of study: No washout between test periods; baseline diets and dietary intake during treatment periods not reported; total dietary SF was not reported. Small sample size. No dietary data. No weight changes. Both guar and oat fibers consumed before meals--not typical dietary intake.
Stewart et al., 1992 (Ref. 36)	Clinical study, randomized, cross-over, self-controlled 24 adults (11 men and 13 women), ages 21-67 yrs, hypercholes-terolemic (TC 215.8 - 328 mg/dL) already prescribed a diet with <30% E from fat; free living	Ss consumed an oat-free, low fat diet (<30 of E from fat) diet for a 6-wk run-in period followed by a second 6-wk period on the diet as part of the trial (C1). Ss were then randomized to receive 50 g OB or to continue on the C diet (C2). After 6 wks, Ss crossed over to other diet for another 6 wks. A 3-d food diary was kept during wk 3 of each period. Two-tailed student t-tests used to assess differences between groups, the two C periods, and the second C period and the OB periods. Regression curves used to compare changes between C and OB, weight (basal metabolic index (BMI)), E intake, % fat intake, and OB consumption. Differences between wks 5 and 6 were analyzed with a repeatability coefficient. Paired samples used.	Baseline data: mean C1 / C2 / OB E, Cal: 1711 / 1680 / 1731 Fat, % E: 29.3 / 29.7 / 28.9 OB, g: - / - / 51.7 Weight, BMI: 23.3 / 23.3 / 23.4 No signif. differences found in the above data Serum Lipids: mean C1 / C2 / OB (mg/dL) TC: 259.0 / 260.6 / 258.2 LDL: 177.9 / 178.7 / 177.9 HDL: 56.7 / 55.2 / 55.2 No signif. differences found in the above data	Sat fat, SF, and TDF contents of diets were not reported. SF content of oats was not reported. New Zealand oats reportedly contain less SF than U.S. cultivars. Compliance with the dietary protocol in this study was not good. Authors reported wide variability in Ss' diets: at baseline total E intake ranged 928 Cal to 2,852 Cal; fat 20 to 44.1% (mean 29.3%) of E, and protein 13.3 to 32% (mean 17.8). The remaining balance of E was from alcohol. Mean OB intakes ranged from 29.2 g to 112.5 g. Changes in dietary components between C2 and OB periods and between C1 and C2 were small and not statistically significant.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Swain et al., 1990 (Ref. 37)	Clinical study, randomized, double blind, cross-over 4 male, 16 female hospital employees; 23-49 yrs old; free-living but foods prepared in metabolic kitchen and taken home; normal cholesterol: mean 185 mg/dL	1-wk baseline; 6-wk test period followed by a 2-wk washout, then cross-over to other diet for 6 wks. OB and WB were added to Ss' regular diets. Dietary intake assessed with food frequency questionnaire; 4-d food records kept during 5th wk of each test period. Test foods were prepared in a meta-bolic research kitchen and given to Ss to consume at home. OB: 87 g/d consumed (estimated SF about 5.65 g). OB provided in entrees (60 g) or muffins (20 g). Wheat: 93 g/d consumed (about 3.7 g SF). Wheat provided in Cream of Wheat cereal and refined white flour. Base diet: Fat 31% of E; high fiber period had 35% E as fat, which came from unsaturated fat in OB supplements.	Oat fiber: TC ↓7.5%*+ LDL ↓9.1%*+ Wheat fiber: TC ↓7.1%*+ LDL ↓6.4%*+ *significantly lower from baseline +no difference between groups	No placebo. Study results limited by small number of subjects. Total dietary soluble fiber was not reported. Dietary intake assessed by two different methods. Author proposes that substitution of either wheat or oat fiber for dietary saturated fat causes the decrease in TC.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Törrönen et al., 1992, (Ref. 38)	Clinical study, randomized, double blind, controlled 28 adult males, ages 25-52 yrs, mild to moderate hypercholesterolemic (TC 216.2 to 343.5 mg/dL for C group; 223.9 to 289.5 mg/dL for oat group), free living	A 12-wk study consisted of a 2-wk baseline period, an 8-wk test period, and a 2-wk followup period. An OB concentrate (with 2- to 3-fold concentration of both TDF and β-glucan) was made and incorporated into bread. The C group consumed bread containing wheat flour. Ss consumed regular diets during baseline and follow-up (post) periods. During first 2-wk of test period, Ss in oat group consumed 1/2 roll of oat bread (5.6 g β-glucan/d) and an entire roll of bread (11.2 g β-glucan) divided in two meals for the last 6 wk. No other dietary restrictions. 3-d food record kept during the last week of each period. Body weight was monitored. Data analyzed by one-factor ANOVA for repeated measures, followed by 2-tailed t-test for paired data.	Nutrient intake: Base / Test / Post / ANOVA E, Cal/d: C 2344.5 / 2368.4 / 2224.9 / NS; O 2210.0 / 2320.6 / 2201 / NS Fat, %: C 35.0 / 34.6 / 36.5 / NS; O 35.2 / 32.4 / 37.9 / NS Sat Fat % E: C 14 / 13 / 14.8 / NS; O 14 / 11.1* / 13.9 / p<0.05 Fiber g: C 26.8 / 23.1 / 25.1 / NS; O 28.3 / 39.7+ / 23.7 / p<0.001 * p<0.05, + p<0.001 }compared to base Lipid analysis: Time: 0 / 2 Wk / 4 Wk / 8 Wk / Post (mg/dL) TC: C 246.7 / 244.7 / 247.8 / 244.7 / 252.1; O 246.7 / 236.2 / 233.5 / 242.0 / 244.1 LDL: C 164.8 / 169.1 / 167.1 / 164.8 / 177.9; O 171.4 / 166.0 / 167.9 / 165.6 / 174.9 HDL: C 55.6 / 54.8 / 54.4 / 53.6 / 53.6; O 49.4 / 47.9 / 47.9 / 47.1 / 48.2	There were no statistically significant effects of the β-glucan concentrate-enriched bread on TC, LDL or HDL. Authors suggest that the reduced intake of Sat Fat (21% less) during the test period by the oat group may account for the slight reduction in TC observed. SF content of OB concentrate not provided. Results of this study do not provide evidence for a CHOL-lowering effect of concentrated β-glucan from OB. The authors suggest that the method of concentrating and processing the β-glucan may have affected the effectiveness of the β-glucan in lowering serum cholesterol. Authors state "a weak effect is to be expected due to poor solubility or due to enzymatic breakdown of β-glucan during the concentration or isolation processes * * *."
Turnbull and Leeds, 1987 (Ref. 39)	Clinical study, randomized, cross-over 9 men and 8 women, ages 23-59 yrs. Initial TC of about 255 mg/dL, free living	All Ss followed a low fat diet (≤ 35% E from fat) during a 1-mo run-in period. Ss randomly assigned to oat diet, 150 g/d (50 g/d oats at breakfast and 100 g oats as biscuits consumed over the course of a day) or a wheat diet (37 g/d wheat biscuits at breakfast and 100 g wheat as biscuits over the course of a day) for a 1-mo period before cross-over to the other diet. TC following the run-in period on the low fat diet was 232 mg/dL. Oats provided 5.4 g/d SF Wheat provided 3.1 g/d SF	Baseline / Final (mg/dL) Oats: TC 232 / 220*; LDL 167 / 143**; HDL 46 / 54 * p=0.02 compared to baseline ** p=0.003 compared to baseline Wheat: TC 228 / 232; LDL 159 / 163; HDL 50 / 50	Statistical methods not given. TC ↓ 5.2% and LDL 13.9%, compared to baseline, when Ss consumed the oat diet. Total fat and E intake ↑ during oat period and ↓ during wheat period. Mean body weight ↓ in some Ss on oat diet. These changes do not invalidate CHOL-lowering effect of oats. No sat fat or CHOL intake data provided. Authors state that no attempt was made to measure compliance, but subjectively it seemed that the Ss who achieved the greatest reduction in TC were those who were most compliant.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Uusitupa et al., 1992 (Ref. 41)	Clinical study, randomized, double blind 36 adults (20 males, 16 females), mild to moderate hypercholesterolemia (TC 212 to 328 mg/dL) on CHOL-lowering diets	4 wk run-in during which medical history was taken and Step 1 AHA diet was reenforced. 8-wk trial with Ss consuming OB or WB. OB (Finnish variety), enriched with β-glucan, contained 10.3 g fat, 48.1 g TDF (16.6 g β glucan) in 100 g dry material. The brans were provided in sachets and the Ss instructed to increase their daily dose stepwise until they consumed the entire sachet (estimated to have 62 g of bran) or the highest tolerable dose. Dietary records were kept during run-in and study period. Statistical analysis: multivariate ANOVA for repeated measures to find the differences between groups and changes within groups. All p values were two-sided.	Dietary intake: wk / OB / WB E, Cal/d: 0 1678.2 1796.6; 8 1665.8 1811.7 Fat, % E: 0 32.6 32.3; 8 32.8 33.9 Sat Fat, % E: 0 11.5 11.0; 8 11.7 11.8 CHOL, mg: 0 211 223; 8 198 224 Fiber, g: 0 22.7 24.4; 4 21.5 21.8; 8 20.9 19.0* Bran, g: 4 50.5 48.9; 8 49.7 48.9 * p<0.001 compared to baseline Serum lipids: wk / OB / WB (mg/dL) TC: 0 271.8 281.1; 4 259.9* 286.2; 8 266.4 282.3 LDL: 0 189.5 202.6; 4 178.3 207.3; 8 183.3 199.1 HDL: 0 54.5 50.7; 4 54.5 51.4; 8 54.9 53.7 * p=0.028 compared to baseline	Ss did not adhere to Step 1 diet. Fat calories ranged from 32% to 34% E, Sat fat 11-11.8%, and polyunsat fat 10.6 to 11% of E. Overall results of this study show no statistically signif. differences in TC between the OB and C groups. TC and LDL showed significant reductions at 4 wks (↓4.4%, p<.03; and ↓5.9%, p<0.04, respectively). There was incomplete adherence to the OB and WB dosages. Authors reported that an analysis of data showed that those who adhered to the diet instructions showed a decline in TC and LDL. 86% of Ss considered the daily dose to be too much. Authors reported significant decline in TDF intake in wheat bran group from baseline to 8 weeks. Results of this study suggest only a short term effect of OB on TC and LDL-cholesterol.
Van Horn et al., 1988 (Ref. 42)	Clinical trial, randomized 236 men and women, ages 30-65, free living; normo-cholesterolemic (163-247 mg/dL)	A 12-wk study: 4 wks on C diet and 8 wks on test diet. Both test and C groups consumed the Phase II AHA diet throughout the study. The test group consumed 56 g OM/d (2.3 g of SF) for 8 wks. Oatmeal was consumed as hot cereal and used in muffins and other foods. Phase II AHA diet: total fat: ≤ 30% Cal; equal distribution among saturated, mono-unsaturated, and polyunsaturated fats. Dietary CHOL: 250 mg/day.	Group / Base / AHA Diet / Intervention Wk 4 / Wk 8 TC mg/dL AHA only: 205.3 194.5 192.4 191.7 AHA+OM: 203.9 193.0 186.1* 187.0 * P=0.008 compared to AHA group At wk 8, the 3.1% ↓ in TC in OM group was not significantly different from the 1.4%↓ in the C group. Changes in LDL paralleled changes in TC. Similar and nonsignif. ↑ occurred in HDL in both groups. Subgroup analysis showed that Ss in test group with highest baseline TC had greater reductions in TC.	No significant benefit of oatmeal in lowering TC beyond that achieved with the AHA diet only after 8 wks. The low fat diet was effective in lowering TC.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Van Horn et al., 1986 (Ref. 43)	Clinical trial, randomized, controlled 208 men and women, ages 30-65 yrs, mean TC 208 mg/dL	12-wk study. Ss attended a series of 6 weekly nutrition education classes and were instructed on an AHA diet. No oat products were consumed during first 6-wk period. Intakes of fruits, vegetables, and grains were not altered during wks 7-12. Ss randomized to 1 of 3 groups at end of first 6 wks. Wks 7-12 groups 1 and 2 added 2 oz (56 g) OB (14 g SF/100 g) or OM (7.7 g SF/100 g) to the AHA diet, substituting for other carbohyrates. Recipes using OB or OM were provided. Group 3 was the control on AHA diet only. 3-d food records were kept. The null hypothesis was that no differences in TC reduction would occur between groups on AHA diets with or without oats. Sample size calculations were based on assumption that difference in TC between test and C groups would be at least 20 mg/dL.	Total Cholesterol Group / Base / End AHA Period / End Oat Period mg/dL C n=70: 209.3 / 201.0 / 199.7 1 OB n=69: 207.7 / 196.4 / 191.1 2 OM n=69: 208.2 / 195.2 / 188.8 Total n=208: 208.4 / 197.6 / 193.2 After 6 wks diet only, TC signif. reduced 5.2% ($p<0.001$) from baseline. Oat bran intake at 12 wks was 39 g/d (5.5 g SF) and OM intake was 35 g/d (2.7 g SF)	Although the OB and OM group experienced an additional reduction in TC of 2.7% and 3.3%, respectively, during the oat intervention period, there was no signif. difference in TC among the 3 groups at end of the study. Compared to baseline values, all groups were statistically significant ($p<0.05$). TC ↓ 8% in the OB group, 9.3% in the OM group, and 4.5% in the diet only control group.
Van Horn et al., 1991 (Ref. 44)	Clinical study, randomized, controlled 80 men and women, mild to moderate hypercholesterolemia (213-285 mg/dL)	Two groups: control group consumed regular diet; test group consumed regular diet plus instant oats (2 packets/d - 57 g). Baseline diets Test group / Control E, Cal: 1909.5 / 2007.4 Fat, % E: 36.8 / 37.0 Sat fat, % E: 12.6 / 12.6 TDF, g: 14.5 / 16.0 SF, g: 5.2 / 5.5 TDF / SF / IF OM: 5.6 g / 2.2 g / 3.4 g	Test group, while supplementing their diet with OM: TC ↓ 6.25% (signif.) Both LDL and the LDL/HDL ratio ↓ 9%. Control group: TC ↓ 1.4%; LDL ↓ 3.7%.	The study was not blinded; the test group reduced their intake of total fat, saturated fat and CHOL, and may have made other lifestyle changes. The C group increased their intake of total fat, sat fat, and CHOL.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Whyte et al., 1992 (Ref. 45)	Clinical study, randomized with cross-over 23 men, mean age 45 years, moderate hypercholesterolemia (TC 209 to 259 mg/dL), free living.	Ss randomly assigned to either the wheat cereal or the oat cereal group after a 3-wk baseline diet. During baseline, all Ss consumed wheat cereal. Preweighed packages of cereal were provided: 54 g of WB/d; 123 g OB/d. Base diet: typical Australian diet- approximately 30-34% of E as fat. Ss instructed on how to keep dietary records, measure and restrict fiber (so all Ss would have approximately same total fiber intake of less than 30 g/d). 2 servings/d cereal was consumed for 4 wks, then cross-over to other cereal for another 4 wks. Oat cereal: 10.3 g/d SF Wheat cereal: 3.4 g/d SF All diets: TDF approximately 27 g/d.	Data analysis showed no effect of treatment order. TC / LDL / HDL (mg/dL) Baseline 226 / 159 / 47.6 Oats 218* / 150* / 49.9 Wheat 228 / 159 / 51.0 * Significantly different ($p<0.01$) compared to both baseline and wheat period.	Consumption of total fat and Sat Fat during both test periods was about the same (35.5 g fat/1,000 Cal and 12.7 to 13 g Sat Fat/1,000 Cal). No significant changes in body weight. No dietary CHOL intake data provided.
Zhang et al., 1992 (Ref. 46)	Clinical study, randomized, controlled, cross-over. Ss studied on outpatient basis except on sampling days when they were admitted to research ward. 9 men and women, ages 45-67 yrs, with ileostomies. Mean TC 231 mg/dL	During each test period, Ss instructed to eat diets that were low in dietary fiber. Ss randomly assigned to either a high fiber diet group, in which an experimental bread made with OB was added to the low fiber base diet, or a low fiber diet group, in which Ss consumed their base diet with an experimental bread made with wheat flour. Test periods were 3 wks. Ss free living except on sampling days when they were given a diet with an average of 31% of E from fat. OB intake: 118 g; Bread had 29 g TDF Wheat bread: 4.9 g TDF	TC, mg/dL All Ss Wheat 214 Oat 194.5* * Significantly different from low fiber period	Total E, dietary fat, sat fat, SF, and CHOL of Ss diets on nonsampling days were not provided. All Ss had ileostomies. Conclusions about oat mechanisms in lowering serum lipids may not apply to general population.

Abbreviations:
CHOL = Cholesterol
TC = Total Serum Cholesterol
LDL = Low density lipoprotein cholesterol
HDL = High density lipoprotein cholesterol
P:S = Polyunsaturated to saturated fatty acid ratio
TDF = Total dietary fiber
IF = Insoluble fiber
SF = Soluble fiber
Sat Fat = Saturated Fat
E = Energy (Calories)
Cal = Calories
C = Control
OB = Oat bran
OM = Oatmeal
WB = Wheat bran
ANOVA = analysis of variance
NS = nonsignificant