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- Select the option: [1] FedWorld
- Logon to the FedWorld system
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Standards for Business Practices of Interstate Natural Gas Pipelines; Notice Regarding Electronic Filing of Pro Forma Tariff Sheets

[Docket No. RM96–1–000]

July 31, 1996.

In the Commission's July 17, 1996 order in this docket,[1] the Commission established a schedule for pipelines to file *pro forma* tariff sheets to comply with the business practice standards adopted by the Commission. Pipelines making *pro forma* tariff filings in response to this order should make these filings electronically as provided in Section 154.4 of the Commission's regulations.

[1] Standards for Business Practices of Interstate Natural Gas Pipelines, Order No. 587, 61 FR 39053 (July 26, 1996), 76 FERC ¶61,042 (July 17, 1996).

Lois D. Cashell,

Secretary.

[FR Doc. 96–19927 Filed 8–6–96; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94N–0031]

RIN 0910–AA19

Food Labeling; Nutrition Labeling, Small Business Exemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to modify the basis on which low-volume food products of small businesses are exempted from the requirements for nutrition labeling. The regulations also establish a notification procedure for small businesses to claim exemption for qualifying food products. This final rule is in response to the Nutrition Labeling and Education Act Amendments of 1993 (the 1993 amendments), and it is intended to provide an understanding of how the small business food labeling exemption provisions of the 1993 amendments operate.

DATES: The effective date of this rule is October 7, 1996.

Submit written comments on the information collection requirements by October 7, 1996. This information collection has been approved by the Office of Management and Budget (OMB) for 90 days, under OMB control no. 0910–0324.

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

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–151), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

A. Procedural

On November 8, 1990, the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (the 1990 amendments) was enacted. 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 is that they added section 403(q) to the act (21 U.S.C. 343(q)). This section, as amended by the Nutrition Labeling and Education Act Amendments of 1993 (Pub. L. 103–80) (the 1993 amendments) and the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103–417) (the DSHEA), provides that, with certain exceptions, a food, including both conventional foods and dietary supplements, is misbranded unless its label or labeling bears certain nutrition information (nutrition labeling).

Among the exceptions that Congress made to the nutrition labeling requirement was one for small businesses based upon the value of their gross sales (section 403(q)(5)(D) of the act). Following the expression of concerns by small businesses about the narrow coverage of the exemption and about the problems that relatively small firms would have in meeting the requirements of the new law, Congress passed the 1993 amendments establishing a new exemption for low-volume food products of small businesses under section 403(q)(5)(E) of the act. This section provides that low-volume products of small businesses need not be nutrition labeled.

What constitutes a low-volume food product is defined in the act by the number of units of the product sold per year; what constitutes a small business is defined by the number of full-time equivalent employees (FTE's) that the firm employs. For a food product to be exempt under this section, a small business must file a notice with FDA claiming the exemption and providing information as to: (1) The average number of FTE's for itself and all of its affiliates and (2) the approximate number of units of its sales in the United States for each product for which an exemption is claimed. For products that were on the market before May 8, 1994, the 1993 amendments provide a gradual phase-down of what constitutes a low-volume food product of a small business. The number of units decreases from ''fewer than 600,000'' for the 12-month period before May 8, 1994; to ''fewer than 400,000'' for the 12-month period before May 8, 1995; to ''fewer than 200,000'' for the 12-month period before May 8, 1996; and to ''fewer than 100,000'' thereafter. The number of FTE's starts at ''fewer than 300'' through May 8, 1995, decreases to ''fewer than 200'' for the year before May 8, 1996, and down to ''fewer than

100'' thereafter. Products that initially come onto the market after May 8, 1994, are subject to the ''fewer than 100,000 unit and 100 FTE'' limit.

Thus, the 1993 amendments provide additional time before low-volume food products of small businesses must conform with the requirements for nutrition labeling. By doing so, the 1993 amendments permit small businesses to use up stocks of labels, thereby reducing the costs of label inventory disposal, and to avoid having to compete for design and printing resources with larger firms. By providing that no food product from a firm having fewer than 100 employees and for which there are sales of fewer than 100,000 units per year will have to be nutrition labeled (at least until after May 8, 2002), the 1993 amendments save small firms the expense of nutrient analysis and preparation of new labels for those products.

Under the provisions of the 1993 amendments, as noted above, persons that claim an exemption for a low-volume food product must file an annual notice with FDA claiming the exemption. For products on the market before May 8, 1994, the first such notice was due May 7, 1994, and a second notice was due on May 7, 1995 (section 403(q)(5)(E)(iii) of the act). Although the filing of the notice is necessary for an exemption, it does not entitle a firm to an exemption. Under section 403(q)(5)(E)(I)(I) and (q)(5)(E)(ii) of the act, a product is not exempt if its labeling provides nutrition information or bears a nutrient content or health claim.

One other aspect of the small business exemption is relevant for background purposes. In providing the new exemption for low-volume food products of small businesses (section 403(q)(5)(E) of the act), Congress noted that FDA had misinterpreted its intent as related to the small business exemption in the 1990 amendments, which is based upon total gross sales, by applying it to manufacturers, packers, and distributors in addition to retailers (section 403(q)(5)(D)). However, recognizing that FDA had issued regulations that small businesses were relying on, Congress provided that section 403(q)(5)(D) of the act would apply to all firms through May 7, 1995, but only to firms that sell directly to the consumer (i.e., retailers) after that date (Statement of Explanation, H.R. 2900, 139 Congressional Record H6358 (August 6, 1993)).

The 1993 amendments were self-effectuating in establishing the provisions for exemption from nutrition labeling for low-volume foods of small businesses. In passing the 1993 amendments, Congress was concerned that action be taken quickly. In discussing the need for quick action, Senator Bumpers noted that: ''To come into compliance with the May 1994, effective date of the Nutrition Labeling and Education Act requirements, small businesses must in the very near future begin to incur the cost of initiating product analysis and labeling redesign.'' (139 Congressional Record S10818 (August 6, 1993.)

Further, in introducing H.R. 2900 (the bill that became the 1993 amendments) for consideration, Senator Kennedy stated that: ''No action or response by the FDA is required for the exemption to be in place. Businesses with fewer than 10 employees, which sell fewer than 10,000 units of products, are (not) required to file any notice with the FDA.'' (139 Congressional Record S10817 (August 6, 1993).) The provisions of the 1993 amendments became effective upon their enactment on August 13, 1993.

Although FDA recognized that the 1993 amendments were self-effectuating, it concluded that rulemaking would be useful in providing a common understanding of how the exemption provisions operate. Thus, to facilitate implementation of the 1993 amendments, FDA published in the Federal Register of March 14, 1994, a proposal entitled ''Food Labeling; Nutrition Labeling, Small Business Exemption'' (hereinafter referred to as ''the small business exemption proposal'') (59 FR 11872) to: (1) Modify § 101.9(j)(1)(21 CFR 101.9(j)(1)) and § 101.36(f)(1) (21 CFR 101.36(f)(1)), which provide for a small business exemption based upon gross sales, to reflect the provisions of the new law, (2) incorporate the provisions for exemption of low-volume food products of small businesses, and (3) establish procedures for the filing with FDA of notices from small businesses claiming exemptions for low-volume food products.

FDA received 30 letters, each containing one or more comments, to the small business exemption proposal. The responses were received from trade and retail associations, Federal and State government agencies, and industry. A number of the comments supported various aspects of the proposal. Several comments addressed issues outside the scope of this proposal, which will not be responded to here. A number of comments suggested modifications in, or were opposed to, various provisions of the small business exemption proposal. A summary of the arguments and changes suggested by these latter comments, and the agency's responses, are provided below.

B. FDA's Experience with the Filing of Notices

Before responding to the comments, it may be informative to discuss FDA's experience with the notices that have been submitted claiming exemptions under the 1993 amendments. FDA began receiving notices almost immediately after enactment of the 1993 amendments with approximately 150 notices being received by March 14, 1994, when it published the small business exemption proposal. Approximately, 3,600 more notices were received by May 7, 1994, the date when all such notices were to have been filed for products already on the market. The agency has continued to receive notices from firms claiming exemption for products that had been on the market before May 8, 1994, as well as notices for new firms and new products.

Although not required by the 1993 amendments to approve or even review the notices, FDA has maintained a file on each notice and has attempted to acknowledge receipt of the notice. One of FDA's first steps following receipt of a notice has been to record the name and address of the firm in a computer data base. In establishing and maintaining its file of notices claiming an exemption, FDA has reviewed each notice to determine whether it contained the basic information on the number of employees and the number of units of food products sold by the firm in the United States. Finally, FDA has issued a letter acknowledging receipt of the notice for each notice that appeared to contain complete information and appeared to, in fact, be qualified for the exemption.

One of the intended uses of the computer data base information on firms that had submitted notices to the agency was to develop for FDA field offices and State enforcement agencies a list of firms that had submitted notices claiming an exemption under the provisions of the 1993 amendments. Enforcement action under the 1990 amendments was delayed until after August 8, 1994, by enactment of Pub. L. 103–261 on May 26, 1994. This public law extended the time period for compliance with the provisions of section 403(q) of the act until after August 8, 1994, for certain food products. By August 8, 1994, FDA had received approximately 6,000 notices claiming exemption under the 1993 amendments. Between that time and the present, FDA has received approximately 3,000 notices from

additional firms claiming exemptions under the 1993 amendments.

In August 1994, FDA made its data base of the names and addresses of each firm that had submitted a notice under the provisions of the 1993 amendments available to its field offices and State enforcement agencies through a computer bulletin board system called ''FDA PRIME CONNECTION,'' which is maintained by the agency. FDA also placed information concerning the names and addresses of foreign firms and American importers filing notices on a second bulletin board system called ''FIARS'' (''FDA Import Alert Retrieval System'') that is available to FDA's import offices. FDA's enforcement offices were advised to review these listings to determine whether a firm had submitted a notice under the 1993 amendments if a product appeared to be out of compliance with the nutrition labeling requirements of the act.

As stated above, under the 1993 amendments, the notice claiming an exemption must be resubmitted every 12 months. The anniversary date for most such notices, i.e., those covering products on the market before May 8, 1994, is May 7th of each year. By May 7, 1995, FDA had received just over 1,100 notices claiming a continued exemption for food products for the time period of May 8, 1995, to May 7, 1996, under the provisions of section 403(q)(5)(E)(ii)(II) of the act. In the beginning of June, the agency sent a letter to each firm that had not yet renewed its exemption reminding it of the need to submit a new exemption notice to claim exemption for eligible products for the time period of May 8, 1995, to May 7, 1996. The reminder letter asked that the notices be submitted to the agency by July 10, 1995. By July 31, 1995, FDA had received a total of approximately 4,000 notices for the time period of May 8, 1995, to May 7, 1996. A small number of firms responded to the June reminder letters by stating that they were out of business or had revised the labels of their products to comply with the requirements for nutrition labeling.

A small number of the notices submitted to the agency were deficient, or inconsistent with the provisions of the 1993 amendments, in one or more aspects. A small number of the notices were deficient in that they did not supply information on the average number of FTE's or the number of units of product sold in the United States. Others were deficient in that they did not name the products sold in the United States for which the firm was claiming exemption. Some notices were inconsistent with the provisions of the 1993 amendments in that the average number of FTE's was 300 or more, or the number of units sold in the United States was 600,000 or more. To the extent that its resources permitted, FDA contacted by telephone or by mail those firms that had submitted notices that were deficient or contained information inconsistent with the provisions of the 1993 amendments. In some cases, products appeared to be ineligible for the exemption without further clarification; e.g., a bakery claimed an exemption for ''cookies'' and listed total sales of less than one million units. Upon questioning concerning the information in the notice, the firm advised that it produces several different types of cookies, none with sales of greater than 100,000 units. While resolving such questions, FDA has retained the firm's name and address in the data bases for exempt firms and for products. There were some instances where FDA advised firms submitting notices that one or more products listed in their notice were not exempt from nutrition labeling because either they did not qualify as a small business or the product was not a low-volume food product. In such a case the firm or the product were removed from the computer listing of exempt firms or exempt products.

II. The Final Rule

A. Provisions Rendered Moot by Passage of Time

Certain provisions contained in the small business exemption proposal are subject to timeframes, after which they no longer have an effect. Proposed § 101.9(j)(1)(i) would have provided an exemption until May 7, 1995, for food offered for sale by a manufacturer, packer, or distributor based upon the firm's gross sales. Proposed § 101.9(j)(18)(i)(A) would have provided an exemption for low-volume food products for the time period of May 8, 1994, to May 7, 1995. The passage of time has rendered both of these proposed provisions moot. Accordingly, FDA is not incorporating § 101.9(j)(1)(i) and (j)(18)(i)(A) as proposed on March 14, 1994 (59 FR 11880), and is renumbering the remaining paragraphs in § 101.9(j)(1) and (j)(18) in this final rule. Because § 101.9(j)(1)(ii) is identical to the existing regulation, it will not be set out in this final rule.

B. Dietary Supplements

On January 4, 1994, before it issued the small business exemption proposal, FDA issued final rules on nutrition labeling and nutrient content claims for dietary supplements. At that time, the act provided an exemption from nutrition labeling for dietary supplements of vitamins or minerals but not for dietary supplements of herbs or other nutritional substances. Thus, in the small business exemption proposal, FDA included provisions for conventional foods and dietary supplements of herbs and other nutritional substances under proposed § 101.9(j)(18) and for dietary supplements of vitamins and minerals under proposed § 101.36(f)(2).

The DSHEA amended section 403(q)(5)(F) of the act to eliminate the distinction between dietary supplements of vitamins or minerals and dietary supplements of herbs and other nutritional substances. In addition, even though the nutrition labeling and nutrient content claim requirements for dietary supplements were to go into effect on July 1, 1995, in the wake of the DSHEA, FDA published a notice on February 9, 1995 (60 FR 7711), in which it stated that, given the need to modify its regulations on nutrition labeling and nutrient content claims for dietary supplements to respond to the DSHEA, it did not intend to enforce those regulations until after December 31, 1996. The agency published a document proposing appropriate changes to its regulations for the nutrition labeling and nutrient content claims for dietary supplements on December 28, 1995 (60 FR 67194).

FDA notes that the DSHEA does not alter the exemption for low-volume food products created by the 1993 amendments as they relate to the submission of notices to claim exemption for dietary supplements. The agency has received some notices claiming exemption for dietary supplements under the provisions of the 1993 amendments even though the agency has yet to enforce the labeling requirements with respect to this class of products. FDA is unaware of any basis for not moving forward to establish provisions for the exemption of dietary supplements under the 1993 amendments. None of the comments on the small business exemption proposal raised a question about its application to dietary supplements. To streamline the regulations and to be consistent with the manner in which other exemptions and special labeling provisions are listed under § 101.36(g)(21 CFR 101.36(g)), FDA has modified § 101.36(f) to cross-reference the small business exemption in § 101.9(j)(1) and the exemption for low-volume food products of small businesses in § 101.9(j)(18), rather than codify those exemptions in § 101.36.

C. Definition of ''Person''

1. Two comments stated that the agency should clarify that the exemption is available to private label packers and distributors as well as to manufacturers. The comments urged that FDA state that a ''person'' entitled to apply for the low-volume food product small business exemption includes a manufacturer, a packer, or a distributor of such food products. The comments stated that the clarification that they suggested is consistent with the law and with the preamble to the proposal and would prevent confusion over the exclusion of manufacturers, packers, and distributors from the exemption based on gross sales.

FDA agrees that the 1993 amendments should be interpreted to give as much relief to small businesses as can fairly be provided. FDA recognizes that, by tracking the language of the 1993 amendments and using the term ''person'' in the proposal, the agency may not have made clear that all types of small businesses are eligible to submit a notice for the exemption for low-volume foods. The agency has modified § 101.9(j)(18) to clarify that a small business, whether it is a manufacturer, a packer, a distributor, including an importer or a retailer that introduces the food into interstate commerce, is eligible to claim an exemption for a low-volume food product under the 1993 amendments.

2. One comment stated that the ''person'' claiming the exemption for a product should not be limited to the manufacturer or the company whose name is on the label of the food product. The comment argued that the person that is the exclusive sales agent for a firm's products also should be able to file the notice. The comment argued that, because the 1993 amendments consistently refer to the person who claims an exemption for a food product, the exemption need not be linked to the manufacturer of the product but can be claimed by the firm that makes sales of the food product in the United States. The comment stated that the focus of the 1993 amendments is on making accountable the person who presents the product to the consumer. The comment identified three provisions of the 1993 amendments that it stated supported its position:

(1) The law does not mandate that one affiliate (manufacturing) instead of another (marketing) file the notice,

(2) The very small business exemption from the notice requirement applies to a person who sells fewer than 10,000 units of a food product in a year, and

(3) A notice may be filed by importers, who of course are not manufacturers of the products they handle.

The comment concluded that the exclusive sales agent knows the total number of units of a food product sold in the United States and can make an accurate statement of those sales on the notice.

As noted in response to the preceding comment, FDA agrees that the law does not mandate that the ''person'' filing the claim be the manufacturer or the company whose name is on the label. The agency agrees that an exclusive sales agent can file a notice claiming an exemption for a low-volume food product under the 1993 amendments.

This comment interprets the intent of the 1993 amendments too narrowly, however, by linking the exemption directly to the seller of the food product, as opposed to the manufacturer, repacker, or distributor. The 1993 amendments are silent in defining what type of small business constitutes the ''person'' that may submit a notice claiming an exemption for a low-volume food product. The only specific requirement that relates to that person is that the average number of FTE's of the person, and of all of its affiliates, be fewer than the number established as the standard by the statute (i.e., less than 300 between 1994 and 1995, less than 200 between 1995 and 1996, and less than 100 after that date or less than 100 for any product initially introduced into interstate commerce on or after May 8, 1994). The modification to § 101.9(j)(18) that FDA has made in response to comment 1 in section II.C.1. of this document will adequately address the concerns of this comment.

3. Several comments addressed the relationship of affiliated firms to those firms claiming an exemption under the provisions of the 1993 amendments. One comment stated that the guiding notion in defining ''affiliate'' should be whether one entity actually exercises control over a small food company. It stated that indirect and unexercised control should not create the status of affiliate. The comments argued that tenuous relationships linking far flung affiliates, and standard contractual arrangements that permit small food companies to exist, should not be considered an affiliation.

The Statement of Explanation presented by Mr. Waxman in presenting the bill that became the 1993 amendments explains that:

> Section 403(q)(5)(E)(vi)(III) defines person, in the case of a corporation, to include all domestic and foreign affiliates of the corporation. The FDA should consider the regulations issued by the Small Business Administration on this issue. 13 CFR. 131.401 (sic) (1993).
>
> (139 Congressional Record H6358 (August 6, 1993).)

Section 121.401 of Title 13 of the Code of Federal Regulations (13 CFR 121.401) sets out the provisions established by the Small Business Administration (SBA) concerning affiliation. (FDA presumes that the reference in the Congressional Record to 13 CFR 131.401 was a typographical error because that section does not involve the question of affiliation.) 13 CFR 121.401 provides a general rule on the determination of affiliation plus more specific instructions on how to determine whether affiliation exists between two firms. Among other things, 13 CFR 121.401 states that size determinations shall include the applicant concern and all its domestic and foreign affiliates. Moreover, all affiliates, regardless of whether organized for profit, must be included. Concerns are affiliates of each other when either directly or indirectly one concern controls or has the power to control the other; or a third party or parties controls or has the power to control both; or an *identity of interest* between or among parties exists such that affiliation may be found. In determining whether affiliation exists, consideration shall be given to all appropriate factors, including common ownership, common management, and contractual relationships.

FDA agrees with the comment that stated that standard contractual arrangements, to the extent that they do not create an identity of interest, should not be considered as evidence of affiliation. However, the other comments on affiliation are inconsistent with the provisions of 13 CFR 121.401. The other comments argued that affiliation is not present if an entity is not actually exercising control over the affiliate. The SBA regulation provides, however, that concerns are affiliates of each other when one ''controls or has the power to control.'' None of the comments attempted to explain how their suggested interpretations of the term ''affiliation'' were consistent with 13 CFR 121.401.

Because the suggestion for the interpretation of affiliation presented in the comments is not consistent with the congressional intent, as evidenced by the Statement of Explanation, FDA concludes that modification of the meaning of ''affiliation'' as suggested by the comments would be improper, and the agency is not making the suggested change. To reduce the potential for confusion over the use of the term

''affiliate'' in its regulation, however, FDA is modifying the definition of the term ''person'' in § 101.9(j)(18)(vi)(C) to include a reference to 13 CFR 121.401 as defining ''affiliate.''

4. One comment stated that FDA should not expand upon Congress' definition of ''person'' to include, for companies that are not corporations, all affiliates of that company.

FDA recognizes that the 1993 amendments specifically refer to corporations when stating that: ''the term 'person' in the case of a corporation includes all domestic and foreign affiliates of the corporation.'' Accepting the view that the 1993 amendments are silent with respect to how entities other than corporations are to be treated, the fact remains that section 201(e) of the act (21 U.S.C. 321(e)) states that the ''term 'person' includes individual, partnership, corporation, and association.'' Even though the 1993 amendments are silent as to how persons other than corporations should be treated, there is nothing that suggests that those persons should be treated differently than corporations. None of the comments presented any basis for treating these other persons differently than corporations. Therefore, FDA concludes that the best approach would be to treat all persons the same. Thus, in § 101.9(j)(18)(vi)(C), the term ''person,'' as relates to an entity that is not a corporation, includes all affiliates as defined in 13 CFR 121.401 for purposes of section 403(q)(5)(E) of the act.

D. Definition of ''Unit''

5. Some comments stated that whether a food is a low-volume food product should be based upon the number of units of a food product for which the packer or distributor is responsible, regardless of the number of similar units produced by its manufacturer for other persons. These comments stated that FDA has inadequately explained in the proposal how the number of units criterion and the definition of ''food product'' should be applied to private label food products. They stated that a private label packer or distributor that is a small business should be able to apply for, and claim the benefit of, the small business exemption based on the number of units of food products the packer or distributor sells annually under its own private label. They reasoned that this approach would be consistent with the agency's explanation of the application of the small business exemption based upon gross sales, where the name of the firm on the label determines responsibility for the label for the purpose of determining the firm that must have sales of less than $500,000 for purposes of section 403(q)(5)(D) of the act, which was passed as part of the original 1990 amendments. The comments stated that FDA's interpretation of eligibility for exemption under the 1993 amendments should be consistent with its interpretation under the 1990 amendments.

Having evaluated these comments and the notices that it has received over the past year, FDA concludes that there are some basic misunderstandings about the products that are eligible for exemption under the 1993 amendments, particularly with respect to how to count units in determining whether a product is a low-volume food product. The comments also evidence a belief that the agency has considerable leeway in its interpretation of the 1993 amendments. To the contrary, the 1993 amendments are highly specific and prescriptive in providing an exemption from the requirements of mandatory nutrition labeling for low-volume food products of small businesses and leave little room for interpretation by FDA.

It is not clear that those submitting the comments understand fully the differences between the exemption for small businesses under the 1990 amendments and the exemption under the 1993 amendments. In presenting guidance on the 1990 small business exemption in ''Food Labeling QUESTIONS AND ANSWERS'' (Office of Food Labeling, FDA, August, 1993), FDA stated that, for a food to be eligible for the exemption, the firm that was responsible for the labeling of the food, i.e., the firm whose name appeared on the label of the food product, would be the firm whose total gross sales would be considered; that is, the firm whose gross sales must be less than $500,000 for the product in question to be eligible for exemption.

Under section 403(q)(5)(E) of the act, which was added by the 1993 amendments, however, whether a food product is eligible for exemption is based on two factors, neither of which involves the value of the firm's gross sales. One factor is the number of employees of the firm that is submitting the notice claiming the exemption (see the discussion above under section II.C. of this document on the definition of ''person'' and the discussion under section II.F. of this document on ''calculation of average number of FTE's.'' The other is the number of units of the product that is sold in the United States. The latter factor is the one that is not well-understood by the comments.

Under section 403(q)(5)(E) of the act, whether a food product is a low-volume food product, and, thus, eligible for the exemption, is not dependent on the identity of the firm claiming the exemption. This determination depends only on the total number of units of that specific food product that are sold in the United States (see, e.g., section 403(q)(5)(E)(I)(IV) of the act).

A specific food product is defined by three parameters: (1) Its being from a single manufacturer or bearing the same brand name; (2) bearing the same statement of identity; and (3) having a similar method of preparation (section 403(q)(5)(E)(vi)(II) of the act). This definition means that, in counting the number of units of a food product, e.g., a cake mix, for purposes of claiming an exemption, firms must consider: (1) The total number of units of the cake mix produced by the manufacturer for sale to consumers in the United States regardless of the brand name under which it is packaged and (2) the total number of units of the cake mix labeled under one brand name, regardless of the number of manufacturers that produced it. If either number exceeds the low-volume criteria, the product is not eligible for the exemption.

Presume, for example, that a manufacturer produces one million packages or units of a cake mix for sale in the United States. The cake mix is not a low-volume food product and, thus is not eligible for exemption under the 1993 amendments, even if the manufacturer ships all of the product in equal quantities to 20 small businesses, and each puts its own brand name on the cake mix that it sells. Alternatively, if one million packages of a cake mix are made in equal quantities by 20 different manufacturers, but all bear the same brand name, the cake mix is not eligible for exemption under the 1993 amendments, even if each of the manufacturers has less than 100 employees, because, again, it is not a low-volume food product.

On the other hand, a food product could be eligible for the exemption even though it is manufactured by a large firm, if the food product qualifies as a low-volume food product. If a manufacturer with too many employees to qualify for the exemption were to make a product under another firm's brand name, the product may qualify as a low-volume food product if the sales of that private formula food product are less than the applicable number defining a low-volume food product.

In the case of the cake mix, for example, presume that a small business with only 15 employees contracts with 1 large copacker or manufacturer to

make 50,000 units annually of that small business's special private formula cake mix which is not available to any other firm. In such a case, the private formula cake mix would be exempt under the 1993 amendments upon the submission of a notice by the small business claiming an exemption, regardless of the number of employees of the copacker and regardless of the amounts of other products that the copacker produces. The cake mix would be exempt because the firm claiming the exemption is small (15 employees), and the cake mix is a low-volume food product (neither the total number of units produced for sale in the United States, nor the total number of units sold under the brand name in question, exceed 50,000).

In summary, contrary to the assertions by the comments, under the 1993 amendments (section 403(q)(5)(E) of the act), and in contrast to the small business exemption established in the 1990 amendments (section 403(q)(5)(D) of the act), the size of the company listed on the label of a food product is not necessarily determinative of whether that product is exempt from the nutrition labeling requirement. While that firm must be a small business (that is, have less than the requisite number of employees) to be eligible to claim an exemption, the number of products sold in the United States must be below the requisite levels for the product to be eligible for the exemption, and that number may include products sold by companies other than the company that is seeking the exemption. A product qualifies for the exemption under section 403(q)(5)(E) of the act only if the company submitting the notice is small, and the product is a low-volume food product.

6. Several comments stated that the suggested method for counting products from a private label manufacturer that was in the small business exemption proposal was inappropriate. One comment suggested that the 600,000-unit exemption be based on the sales/production of the firm that takes control of (i.e., owns) the label and packaging on which nutrition information would otherwise be included. According to the comments, in many cases, that firm will be the private-label manufacturer; in other cases, that firm will be the distributor and marketer.

Another comment stated that a private label distributor should be able to claim an exemption if the number of units sold in the United States under the distributor's own label meets the statutory requirement. The comment explained that it would defeat the purpose of the exemption to require a distributor to aggregate all units of a food produced by a common manufacturer and sold by other firms. Such an interpretation, according to the comment, would require a small distributor that sells a food in a low-volume to provide nutrition labeling, contrary to Congress's intent to relieve the burden on such firms. The comment noted that the approach that it was suggesting is the only feasible way in which the exemption provision can be administered because a distributor cannot know how many units of the food produced by the particular manufacturer were sold in the United States by other distributors under other brand names. Another comment stated that the proposed requirement that a private label manufacturer count all production in determining whether it is eligible for the exemption is inconsistent with the 1993 amendments and may produce a hardship on ''mom and pop stores'' that cannot produce product on their own, particularly if each has to supply labels to the manufacturer for labeling of the product.

FDA agrees that the intent of the 1993 amendments was to provide relief for small businesses. In considering the intent of the 1993 amendments, it is important to remember that Congress amended a section of the act (section 403(q)) that was added by the 1990 amendments. The overall intent of the 1990 amendments is to ensure that nutrition information is available on almost all foods marketed in the United States. The 1993 amendments were enacted to provide relief for small businesses from the economic burden of having to nutrition label low-volume food products. This fact does not mean, however, that Congress intended to exempt all products that bear the name of small businesses. Rather, Congress sought to exempt those products that, because of the size of the firm that sold them and the number of units of the product that were sold, would likely be discontinued by the firm because the costs of relabeling would be too great to make continued marketing of the product economically feasible. Thus, Congress tailored the qualifications for an exemption to meet these goals.

Congress apparently felt that, in circumstances where a firm that sells the product is small, but the firm that manufactures it is large and manufactures it for other firms as well, in numbers that exceed the ''low-volume'' standard, it is reasonable to expect that the larger company would assist the smaller company in coming into compliance with the law by, for example, providing nutrition information for the product. Regardless of whether it is reasonable to expect that a firm will not place its suppliers or customers in jeopardy of violating the law, it is FDA's responsibility to ensure that there is compliance with the provisions of the 1993 amendments.

Section 403(q)(5)(E)(vi)(II) of the act states that a ''food product'' means food in any sized package that is manufactured by a single manufacturer, bears the same statement of identity, and has similar methods of preparation. Thus, if a manufacturer makes 1,000,000 units of a ''cola'' for six private label soft drink firms, 1,000,000 must be used as the number of units for each firm for the purposes of deciding whether that firm's ''cola'' is eligible for the small business exemption for the purposes of section 403(q)(5)(E)(i) or 403(q)(5)(E)(ii) of the act. It is important to note that in both of the latter provisions, the statute is talking about ''units of such product [that] were sold in the United States,'' not about the units of such product that were sold in the United States by the person seeking the exemption.

7. Several comments addressed FDA's proposal that, in counting units, a small business must total all units of all of the various sizes in which a food is packaged and all of the ways it is sold unpackaged. These comments claimed that this proposed definition of ''unit'' by the agency basically eliminated the exemption for their firms. Noting that the intent of Congress was to mitigate cost to small businesses, another comment stated that it would be severely damaged if food in any sized package that is manufactured by a single manufacturer, no matter what the brand name, is considered a unit of that food. One comment complained that FDA's interpretation is blind to the cost of changing each label size for low-volume packages, and that it overlooked the congressional intent to mitigate the cost of labeling conversion for small manufacturers. The comment proposed that the first year exemption for small businesses under 300 employees be allowed on all packages under 600,000 units of sales per year provided that printing films are different. Another comment stated that the proposed definition does not take into account exactly what is a ''Package/Label.'' The comment stated that FDA should allow individual, distinct packages of a food product, as defined by the UPC (Universal Product Code) number, to be counted separately in determining exemption eligibility, rather than the proposed combination of all types of products and sizes of packages.

One comment supported the agency's definition of ''units.'' The comment

stated that it would be absurd and contrary to congressional intent to exempt the many identical products made by a private label manufacturer on the theory that each individual brand label was produced at levels below the regulatory maximum.

The agency agrees with the latter comment and finds that the others present suggestions that are contrary to the 1993 amendments. FDA understands the concerns that are being raised by the comments. FDA has no desire to implement the 1993 amendments unfairly, but it is its duty to enforce the law in accordance with its terms.

In the counting of units, it is the definition of ''food product'' that is controlling. That definition states that a food product includes food in any sized package which is manufactured by a single manufacturer or which bears the same brand name. Given that being manufactured by a single manufacturer is alternative to bearing the same brand name, it means that products manufactured by the same manufacturer that do not bear the same brand name would still be considered a single product as long as they meet the other aspects of the definition of ''food product.'' Thus, FDA's definition is fully consistent with the act.

FDA is aware of the various factors that pose economic burdens to small businesses that are identified by these comments, but it still has an obligation to implement the act as written. In the face of the statute, given the use of the words ''in any sized package'' in the definition of ''food product,'' it is apparent that Congress decided not to take into account the additional factors to which the above comments point. Although the agency recognizes that the use of different printing films or different UPC numbers would provide greater economic relief for small businesses, as noted above, FDA is bound by the terms of the act. Neither of these considerations are permitted or even addressed in the 1993 amendments. As explained above, FDA's approach is fully consistent with, and responds to, the act.

8. One comment objected to FDA's definition of a unit for soft drinks as being the individual bottle rather than the case, noting that there might as well not be a small business exemption for their industry.

FDA was well aware of the concern raised by this comment and attempted to address it in the small business exemption proposal. In that proposal, FDA stated that, if the individual cans or bottles of a case or carton were labeled in accordance with the provisions for multiunit packages under § 101.9(j)(15), the case or carton could be treated as a single unit for the purpose of counting units of food product (59 FR 11872 at 11874). To be in compliance with § 101.9(j)(15), the individual can or bottle of a multiunit package must bear the statement ''This Unit Not Labeled For Retail Sale.'' This possibility still exists for producers of soft drinks.

However, as noted in the small business exemption proposal, soft drinks are not normally packaged in this manner, but instead they are packaged in bottles or cans that are amenable to sales either as individual packages or as part of a carton or a case. Historically, consumers have often been able to mix individual flavors of particular soft drinks when purchasing them by the carton or case. Thus, FDA tentatively concluded in the proposal that the total number of individual cans or bottles of a soft drink is controlling for the purpose of counting the number of units sold in the United States.

In considering this comment on how units of soft drinks should be counted, the agency has reviewed its tentative conclusions on this matter. FDA now finds that there is a basis for counting the cases or cartons of cans or bottles of soft drinks as individual units for the purposes of the 1993 amendments. FDA agrees that there may be instances where a case of soft drinks should be considered to represent a unit. In the proposal, FDA stated its tentative finding that the case is a convenience used by the manufacturer to deliver 12 or 24 individual units to the customer. As noted above, this finding was based on the historical practice of the consumer being able to mix units of soft drinks when purchasing a case of 24 bottles. However, upon considering this matter as part of its review of the comment, FDA recognizes that there may be instances where the unit being sold to the consumer is the carton or the case of soft drinks. Such situations would be those where soft drinks are sold in cartons or cases that are sealed or have plastic over-wraps that deter individual sales or mixing of individual cans or bottles in the carton or case. FDA agrees that a firm may count such sealed cartons or cases as individual units for the purpose of a claim under the 1993 amendments, regardless of whether the individual units are labeled in accordance with § 101.9(j)(15), if the firm has evidence of the extent to which its soft drink is sold by the carton or case instead of by the individual can or bottle. FDA notes that if a firm intends to rely upon the provisions of the 1993 amendments to claim an exemption from the requirements of nutrition labeling for one of its products, then it is incumbent upon that firm, for the purpose of reporting the number of units, to have knowledge of how the product is sold to the consumer.

9. Two of the comments stated that FDA should clarify how units should be counted for a product that is not sold in a package. One comment representing foreign firms noted the potential differences in marketing in the United States as compared to another country and the difficulties a foreign firm faces in learning about U.S. marketing practices. The comment suggested that FDA include in the final rule that the counting of units could be based upon a person's reasonable determination of U.S. marketing practices even if that determination deviated somewhat from actual marketing practices in the United States. Another comment requested that FDA clearly set forth in the preamble accompanying the final regulation how this aspect of the ''unit'' definition (i.e., sales of food not in package) will be applied to confectionery and similar items sold individually and priced by weight.

FDA recognizes that estimating the number of units of a product that is sold to consumers in an unpackaged form may be difficult for a firm seeking to submit a notice claiming exemption under the 1993 amendments, particularly for a foreign firm. This is especially true for candies which were mentioned in these two comments. Depending upon the type of candy and its quality, a particular product may be sold at retail by the piece (either because it is expensive or for a low price, such as penny candy); by the half-pound or by the pound; or by the package. In such a case, the candy manufacturer would total the number of units sold by the piece or by the half-pound (or the pound) with those sold in packages to determine the total number of units of candy sold in 12 months. It is incumbent upon the firm that provides an approximation of the number of units of a product sold in the United States as part of a claim for exemption from nutrition labeling under the provisions of the 1993 amendments to have adequate knowledge of the sales of that product in the United States. This knowledge is necessary for the firm to be able to report accurately in its notice claiming exemption the number of units that it sold.

FDA has modified the instructions contained in Appendix II to provide more details on the counting of units of a food that is sold unpackaged. The agency has retained in § 101.9(j)(18) language from the 1993 amendments as

the appropriate description of how to count units of a food that is sold unpackaged. FDA is concerned that to be more specific in the regulations may reduce the degree of flexibility available under the definition of ''unit.'' This definition (section 403(q)(5)(E)(vi)(I) of the act) provides that ''the term 'unit' means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers.'' Many foods are sold to the consumer in an unpackaged form, such as by the piece, by the slice, or by a measured amount. Thus, to comply with definition of ''unit,'' a small business would include in its count of units in a notice claiming an exemption under the 1993 amendments both packaged and unpackaged product. The agency provided an example of counting units of unpackaged food products for flour in the proposal (59 FR 11872 at 11874). As stated in the proposal (59 FR 11872 at 11874), the small business should make its determination of the specific ''unit'' to use as a basis for reporting sales of unpackaged food products according to the normal sales practice for that food product in the United States.

E. Definition of ''Food Product''

10. Although some comments commended FDA for its definition of ''similar method of preparation,'' discussed in the preamble of the small business exemption proposal (59 FR 11872 at 11875), some comments asked for further clarification of the definition, in particular as it related to nutritive value. One comment stated that the definition of ''food product'' must be limited to the factors referred to in the 1993 amendments. The comment added that the 1993 amendments link the definition of ''food product'' to the food's statement of identity and neither explicitly nor implicitly permit the use of nutritive value as a factor in distinguishing one food product from another. Other comments, however, encouraged the use of the concept of ''nutritive value.''

One comment stated that FDA should incorporate into the regulation the preamble language that explains the intended meaning of ''similar preparation methods,'' including an explanation of criteria that will allow businesses to determine when the lack of similarity of their products' nutritional profiles is such that they must consider products to be different than each other. One comment stated that products that have the same common or usual name, have identical nutrition profiles, but that are subjected to different scheduled processes because of the size of their container, should be counted as the same product. The comment added that products that are basically the same but have differing names for differing shapes/forms, such as taco shells and chalupa shells, which are both forms of tortilla shells, should be counted as the same product.

Another comment stated that FDA should clarify that variations of a product with formulation differences, such as different flavors, are considered different ''food products'' for purposes of the small business exemption. The comment stated that the preamble to the proposal stated that the term ''similar preparation methods'' included ''all aspects in the manufacture of the food product, from the initial steps of determining the ingredients to be used, i.e., formulation * * *'' (59 FR 11872 at 11875). The comment stated that this statement should be set forth in the final regulatory text itself, along with language to the effect that even minor formulation differences, such as differences in flavor ingredients in some cases, result in two different food products, regardless of whether the formulation differences result in differences in nutrient profiles between the two different food products. The comment noted that for many firms and many products there will be no way of determining whether two similar products have the same nutrient profile without nutrient analyses of each product. The comment added that requiring small businesses to undertake such analyses solely for the purpose of ascertaining whether they qualify for the small business exemption would undermine much of the benefit of the exemption and be contrary to the congressional intent.

After considering the various comments seeking clarification of the term ''similar method of manufacture,'' FDA has decided to adopt the definition for ''food product'' that it proposed. Also, after reviewing the comments, FDA is emphasizing that consideration of nutritive value is not a necessary consideration in the definition of ''similar preparation methods.'' The comments appear to have misinterpreted FDA's intent as it relates to the use of ''nutritive value'' of foods.

Although the legislative history for the 1993 amendments discusses what is meant by ''statement of identity,'' it provides no insight into what factors led Congress to establish ''similar preparation methods'' as the third factor in the definition of ''food product.'' The agency intended that the concept of ''nutritive value'' could be used by firms as an informal guideline in determining whether the manufacturing processes for food products meet the parameter of ''similar preparation method.'' FDA had presumed that firms would be faced with situations where there were minor differences in the method of preparation that would lead them to question whether the food products should be counted as being the same. FDA was stating that a firm could use nutritive value as a determinant in resolving this question. The agency did not mean to imply that if two foods prepared by dissimilar processes were found to have the same nutritive value they should be considered to be the same food product. Further, FDA did not intend that firms should analyze foods to determine nutritional value to determine whether they should be considered to be different foods because to expect firms to do so would be contrary to the intent of the 1993 amendments.

The agency has included an additional discussion in Appendix II concerning the term ''similar preparation methods'' to assist firms that submit notices to FDA under the 1993 amendments. However, the agency is not providing further explanation of the meaning of the term ''similar preparation methods'' in the regulations. FDA is concerned that any attempt to elaborate on a definition of ''similar preparation methods'' would only result in a regulation that is more restrictive than the statutory definition.

FDA agrees with the comment that urged that minor differences in scheduled processes or differences in shapes for the same product should not be considered as resulting in different products. FDA does agree, however, that differences in formula, even differences that involve different flavors, would be sufficient to consider foods having such differences to be different food products.

11. One comment requested that FDA clarify in any final rule that similar foods whose preparation methods result in different nutritional profiles represent only one example of different ''food products'' for exemption eligibility purposes. The comment stated that the agency should make clear that other significant differences in preparation that do not affect nutrient content, such as kosher preparation, can also serve to differentiate ''food products'' for exemption eligibility purposes. The comment also noted that certain such differences, like kosher preparation, but for being symbolically rather than expressly declared in labeling, also would differentiate products in terms of a distinguishing statement of identity (e.g., ''kosher green beans'' as compared to ''green beans''), thereby contravening the second

element of the ''food product'' definition.

As discussed in response to the previous comment, this comment misinterprets the way in which FDA had meant for the concept of nutritive value to be used. FDA had never intended that the concept of nutritional value should be used as a basis for concluding that food products with differing methods of preparation but the same levels of nutrients should be considered the same food product for the purpose of counting units. However, the comment raises the issue of whether both perceived and real differences in the method of preparation should be considered in distinguishing between food products.

A determination of whether real and perceived differences distinguish particular foods can only be made on a case-by-case basis. It is not possible to provide guidelines that would cover every case. FDA believes that real differences, such as differences in formulation or differences in preparation, would be used to distinguish a ''Kosher'' product as a different food product. However, there may be steps in the production of a ''Kosher'' product that would not distinguish it from a nonkosher product; e.g., the comment mentioned rabbi inspection as a step that distinguishes kosher food products from other food products. FDA does not agree that rabbi inspection would be sufficient to result in differing food products for the purposes of the 1993 amendments. As noted above, such distinctions will have to be made on a case by-case-basis.

12. One comment suggested that identically formulated products in different size packages or types of packages should be considered different ''food products'' for purposes of the small business exemption.

This suggested approach is contrary to the wording in the 1993 amendments themselves. The definition of food product states: '' 'food product' means food in any sized package'' (section 403(q)(5)(E)(vi)(II) of the act). This wording makes clear that, for the purpose of counting units of a food product, all of the various sizes and forms in which a food product is sold are to be combined. Thus, FDA cannot modify the definition for ''food product'' in the manner suggested in the comment because to do so would be contrary to the 1993 amendments themselves. (See comment 7 in section II.D. of this document.)

F. Calculation of the Average Number of FTE's

13. Three comments raised questions concerning the proposed provision that the average number of FTE's should be based upon the total number of individuals employed by the firm and by all of its affiliates, both domestic and foreign. Two comments stated that, for the purpose of calculating the average number of FTE's, the employees that are considered should be limited to those of the firm claiming the exemption and not of separately incorporated affiliates. One of the comments contended that including employees of unrelated businesses would severely undermine the purpose and scope of the amendment. The comment stated that a fundamental assumption of the amendment is that each product is an independent ''profit center,'' and, accordingly, nutrition information is only mandated when it is economically feasible given the economies pertaining to the production and sale of an individual food item. Although family owned retail confectioners often are involved in other business enterprises, the comment continued, the size or nature of those outside business interests is irrelevant to whether the retail confectioner can cover the cost of nutrition labeling of a particular item.

One comment stated that, in the explanation of the term ''FTE,'' FDA added a discussion that links this definition with the definition of ''person.'' The comment stated that the effect is to require that the employees of a domestic company be combined with those of an affiliate company regardless of whether their operations are related to sales of food products in the United States. The comment stated that there is nothing in the 1993 amendments that points to or requires this conclusion. The comment argued that the relevant issue is how many employees were employed in the United States, not overseas and not in unrelated positions.

FDA disagrees with the conclusion that is reached in these comments. Each of the above comments raises the same basic argument, that the calculation of the average number of FTE's should be based only on the employees of the company submitting a notice claiming an exemption under the 1993 amendments and then only on those employees involved in the production of the food product for sale in the United States. Although the comments state that nothing in the 1993 amendments supports the approach proposed by FDA, they do not provide specific citations to language in the 1993 amendments or the legislative history of the 1993 amendments that support their conclusions. One comment said that a fundamental assumption of the 1993 amendments is that each product is a ''profit center'' but did not offer a citation to where this assumption is either explicit or implicit in the 1993 amendments. FDA concludes that the approach suggested by the comments is contrary to the clear meaning of the 1993 amendments.

In introducing H.R. 2900 (the bill that became the 1993 amendments), Congressman Waxman stated:

> certain small businesses will have extreme difficulty complying with the NLEA by May 8, 1994. * * * Under the amendments, qualifying businesses will be given 1 to 3 additional years to comply with the NLEA. After May 8, 1997, any business with fewer than 100 employees can qualify for an exemption for any products for which it sells fewer than 100,000 cans or other units per year.

(139 Congressional Record H6358 (August 6, 1993).)

The 1993 amendments state as criteria under which a product would be exempt from the requirements for mandatory nutrition labeling that ''the person who claims for such product an exemption from such paragraphs employed fewer than an average of 100 full-time equivalent employees'' (section 403(q)(5)(E)(i)(II), or 300 or 200 in the cases of subparagraphs I and II or III of section 403(q)(5)(E)(ii) of the act, respectively). In describing the notice to be filed to claim an exemption under the 1993 amendments, section 403(q)(5)(E)(iii) of the act states that the notice shall ''state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption.'' In providing for the exemption of low-volume food products from nutrition labeling, the 1993 amendments state that ''the term 'person' includes all domestic and foreign affiliates of the corporation'' (section 403(q)(5)(E)(vi)(III) of the act). As noted above, the ''Statement of Explanation'' for H.R. 2900 also explains: ''Section 403(q)(5)(E)(vi)(III) defines person, in the case of a corporation, to include all domestic and foreign affiliates of the corporation. The FDA should consider the regulations issued by the Small Business Administration on this issue.'' FDA is unaware of any further discussion on the calculation of the average number of FTE's in the 1993 amendments or related legislative history. Contrary to what was suggested by one comment, there is no indication that FTE's should only be determined based on those employees that are related to the

production of the food that is the subject of the notice. In fact, the clear implication is to the contrary. Both the 1993 amendments and their legislative history state that the term ''person'' includes both domestic and foreign affiliates.

FDA finds that the above references in the 1993 amendments and their legislative history are unambiguous as to the calculation of the average number of FTE's for a firm or other person submitting notice claiming an exemption under the 1993 amendments. Thus, the notice claiming an exemption must state the average number of FTE's of the firm or person submitting the notice, including the employees of all domestic and all foreign affiliates as defined in 13 CFR 121.410. Further, because neither the 1993 amendments nor their legislative history make a distinction with respect to the business of the affiliates, the average number of FTE's must be reported based on all the employees of all affiliates regardless of the nature of the business of the affiliate. Given the language of the 1993 amendments and their legislative history, FDA finds that no other interpretation of how the average number of FTE's is to be determined is reasonable.

14. One comment stated that the average number of FTE's should be based on actual hours worked in a year, 1,824 (i.e., the time that a person that is actually on the job) instead of the proposed 2,080. The comment provided the following explanation of the derivation of 1,824 hours as the amount of actual hours worked in a year:

> An hourly person paid only for amount of time on the job is on the job only 1,824 hours (2,080–80 annual, -80 sick, -96 for 12 holidays = 1,824 hours). Using 2,080 hours instead of 1,824 would allow a firm to omit the declaration of a ''ninth'' employee for every eight full-time employees.

Another comment stated that FDA should retain its proposed method for determining the number of employees and should maintain the 2,080 hour denominator for the calculation.

There are any number of approaches that FDA could have used to define ''full-time'' for use in calculating the average number of FTE's. For any particular situation, however, each possible denominator might over- or undercount the actual number of persons. For example, a firm may hire large numbers of part-time employees for which it does not provide vacation or sick leave hours. Other firms may have more generous or less generous annual leave provisions. Still other companies may recognize fewer or more holidays. For this reason, FDA tentatively decided to simply take the standard full-time work week established by the Department of Labor, 40 hours, and multiply by the number of weeks in a year, 52, to obtain the number to be used in the denominator for calculating the average number of full-time employees. Although FDA recognizes the concern of the comment that suggested using 1,824 hours as the denominator, the use of 1,824 could result in a hardship to those small businesses that provide less amount of time for leave or holidays per employee than suggested by the comment in that it would lead to an overcounting of employees. The agency concludes that use of 2,080 as the denominator provides an equitable approach for a formula to be used in determining the average number of full-time equivalents and is retaining this value in its regulations.

15. One comment stated that FDA should consider as employees only those persons for whom the small business pays income and social security taxes. The comment stated that the calculation of average number of FTE's should not include all ''individuals that render service'' to a company, which would include lawyers, mail carriers, and accountants that are not under the direct employ of the small business. The comment stated that FDA should narrow the definition of employee, and that, in case of doubt, the approach of the Internal Revenue Service could provide guidance. Another comment stated that FDA should reconsider who it counts as employees to exclude contract distribution personnel. The comment explained that many small businesses use route salesmen to service retail establishments. These route salesmen were described by the comment as independent small businessmen who receive compensation from the manufacturers usually as a percentage of the sales. The comment stated that firms should not be precluded from qualifying for the exemption because they chose this form of distribution for their products.

The small business exemption proposal stated that the average number of FTE's ''shall be determined by dividing the total number of hours of salary paid directly to individuals, or companies that employ those individuals, that render service to the person.'' In proposing the definition in this way, FDA was attempting to ensure that persons calculating the average number of FTE's considered all employees (e.g., all owners, officers, the secretarial staff, and part-time employees) of the firm and not just those that are directly involved full-time in the production and sales of food products. The agency had seen this as a potential problem because some of the early notices submitted to the agency had reported ''0,'' ''Zero,'' or ''None'' as the average number of FTE's.

After reviewing the comments and the language of the proposed definition for an FTE, FDA finds that the explanation for the calculation of the average number of FTE's was overly broad and subject to confusion. For example, FDA agrees that it is not normally necessary to include in the determination of FTE's individuals that perform services for the small business as part of the responsibilities of their employment, such as the mailman, fireman, policeman, or even grocery store clerk. FDA finds that such individuals need not be included in the count of the average number of FTE's unless they work for an affiliate of the firm.

The agency has modified the definition of the term an FTE in § 101.9(j)(18)(vi)(D) to narrow it to refer simply to ''employees'' instead of all individuals that render service to the firm. To ensure that there is no misunderstanding of which employees to count, FDA is also modifying the discussion of the calculation and reporting of the average number in Appendix II to refer to the ''employees of the person and of all of its affiliates.''

G. Small Business Food Labeling Exemption Notice

16. Two comments suggested changes in the model form that the agency included as Appendix I to the proposal. One comment suggested that the agency include a place on the form for the telephone and FAX numbers of the firm. The comment stated that the form or instructions should also contain the address to which the form is to be mailed. The other comment stated that the small business food labeling exemption notice should be modified, printed, and made available to the public. The comment suggested use of a form prepared by the National Association for the Specialty Food Trade, Inc. (NASFT) because it claimed that the NASFT form is less confusing than the one that the agency provided. The comment stated that the model form should make a clear statement referencing the provisions of 18 U.S.C. 1001 that prohibit the submission of false information to the Federal Government. The comment also stated that FDA should make the modified form publicly available.

FDA has modified the form in line with the comments and has included the modified form in Appendix I to this

final rule. The agency contacted the NASFT to gain its agreement that the agency could incorporate parts of NASFT's form into the form supplied by FDA. FDA has modified the form to include spaces for a telephone number and a FAX number. In reviewing notices, FDA has found that use of the telephone is frequently an expeditious way of resolving questions that arise. The agency has also made the address to which the form should be sent more prominent in the instructions.

FDA has also modified the form to include specific spaces for the date that the form was prepared and for the name of a contact person. The agency has found that information on the date of preparation is important to help keep multiple notice submissions separate. The name of a specific contact person for a firm has helped the agency to resolve rapidly questions that have arisen during its review of a notice.

Because it has received numerous inquiries as to whether a form exists for the submission of the notice, FDA is providing a model form in Appendix I of this document, along with instructions for completing it in Appendix II of this document. This model form may be used by firms to claim exemptions. FDA advises, however, that it is not necessary to use this form.

The agency also advises that the small business exemption for a food product will be in effect once a notice has been filed with FDA, even though it may be necessary for the Office of Food Labeling to work with the firm that is filing the notice to address deficiencies in it. Although no action by the agency is required, FDA will attempt to review all notices to ensure that they are complete and to notify companies of the receipt of the notice, and whether additional information needs to be submitted.

FDA is initiating the steps necessary to obtain approval from the Office of Management and Budget (OMB) for printing and distribution of the ''model form'' as an official Government form. OMB approval is required under provisions of the Paperwork Reduction Act of 1995.

17. One comment stated that the section of the notice requesting information on the manufacturer of a product, if it is other than the person claiming the exemption, is irrelevant and should not be required. The comment stated that adding irrelevant information increases the paperwork burden, forces companies to give the Government unnecessary information, and enlarges the scope of the 1993 amendments. The comment suggested that FDA may be asking for the name of the manufacturer because it hopes to exclude from the small business exemption small companies that have product made by a copacker.

The 1993 amendments require that the firm filing a notice provide information on the total number of units that it sold in the United States in the preceding year. As a number of comments stated, and as FDA agrees, a firm can only be held responsible for knowing, and reporting, the number of units that it sold, not the total number of units of a product sold in the United States by all firms that might sell the product. However, as noted above in response to comment 5 in section II.D. of this document, whether a food product is eligible for exemption under the 1993 amendments depends not on the total number of units sold in the United States by the firm claiming the exemption, but it depends on the total number of units sold in the United States by all firms that sold the food product. In the case of a manufacturer or exclusive sales agent, the total number of units sold in the United States may well be the number reported by the firm claiming the exemption. In the case of an own-label distributor, the total number of units sold in the United States may include sales by firms other than the firm claiming the exemption.

FDA has included space in the model form for the listing of the manufacturer, if it is not the person submitting the notice, to enable the agency, if necessary, to identify instances in which the total number of units of a food product sold in the United States might exceed the applicable number for eligibility for exemption under the 1993 amendments. FDA seeks this information not to unfairly harass small businesses, but to ensure that there is a level playing field so that firms are not at a competitive disadvantage. Equally importantly, FDA is seeking the information to ensure that consumers have access to nutritional information on products when they have a right to it.

In its discussion with firms that were preparing notices to claim exemption under the 1993 amendments, FDA has become aware that firms may not always know the identity of the manufacturer of the product, particularly if it is an imported product. If this is the case, FDA is asking the person that submits a notice under the 1993 amendments to identify the firm from which they received the product if he or she is unaware of the identity of the manufacturer of the product.

18. Some comments stated that FDA should allow additional time for firms to submit the notice claiming the exemption. One comment suggested 6 months in view of the short time span between the publication of the proposal and the May 7, 1994, filing date for notices. One comment raised a concern about the requirement that notices be filed by May 7th of each year and the attendant lack of flexibility. Another comment stated that no firm should have to refile for exemption before May 8, 1995.

These comments seem to be based on a belief that FDA has more flexibility in the establishment of the date for filing of the notice claiming an exemption than is actually provided by the 1993 amendments. Most of the concerns raised by these comments have become moot with the passage of time. The concern about the inflexibility of the May 7 date for the submission of notices apparently arose from the agency's statement in the preamble that ''[A]ll notices must be filed by May 7, 1994, for the 12-month period beginning May 8, 1994, the date that the new mandatory labeling regulations become effective'' (59 FR 11872 at 11876). FDA advises that the May 7, 1994, date derives directly from section 403(q)(5)(E)(iii) of the act, which requires that the notice claiming exemption under the 1993 amendments be submitted ''prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect.'' Thus, May 7 was established as the date for submitting the claim for exemption for the 12-month periods beginning May 8th of 1994, 1995, or 1996. The agency has no authority to change this requirement.

FDA notes that a person is not restricted to the May 7 date for the submission of a notice claiming an exemption under the provisions of section 403(q)(5)(E)(i) of the act. Such a notice may be submitted on any date as long as it is submitted before the beginning of the period during which the exemption is to be in effect.

19. Two comments stated that it should be permissible to submit a claim for an exemption within a reasonable time after the marketing of a new food product has begun.

As noted above, a food is misbranded if it does not bear nutrition labeling and is not exempt under one of the exemptions provided by the 1990 and the 1993 amendments. Because the exemption for a firm's low-volume food products provided by the 1993 amendments is not in effect until the firm has submitted a notice to FDA claiming the exemption (with the exception of firms other than importers that have less than 10 employees and do not sell more than 10,000 units of the

particular food product), a low-volume food product from a small business would be misbranded if marketed without nutrition labeling before the notice claiming exemption has been submitted.

The 1993 amendments do not give FDA the authority to provide for a reasonable time after a product has been marketed for the submission of a notice claiming an exemption under the 1993 amendments. If a firm begins marketing a product without nutrition labeling before submitting such a notice, the product is subject to regulatory action. As noted above, FDA supplies its field personnel and State enforcement agencies with a listing of all firms that have filed notice for exemption under the 1993 amendments. Firms that wait to submit a notice until after they have begun marketing a product run the risk of regulatory action because their name does not appear on that list.

FDA recognizes that many small businesses may not have adequate resources to be aware of all of the requirements for nutrition labeling on their products or for claiming an exemption. Thus, during the past year, FDA has exercised discretion and restraint with respect to firms that have marketed products before having filed the necessary notice claiming exemption. While the agency intends to continue to exercise such restraint, the agency urges firms that expect to market a food product that will not bear nutrition labeling because it is exempt under section 403(q)(5)(E) of the act to notify the agency of this fact before marketing the product.

20. In the small business exemption proposal, FDA described generally the approach that it intended to take to review and verify the various notices that it received from small businesses claiming the exemption for low-volume food products (59 FR 11872 at 11876). The agency asked for comments on this general approach, stating that it might provide in the final rule specific requirements for the verification of notices, including a provision for inspection.

Several comments asked that FDA clarify how it would verify the appropriateness of notices claiming an exemption under the 1993 amendments. Most of these comments stated that a firm should be able to supply the necessary verification by mail. Several comments expressed their belief that no additional recordkeeping requirements should be imposed.

In its review of the approximately 13,000 notices that it has received since enactment of the 1993 amendments, FDA has attempted to follow the general approach to reviewing and verifying notices that it outlined in the proposal. The agency has considered notices to be acceptable, regardless of their format or approach, as long as they supplied the basic information, that is, the name and address of the firm claiming the exemption, an estimate of the number of employees, a listing of the products for which exemption was claimed, including brand names, and the approximate number of units of each of those products sold by the firm in the United States. Although the 1993 amendments do not require review and approval of the claim by FDA for the exemption to be in effect, FDA is briefly reviewing each notice. This review is directed at four areas: (1) Did the notice provide an estimate of the number of employees; (2) did the notice provide the identity of the specific food products for which an exemption was claimed; (3) did the notice provide the approximate number of units of each food product that the firm sold in the United States in the 12 months preceding the period for the exemption; and, (4) based on the information in the notice, did the product appear to be a low-volume food product (e.g., were total annual sales in the United States between May 8, 1993, and May 7, 1994, less than 600,000 units)?

In its review, FDA has used a flexible approach to resolve questions concerning the information contained in the notices. In the first year, for approximately 90 percent of the notices, FDA found the information in the notice itself to be adequate to justify the claimed exemption. In the remainder, where questions arose concerning the notices, FDA used two approaches for resolving questions. If the notice raised a fairly straight-forward question, such as the number of employees because the number was not included in the notice, the agency called the firm by telephone if a telephone number was available and asked that the firm supply the missing information, either over the telephone or by mail. For more complex questions, such as whether the notice included products that did not qualify as low-volume food products, e.g., it listed products bearing brand names for large national corporations, the agency contacted the firm either by telephone or by letter and requested that the firm modify its notice to include only those products that qualified as low-volume food products based on total sales in the United States.

As noted above, the agency found it necessary during the first year under the provisions of the 1993 amendments to ask for verification or additional information for only a small percentage of the notices submitted. Based on its experience to date, FDA finds that there is no need to provide specific requirements in the final rule for the verification of notices. As was stated in the small business exemption proposal, companies should be prepared to provide information to FDA to support their notices of exemption should FDA question the validity of any information contained in those notices (59 FR 11872 at 11876).

21. A number of comments disagreed with the preamble discussion that the 1993 amendments provide FDA access to firms' records for verification of exemption notices and emphasized that FDA should not use the 1993 amendments as a basis for gaining unintended access to records.

Section 403(q)(5)(E)(iii)(IV) of the act provides that the notice shall contain such information as the Secretary of Health and Human Services (the Secretary) may require to verify the information that is required to be in the notice if the Secretary has questioned the validity of such information. In the preamble to the small business exemption proposal, FDA stated that it might provide in the final rule that companies claiming the exemption will be required to permit inspection of supporting documentation. Because it has not had sufficient experience to have developed a clear view of what such an approach would involve, FDA is not including a requirement concerning inspection of records in the regulations set forth below.

Although FDA continues to hold that the use of an inspection is an appropriate means for obtaining verification information, it agrees that section 403(q)(5)(E)(iii)(IV) of the act does not give it free access to all records of a firm. There must be some question about the validity of information in a notice claiming an exemption under section 403(q)(5)(E) of the act for the agency to obtain such access. Secondly, the information sought must have a nexus to: (1) The number of employees of the firm, (2) the number of units of product sold in the United States, and (3) proof that the product is a low-volume food product. Any other review of records is not authorized by the 1993 amendments.

The agency will normally first try to verify the validity of the information, or otherwise resolve the question that arises, by telephone or mail. However, contrary to the assertion of some comments, there is nothing in the 1993 amendments that prohibits FDA from obtaining through inspection the information necessary to verify the validity of information in a notice. It is

FDA's intent only to use an inspection to obtain verifying information if it is the way that is most likely to produce the information necessary to verify the validity of the notice. FDA has yet to resort to inspection of records as an approach to verifying the information in a notice.

22. Several comments stated that the proposed verification process appeared to be burdensome. Some comments stated that any question concerning eligibility could be promptly and efficiently addressed by requesting written verifying information. The comments noted that the 1993 amendments contemplate that firms will be entitled to the exemption simply by claiming it, absent an FDA request for supporting documentation. The comments stated that, if there is a need for supporting documentation to resolve doubt about the propriety of the claimed exemption, FDA may simply demand that the information be provided, or else the exemption will be revoked.

These comments are mistaken in their concern that the proposed verification process is overly burdensome. However, as noted above, until it has more experience in what is necessary to verify the validity of a notice, FDA is not revising the regulations to specify how it will verify the accuracy of notices, or what information is necessary for such verification. As noted above, the agency found it necessary during the first year to ask for verification or additional information for only a small percentage of the notices submitted. FDA agrees with the various comments that supplemental information to verify the validity of a notice should be limited to that information that is already maintained by the firm and should not require the development of new records.

23. A number of comments addressed the requirement for a certification statement as part of the notice. One comment stated that the requirement was burdensome because it would impose business costs and legal liability not contemplated by Congress and not provided for by the amendments. Another comment stated that the certification requirement should be deleted, noting a number of factors that mitigate against the need for the certification statement, including the fact that FDA can request verification, that anybody providing false information commits a punishable criminal offense, and that FDA can declare the product misbranded. One comment stated that a firm should not be put in the position of having to certify that second-hand information, such as the amount of production of a copacker, that it cannot verify, is true and accurate. One comment stated that the certification requirement should be eliminated, particularly the part about notifying FDA when it becomes ineligible, because it exceeds statutory authority provided by the amendments, is contrary to congressional intent, and imposes burdens on small businesses. One comment stated that FDA should clarify that a company would only be at risk of criminal prosecution if it had intentionally and knowingly provided false information.

FDA included the certification statement as a requirement of the notice claiming an exemption under the 1993 amendments as a confirmation to the agency of the expected; that is, that the information being submitted to the agency complied with the requirements of 18 U.S.C. 1001 and contained only valid information. FDA disagrees with the comments that this requirement creates additional liabilities for the firms or is burdensome. Most comments were aware of 18 U.S.C. 1001 and the prohibition that it contains on the submission of false information to a Government agency. This prohibition exists regardless of whether a notice contains a signed certification from the firm.

Moreover, the certification statement serves as the initial verification of the validity of the information in a notice. As evidenced by the tone of some of the comments, firms will take greater care to ensure the validity of the information in a notice if a responsible individual has to certify to the accuracy of the information. FDA notes that some of the forms that it has received that were devised by firms and associations contain more expansive certification statements than that proposed by FDA. Some of these certifications, for example, contained a statement that there was no nutrition information or claims on the label for any of the products included in the notice.

FDA notes that the greatest concern seems to be over the requirement that a firm notify FDA when a product is no longer eligible for the exemption. FDA included this commitment as part of the certification requirement to ensure that the firm is aware of the provision in the 1993 amendments that the firm has 18 months after its product no longer qualifies for the exemption to bring the label into compliance. The requirement that a firm notify FDA if it becomes ineligible for the exemption is thus fully consistent with the act and the agency's authority to adopt regulations for its efficient enforcement. (See section 701(a) of the act.)

The agency emphasizes that it is asking firms to certify the accuracy of the information that they are submitting as it relates to the operations of their firm only. This information should be readily available to the firm in records maintained during the normal course of its business. Contrary to what was stated by one comment, FDA is not asking a firm to certify to information unknown to it such as the volume of sales of a copacker that produces product for the firm.

24. One comment stated that FDA should take pains to explain its plans for protecting confidential business information included in notices.

FDA advises that any trade secret or confidential commercial information submitted in notices is protected by the safeguards against inappropriate release that are provided by the agency's regulations in part 20 (21 CFR part 20) for the release of information under the Freedom of Information Act.

H. Miscellaneous Issues

25. One comment stated that FDA should not single out imports for enforcement of noncompliance.

FDA advises that it has been acting to ensure that there is compliance with the new labeling regulations in as evenhanded a manner as possible with respect to both foreign and domestic firms. The agency initiated its enforcement efforts for domestic products on August 8, 1994, the date after which the nutrition labeling and nutrient content claim requirements of the act became applicable (see Pub. L. 103–261, enacted May 26, 1994). FDA initiated its import enforcement efforts on September 19, 1994. The approach that the agency's district offices take when they encounter a noncompliant label is similar for both domestic product and imported products. Copies of the agency's domestic and import enforcement assignments explaining the approaches being taken have been placed on public display under this docket number.

26. One comment stated that FDA's proposal places too much emphasis on enforcement, and that FDA should maintain a flexible enforcement policy; e.g., a small company whose notice is deficient (or which is found to exceed a ceiling) should be given a complete written explanation of the deficiency and a reasonable time to submit a compliance plan.

FDA has been maintaining a flexible, lenient enforcement policy, particularly as regards companies whose notice is found to be deficient. The first step that the agency takes upon receipt of a notice is to place the name and address of the firm in its computer data base of firms that have filed a notice and to make that

information available to its field offices by entering the information into the PRIME Connection and FIARS computer bulletin boards. As noted above, the agency next issues a letter acknowledging the receipt of the notice, unless it has a question concerning the information in the notice. If there is a deficiency in the information in the notice, or the agency has some other question concerning it, the agency either calls or writes the firm to ask for clarification of the information. During this time, the name and address of the firm remain on the listing of firms that have submitted a notice claiming exemption under the 1993 amendments.

27. One comment stated that the agency should adopt specific procedures to maintain a list of exempt firms and provide effective means of disseminating the list to districts. This action should be taken, the comment said, to minimize the possibility of needless detention of products for which an exemption has been filed. A foreign firm also commented that FDA should adopt a policy that would permit the manufacturer or its importer to include a statement on the particular import documents that it has filed for a particular exemption, and that such a statement should bar the district from detaining the imported product.

Before launching its enforcement efforts for domestic and imported products, FDA developed a computerized data base listing the firms that have submitted a notice claiming an exemption under the 1993 amendments by name and address. As stated above, FDA made this data base available to its district offices and to State enforcement agencies through an FDA computer bulletin board system called ''PRIME Connection.'' A similar data base listing the names and addresses of foreign firms and recognized importers that filed a notice to claim an exemption for their products was made available to FDA's import offices under FDA's FIARS system. FDA has periodically updated these lists since they were established. Additionally, FDA advises that it has recommended that, and has permitted, statements that a particular product qualifies for an exemption under the 1993 amendments be included in the shipping records for an imported product. The presence of such additional information with the shipping records is considered by FDA in determining whether to release a particular import. Because each import must be considered on a case-by-case basis, however, the presence of such a statement will not serve as a de facto bar to detention.

28. Several comments suggested steps that the agency should take to permit the continued use by small businesses of nutrition labeling in compliance with FDA's former provisions for the voluntary nutrition labeling of food. Most of these comments supported the use of § 101.9(g)(9) for small businesses to request, and FDA to grant, alternative approaches that would enable them to use up labeling that used the former type of nutrient labeling. Some comments suggested that FDA should extend the exemption of the 1993 amendments in the proposed regulation for low-volume food products to cover such products.

Other comments stated that FDA should consider establishing a special rule permitting labels with pre-1990 amendments nutrition information to be used by processors that otherwise would qualify for the small business exemption. One comment noted that if it is barred from using labels bearing pre-1990 amendments nutrition information, it will be required to bear an economic loss for these label stocks, which would be extreme for a company of its size. Other comments noted that denying an extension to firms that had voluntarily cooperated in the past would be unjust. Some comments suggested that limits be created on the use of such pre-1990 amendments labeling; e.g., a certification that the labeling was purchased before January 6, 1993, and that compliance with the new requirements will be achieved by the end of the extension period or the next printing whichever comes first; that there are no claims; that there is no competitive advantage from improper listing of serving sizes, calories from fat, saturated fat, cholesterol, and sodium; and that the product was not introduced into the marketplace since the new nutrition labeling regulations were issued (since January 6, 1993).

Since issuance of the small business exemption proposal, FDA has received a number of requests for permission under § 101.9(g)(9) to exhaust inventories of labels containing nutrition information that was in compliance with FDA's regulations that were in effect before the effective date of the 1990 amendments. FDA has required that these requests contain information showing that the firm and the product would be eligible for exemption under the provisions of the 1993 amendments but for the fact that the product's label bears the former nutrition labeling. FDA has also asked that the requests include a copy of the label for each product for which permission was being sought to exhaust the old label, along with an estimate of the remaining inventory of the label stocks and the estimated time required to exhaust the inventory.

Within its limited resources, FDA has reviewed and granted permission to firms to exhaust labels that contain only the former voluntary nutrition information. In granting permission to exhaust inventories of labeling by a specific date, FDA has advised the firms that the label for the product is to be corrected by either removing the old nutrition information or bringing the label into compliance with new § 101.9. FDA has advised firms requesting permission to continue the use of labels containing nutrient content or health claims that such permission would not be granted.

The process provided by § 101.9(g)(9) appears to be adequate to address the issue of granting permission to small businesses to exhaust their stocks of old labeling. Also, FDA notes that it is using most of the ''limits'' suggested by the one comment in evaluating requests for additional time to exhaust inventories of labels under § 101.9(g)(9). However, the suggested limits on granting permission to exhaust labels printed after January 6, 1993, or for products introduced after January 6, 1993, have largely been rendered moot by the passage of time. Thus, FDA concludes that a special rule permitting labels with pre-1990 amendments nutrition information is unnecessary. Also, FDA advises that it does not have authority to extend the exemption provided by the 1993 amendments to cover products bearing pre-1990 amendment nutrition information. Such products are specifically excluded from the exemption by section 403(q)(5)(E(i)(2) and (ii) of the 1993 amendments.

III. Economic Impact

FDA has examined the impacts of this final rule as required by 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 effects; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief for small businesses.

The agency reported in the small business exemption proposal its finding that the net effect of this rule is the benefit that it creates by reducing labeling costs for exempted companies. This benefit is the result of statutory provisions and not FDA discretion.

There are two types of costs of this regulation: (1) Costs of lost nutrition benefits because nutrition information is not available and (2) costs to comply with the notification requirement.

FDA has estimated that the volume of food product eligible for exemption constitutes less than one percent of the United States diet, and that any lost nutrition benefits are likely to be small. Also, the agency estimated that in the first year approximately 4,500 firms claiming exemption would file notices at a cost of approximately $1,656,000. The agency estimated that in the following 2 years the number of firms filing notices would reduce to approximately 4,000 at a cost of approximately $1,472,640 and approximately 3,200 at a cost of approximately $1,177,640, respectively. However, in the first year that the 1993 amendments have been in effect, the agency has received approximately 9,000 notices claiming an exemption for one or more low-volume food products. Assuming that the number of firms filing an exemption will decrease for the next 2 years at the same rate as previously estimated, then the costs to comply with the notification requirements are estimated to be approximately $3,312,000 the first year, approximately $2,947,000 the second year, and approximately $2,358,000 in subsequent years as the number of firms filing notices decreases. Federal costs for implementing the notification system are estimated (as in the proposal) to be approximately $207,000. The total costs of notification will be less than $4 million for the first year and decrease substantially in subsequent years.

On the other hand, FDA estimates that the cost savings to small businesses that were exempted from labeling to be between $275 and $360 million. These costs are estimated based on the Regulatory Impact Analysis (RIA) (58 FR 2927, January 6, 1993) done for rules implementing the 1990 amendments. In the RIA, FDA estimated relabeling costs of approximately $3,000 per stock keeping unit (SKU). This rule is expected to save costs for between 90,000 and 120,000 SKU's. Because of this positive effect on the economy, this rule is economically significant under Executive Order 12866, but because the rule will not have any adverse effect on small business, the agency believes that, under the Regulatory Flexibility Act, the rule will not have a significant impact on a substantial number of small entities. However,the preceding discussion of the costs and cost savings to small business would constitute a final regulatory flexibility analysis under the Regulatory Flexibility Act.

None of the comments to the small business exemption proposal presented any information, nor is the agency aware of any information, that would serve as a basis for significantly increasing the estimated costs of this regulation or significantly decreasing the estimated cost savings.

IV. Congressional Review

This final rule has been classified as a major rule subject to congressional review. The effective date is October 7, 1996. If, however, at the conclusion of the congressional review process the effective date has been changed, FDA will publish a document in the Federal Register to establish the actual effective date or to issue a notice of termination of the final rule action.

V. Environmental Impact

The agency has previously considered the environmental effects of the action being taken in this final rule. As announced in the small business exemption proposal published in the Federal Register of March 14, 1994 (59 FR 11872), the agency has determined under 21 CFR 25.24(a)(8) and (a)(11) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. No comments questioned this determination. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act

This final rule contains information collections that are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). This information collection has been approved by OMB for 90 days, under 5 CFR 1320.13 and OMB control No. 0910–0324. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Because OMB approval of this information collection is valid for only 90 days, FDA is also taking the appropriate steps to obtain a regular approval. Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). In accordance with 5 CFR part 1320, the title, description, and respondent description of the information requirement are shown below with an estimate of the annual collection and information burden. Included in the estimate is the time for reviewing instructions, gathering necessary information, and completion and submission of the notice.

Title: Food Labeling; Nutrition Labeling, Small Business Exemption.

Description: The final rule provides the procedures for the submission of a notice of a claim by a company for an exemption from FDA's regulations for mandatory nutrition labeling. FDA action on the notice will include review of notices for completeness and acknowledgment that the notice had been received and was or was not adequate. Additionally, FDA will provide to its field personnel and State enforcement agencies a listing of firms that have submitted a notice to FDA along with a listing of the products claimed to be exempt.

The 1993 amendments revise the basis for a small business exemption provided by section 403(q)(5)(E) of the act. This new provision provides an exemption for a food product based on the number of employees and the total number of units sold in the United States on an annual basis. Under the 1993 amendments, to qualify for an exemption, a person must file the notice mentioned in the preceding paragraph with FDA before the time period for the claimed exemption. Sections 101.9(j)(18)(iv) and 101.36(f)(2) reflect the information identified in section 403(q)(5)(E) of the act, as necessary, as part of the notice for a claimed small business exemption.

Descriptions of Respondents: Persons and small businesses, particularly small businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section	Annual number of respondents	Annual frequency	Average burden hours per response	Annual burden hours	Total annual operating and maintenance costs
101.9 and 101.36	10,000	1	8	80,000	$3,312,000

Since enactment of the 1993 amendments, FDA has received notices from approximately 9,000 firms. Although FDA is uncertain how many other firms may take advantage of the exemption provided by the 1993 amendments to file notice, it expects a maximum of 10,000 respondents to file for the exemption. The agency expects that the number of respondents and corresponding annual burden hours will decrease over succeeding years as the basis for the exemption changes. By May 1997, FDA estimates that approximately 5,000 companies may be filing notices to claim the exemption with a corresponding annual burden hours of approximately 40,000 hours. There are no capital costs created by this final rule. As noted above in section III. Economic Impact, FDA estimates that the total operating and maintenance costs to respondents to submit notices to the agency during the first year to be approximately $3,312,000. The agency does not believe that this regulation requires any capital expenditures to comply with the requirements for submitting a notice.

In the small business exemption proposal, FDA requested comments regarding the estimated burden, including suggestions for reducing the burden. Nine responses were received that contained one or more comments concerning the information collection provisions that would be established by the small business exemption proposal. A number of these comments suggested modifications in, or were opposed to, various provisions of the information collection portion of the small business exemption proposal. A summary of the arguments and changes suggested by these latter comments, and the agency's responses, are provided above. None of the comments addressed FDA's estimates of the cost and hour burden associated with the information collection.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted copies of the final rule to OMB for its review of the recordkeeping requirements. In addition, the agency solicits public comment on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection, techniques, or other forms of information technology (e.g., permitting electronic submission of responses).

Individuals and organizations may submit comments on the information collection requirements of this final rule by October 7, 1996. These comments should be submitted to the Dockets Management Branch (address above).

Under the Paperwork Reduction Act of 1995, persons are not required to respond to a collection of information unless it displays a currently valid OMB control number. This final rule contains information collection requirements that have been submitted to OMB for approval. FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection requirements established in this final rule prior to the effective date of such requirements.

FDA advises that the statutory requirements of the 1993 amendments for the filing of a notice with FDA take precedence over the provisions of the Paperwork Reduction Act of 1995. Thus, if small businesses desire to avail themselves of the exemption from nutrition labeling that is provided by the 1993 amendments, they must file notice with FDA as required by section 403(q)(5)(e)(i)(III) or (q)(5)(e)(ii) of the act. Products that are not the subject of such notice will be misbranded unless they bear nutrition labeling as required by section 403(q) of the act regardless of whether OMB has approved the information requirements included in this final rule.

List of Subjects in 21 CFR Part 101

Food labeling, 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, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues 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, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.9 is amended by revising paragraph (j)(1)(i) and by adding new paragraph (j)(18) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(j) * * *

(1)(i) Food offered for sale by a person who makes direct sales to consumers (e.g., a retailer) who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section.

* * * * *

(18) Food products that are low-volume (that is, they meet the requirements for units sold in paragraphs (j)(18)(i) or (j)(18)(ii) of this section); that, except as provided in paragraph (j)(18)(iv) of this section, are the subject of a claim for an exemption that provides the information required under paragraph (j)(18)(iv) of this section, that is filed before the beginning of the time period for which the exemption is claimed, and that is filed by a person, whether it is the manufacturer, packer, or distributor, that qualifies to claim the exemption under the requirements for average full-time equivalent employees in paragraphs (j)(18)(i) or (j)(18)(ii) of this section; and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim.

(i) For food products first introduced into interstate commerce before May 8, 1994, the product shall be exempt for the period:

(A) Between May 8, 1995, and May 7, 1996, if, for the period between May 8, 1994, and May 7, 1995, the person claiming the exemption employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of that product were sold in the United States; and

(B) Between May 8, 1996, and May 7, 1997, if for the period between May 8, 1995, and May 7, 1996, the person claiming the exemption employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of that product were sold in the United States.

(ii) For all other food products, the product shall be eligible for an exemption for any 12-month period if, for the preceding 12 months, the person claiming the exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product were sold in the United States, or in the case of a food product that was not sold in the 12-month period preceding the period

for which exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which exemption is claimed.

(iii) If a person claims an exemption under paragraphs (j)(18)(i) or (j)(18)(ii) of this section for a food product and then, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the appropriate number, or the number of food products sold in the United States exceeds the appropriate number, or, if at the end of the period of such exemption, the food product no longer qualifies for an exemption under the provisions of paragraphs (j)(18)(i) or (j)(18)(ii) of this section, such person shall have 18 months from the date that the product was no longer qualified as a low-volume product of a small business to comply with this section.

(iv) A notice shall be filed with the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204 and contain the following information, except that if the person is not an importer and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units:

(A) Name and address of person requesting exemption. This should include a telephone number or FAX number that can be used to contact the person along with the name of a specific contact;

(B) Names of the food products (including the various brand names) for which exemption is claimed;

(C) Name and address of the manufacturer, distributor, or importer of the food product for which an exemption is claimed, if different than the person that is claiming the exemption;

(D) The number of full-time equivalent employees. Provide the average number of full-time equivalent individuals employed by the person and its affiliates for the 12 months preceding the period for which a small business exemption is claimed for a product. The average number of full-time equivalent employees is to be determined by dividing the total number of hours of salary or wages paid to employees of the person and its affiliates by the number of hours of work in a year, 2,080 hours (i.e., 40 hours×52 weeks);

(E) Approximate total number of units of the food product sold by the person in the United States in the 12-month period preceding that for which a small business exemption is claimed. Provide the approximate total number of units sold, or expected to be sold, in a 12-month period for each product for which an exemption is claimed. For products that have been in production for 1 year or more prior to the period for which exemption is claimed, the 12-month period is the period immediately preceding the period for which an exemption is claimed. For other products, the 12-month period is the period for which an exemption is claimed; and

(F) The notice shall be signed by a responsible individual for the person who can certify the accuracy of the information presented in the notice. The individual shall certify that the information contained in the notice is a complete and accurate statement of the average number of full-time equivalent employees of this person and its affiliates and of the number of units of the product for which an exemption is claimed sold by the person. The individual shall also state that should the average number of full-time equivalent employees or the number of units of food products sold in the United States by the person exceed the applicable numbers for the time period for which exemption is claimed, the person will notify FDA of that fact and the date on which the number of employees or the number of products sold exceeded the standard.

(v) FDA may by regulation lower the employee or units of food products requirements of paragraph (j)(18)(ii) of this section for any food product first introduced into interstate commerce after May 8, 2002, if the agency determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to it.

(vi) For the purposes of this paragraph, the following definitions apply:

(A) *Unit* means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers.

(B) *Food product* means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods.

(C) *Person* means all domestic and foreign affiliates, as defined in 13 CFR 121.401, of the corporation, in the case of a corporation, and all affiliates, as defined in 13 CFR 121.401, of a firm or other entity, when referring to a firm or other entity that is not a corporation.

(D) *Full-time equivalent employee* means all individuals employed by the person claiming the exemption. This number shall be determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in a year, 2,080 hours (i.e., 40 hours×52 weeks).

3. Section 101.36 is amended by revising paragraph (f) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements of vitamins and minerals.

* * * * *

(f) Dietary supplements are subject to the exemptions specified as follows in:

(1) Section 101.9(j)(1) for dietary supplements that are offered for sale by a person who makes direct sales to consumers (i.e., a retailer) who has annual gross sales or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim; or

(2) Section 101.9(j)(18) for dietary supplements that are low-volume products (that is, they meet the requirements for units sold in § 101.9(j)(18)(i) or (j)(18)(ii)); that, except as provided in § 101.9(j)(18)(iv), are the subject of a claim for an exemption that provides the information required under § 101.9(j)(18)(iv); that is filed before the beginning of the time period for which the exemption is claimed; and that is filed by a person that qualifies to claim the exemption under the requirements for average full-time equivalent employees in § 101.9(j)(18)(i) or (j)(18)(ii); and whose labels, labeling, or advertising do not provide nutrition information or make a nutrient content or health claim.

* * * * *

Dated: April 4, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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

Appendix I—Model Small Business Food

Labeling Exemption Notice

(Please type or clearly print)

1. Name of firm

_____

2. Address of firm:

Street address _____

_____

City State _____

Zip or postal code _____

Country _____

Telephone _____
FAX _____

3. Type of firm (Check all that apply)

Manufacturer _____
Packer/Repacker _____
Distributor _____
Importer _____
Retailer _____

4. Twelve-month time period for which you are claiming exemption

FROM: ____ / ____ / ____
MM DD YY

TO: ____ / ____ / ____
MM DD YY

5. Average number of full-time equivalent employees for 12-month period_____

6. Report of units sold (use continuation sheets if necessary)

Product

_____
_____
_____
_____

No. of units

_____
_____
_____
_____

Manufacturer

_____
_____
_____
_____

7. Name and address of manufacturer(s) or distributor(s) of product(s) in Item 6 if different from firm claiming exemption. (Use continuation sheets if necessary.)

B Name of manufacturer or distributor

_____

Address _____

_____

C Name of manufacturer or distributor

Address _____

_____

8. Contact person

_____

9. The undersigned certifies that the above information is a true and accurate representation of the operations of _____ (Name of firm). The undersigned will notify the Office of Food Labeling of the date on which the average number of full-time equivalent employees or the number of units of food products sold in the United States exceeds the applicable number for exemption which is being claimed herein.

Signature _____
Name (Type or clearly print) _____

_____

Title _____
Date _____

Appendix II—Model Small Business Food

Labeling Exemption Notice

Instructions for completion

(Please type or clearly print)

1. Name of firm: Enter the recognized legal name of your firm.

2. Firm address: Enter the mailing address for the principal location of your firm. Also, provide the telephone and FAX numbers.

3. Type of firm: Place a check mark or ''x'' in each block that is applicable to your firm. For example, if your firm manufactures all products that it sells place a check mark after ''Manufacturer.'' If your firm also distributes a product that is manufactured by another firm, also place a check mark after ''Distributor.''

4. Twelve-month time period for which you are claiming exemption: Enter the specific time period for which you are requesting exemption for your products. For products initially introduced into interstate commerce before May 8, 1994, this time period will be from May 8 of the current year to May 7 of next year: e.g., ''FROM 05/08/95 TO 05/07/96.'' For new products, the time period should start with the date on which sales in the United States are expected to begin: e.g., ''FROM 11/01//95 TO 10/31/96.''

5. Average number of full-time equivalent employees for 12-month period: Enter the average number of full-time equivalent employees of your firm and of all of its affiliates for the year preceding the year for which an exemption is claimed under Item 4. The average number should include all employees of your firm and of its affiliates (e.g., owners; officers; and all other personnel such as secretarial, production, and distribution employees). Firms are affiliates of each other when, either directly or indirectly: (1) One firm has the power to control the other, (2) a third party controls or has the power to control both, or (3) an identity of interest exists such that affiliation may be found.

The average number of full-time equivalent employees is to be determined by using the following formula: Total number of employee/hours paid divided by 2,080 hours = average number of full-time equivalent employees. For example, 254,998 paid employee/hours ÷ 2,080 = 122. If the total number of actual employees for your firm and its affiliates is less than 100, you may enter the total number of actual employees instead of calculating the average number of full-time employees; e.g., if your firm has 24 employees that work full-time and 12 employees that work part-time, you may report 36 total actual employees instead of calculating the average number of full-time equivalent employees.

6. Report of units sold (Continuation sheets using the same format for Item 6 may be used if necessary):

Product: Under the column for product, enter the name, including the brand name, for each food product for which your firm is claiming an exemption. A food product is a food in any sized package which is manufactured by a single manufacturer or which bears the same brand name; which bears the same statement of identity; and which has a similar preparation method. In considering whether food products have similar preparation methods, consider all steps that go into the preparation of the food products, from the initial formulation steps to any finishing steps; for example, products having differing ingredients would be considered different food products and counted separately in determining the number of units.

No. of Units: Provide the approximate sales of your firm, in terms of units, for the product for the year immediately preceding the time period for the exemption entered under Item 4. For example, if the time period for which you are claiming exemption for a food product is May 8, 1996, to May 7, 1997, provide an approximation of your sales of that product from May 8, 1995, to May 7, 1996. If the product was not sold for the entire 12 months preceding the time period for the exemption entered under Item 4, provide an approximation of the sales expected to be made during the time period in Item 4. For example, if the time period being claimed in Item 4 is November 1, 1995, to October 31, 1996, for a product that is going to be sold beginning November 5, 1995, provide an approximation of sales for the period from November 1, 1995, to October 31, 1996.

The approximate total number of units is the summation of the number of units of the various package sizes of the food product in the form in which it is sold to consumers; for example, the total of all 2-pound bags of flour plus all 5-pound bags of flour plus all 10-pound bags of flour should be provided as the number of units sold by your firm in the United States. There may also be occasions where a food is sold in bulk or by individual pieces rather than in packaging; e.g., flour may be sold in bulk displays at grocery stores. In such a case, the number of units should be determined on the basis of the typical sales practice for the specific food product; e.g., if 2,000 pounds of flour are sold from bulk displays at grocery stores, and the typical practice for sales to consumers is to price the flour on a per pound basis, then the bulk sales would represent 2,000 units. If the firm sells the same product in package form, then the bulk sales, 2,000 units in the above example, should be added to the sum of the number of packages of the flour sold to determine the total number of units of flour sold by the firm in the United States.

Manufacturer: Under the column designated ''Manufacturer'' enter the letter that corresponds with the name of the manufacturer of the product. The letter ''A'' is used to designate the firm submitting the notice if it is the manufacturer of the product. If the firm submitting the notice is not the manufacturer of the product, use the letter from Item 7 (B or C), or from the continuation sheets for Item 7, that corresponds to the name and address of the manufacturer of the product.

7. Name and address of manufacturer(s) or distributor(s) of product(s) in Item 6 if different from firm claiming exemption: Continuation sheets may be used if necessary. Provide the name and addresses of the manufacturers of the food products for which exemption is being claimed if they are different from the firm claiming the exemption. If the name of the manufacturer is unknown, provide the name of the firm from which the product is purchased. Insert the letter corresponding to the name of the manufacturer (''A'' corresponds to the firm submitting the notice) or distributor in the appropriate block for the name of the product under Item 6.

8. Contact person: Enter the name of a person that can act as a contact for your firm if any questions arise concerning the information included in the notice.

9. Certification: The form is to be signed by a responsible individual for the firm that can certify to the authenticity of the information presented on the form. The individual signing the form will commit to notify the Office of Food Labeling when the numbers of full-time equivalent employees or total numbers of units of products sold in the United States exceed the applicable number for an exemption.

The completed form should be mailed to: Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St., SW, Washington, DC 20204. Questions concerning a claim may be directed to the Office of Food Labeling at the above address or to 202–205–4561.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310 and 1313

[DEA–138F]

RIN 1117–AA32

Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Federal Food, Drug, and Cosmetic Act (FD&C Act)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to remove the exemption for certain products containing pseudoephedrine (which are lawfully marketed under the Federal Food, Drug, and Cosmetic Act) from the regulatory chemical control provisions of the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act. This rule finalizes a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on October 31, 1995 (60 FR 55348).

Due to the large scale utilization of over-the-counter (OTC) pseudoephedrine products for the clandestine manufacture of controlled substances, the DEA has determined that certain products should be subject to recordkeeping, reporting, registration and notification requirements of the CSA to prevent their diversion. Such products include OTC tablets, capsules and powder packets containing pseudoephedrine alone or in combination with antihistamines, guaifenesin or dextromethorphan. This action also reduces the threshold for pseudoephedrine to 48.0 grams pseudoephedrine base. Such a threshold is sufficient to permit the purchase of up to a 244 day supply of OTC pseudoephedrine drug products without the application of regulatory requirements. In addition, the cumulative threshold requirement for multiple transactions of pseudoephedrine drug products in a calendar month will not apply to sales for personal use. To further ensure the availability of pseudoephedrine products to legitimate consumers at the retail level, this action also waives the registration requirement for retail distributors of regulated pseudoephedrine products.

EFFECTIVE DATES: October 7, 1996. Persons seeking registration must apply on or before November 20, 1996, in order to continue to distribute, import or export pseudoephedrine products for which registration is required pending final action by the DEA on their application.

FOR FURTHER INFORMATION CONTACT: Howard McClain Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: On October 31, 1995, the DEA published a Notice of Proposed Rulemaking (NPRM) which proposed the removal of the exemption for certain over-the-counter (OTC) pseudoephedrine products from the chemical control provisions of the Controlled Substances Act (CSA). The NPRM documented the increasing problem of OTC product diversion for use as precursor material in the clandestine production of methamphetamine.

The clandestine manufacture and distribution of methamphetamine are serious national public health problems which require Federal action. Methamphetamine, a Schedule II Controlled Substance, is the most prevalent controlled substance clandestinely synthesized in the United States. Between January 1, 1994 and December 31, 1995, the DEA has been involved in the domestic seizure of 587 methamphetamine laboratories. Ephedrine and/or pseudoephedrine were utilized as the precursor material at the vast majority of these laboratories.

The significance of the abuse of methamphetamine is well known and documented. In recent years the problem has increased dramatically. In 1994. alone, there were over 700 methamphetamine related deaths in the United States.

The DEA monitors Medical Examiner (ME) data from approximately 42 medical examiners located in major cities in the contiguous 48 states. Nationally, ME reported deaths related to methamphetamine increased 145% from 1992 to 1994 and there were 1816 deaths for the period 1991 to 1994. In addition, methamphetamine emergency room episodes increased significantly in 1993 and 1994. Current data indicate the illicit production, distribution and abuse of methamphetamine remain a serious problem.

In addition, evidence of the illicit utilization of pseudoephedrine in clandestine laboratories is increasing. The identification of OTC pseudoephedrine products at clandestine methamphetamine laboratories increased dramatically in 1995.

The NPRM documented that pseudoephedrine was utilized in 22 percent of the laboratories seized from January 1, 1995 through September 1995. DEA thereby acted to place regulatory controls on these products in an effort to further minimize the availability of widely used precursor material and ultimately protect the public health. Since publication of the NPRM, the extent of diversion of OTC pseudoephedrine products has intensified in the United States. End of year data for 1995 indicates that at least 28 percent of the clandestine methamphetamine laboratories seized utilized pseudoephedrine.

In recent years, the diversion of OTC products has been the predominant source of precursor material for the clandestine synthesis of methamphetamine. As regulatory controls were implemented to counter the diversion of specific types of OTC products, clandestine laboratory operators have been successful in circumventing these controls to obtain precursor material through the diversion of millions of OTC dosage units of exempt products. The NPRM documents the progression of the diversion from bulk ephedrine, to single entity OTC ephedrine products, to OTC ephedrine combination products and OTC pseudoephedrine products.

As stated in the NPRM, since 1989 ephedrine has been the primary precursor used in the clandestine synthesis of methamphetamine in the United States. Clandestine laboratory operators exploited the lack of control on OTC ephedrine products (such as tablets/capsules) to purchase millions of dosage units for the synthesis of methamphetamine and methcathinone.