strategy and a contact official; notifying direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm; provide periodic status reports so FDA can assess the progress of the recall. The recall provisions provide the information necessary for FDA to monitor recalls and assess the adequacy of a firm's efforts in a recall. It also permits FDA to evaluate whether a recall has been completed in a manner which assures that unreasonable risk of substantial harm to the public health has been eliminated. The guidelines apply to all regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, cosmetics; and biological products intended for human use.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
7.42	1,712	4	6,848	1.8	12,326
7.46 and 7.49	1,712	4	6,848	4	27,392
7.53	1,712	4	6,848	36	246,528
7.55(b)	1,712	4	6,848	2	13,696
Total					299,942

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15339 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0424]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 9, 1998.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use (Form FDA 2253)

Under § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i)), sponsors of approved applications for marketed prescription drugs and antibiotic drugs for human use are required to submit specimens of promotional labeling and advertisements at the time of initial dissemination of the labeling and at the time of initial publication of the advertisements. Each submission is required to be accompanied by a completed transmittal Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use). Statutory authority for the collection of this information is provided by sections 505(a), (b), (j), and (k), 507(g), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), (j), and (k), 357 (g), and 371(a)).

Similarly, under § 601.12(f)(4) (21 CFR 601.12(f)(4)) (62 FR 39890, July 24, 1997; effective October 7, 1997), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i). Statutory authority for the collection of this information is provided by section 351 of the Public Health Service Act (42 U.S.C. 262), which gives FDA the responsibility to prescribe standards designed to ensure the safety, purity, potency, and effectiveness of biological products. In furtherance of this responsibility, FDA regulates advertising and labeling for biological products. Currently, specimens of advertising and promotional labeling are submitted to FDA with Form FDA 2567, a two-part transmittal form that is also used to transmit other forms of labeling (e.g., circulars, package labels, and container labels) for FDA review when a firm is requesting premarket approval of a product or proposing changes to product carton or container labeling.

FDA is revising Form FDA 2253 to enable it to be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The proposed revised form has the following major changes:

1. The revised, harmonized form will be used by sponsors of approved applications for marketed prescription drugs and antibiotic drugs regulated by the Center for Drug Evaluation and Research (CDER) who must submit specimens of advertisements and promotional labeling to the agency, and may be used by manufacturers of licensed biological products regulated by the Center for Biologics Evaluation and Research (CBER) who submit draft and/or final copies of promotional labeling and advertisements to the agency. Revising and harmonizing Form FDA 2253 will eliminate the need for sponsors to use two different forms to transmit similar materials for submission to the agency; however, manufacturers of biological products may continue to use Form FDA 2567 to transmit advertisements and promotional labeling if they wish. The other uses of Form FDA 2567 will remain unchanged.

2. The revised, harmonized form updates the information about the types

of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure that the submission is complete.

3. Currently, when more than one prescription drug product is promoted in the promotional labeling or in an advertisement, sponsors submit specimens of the promotional labeling or advertisement to the approved application for each product promoted in the promotional labeling or advertisement. The revised form, provides for sponsors to submit specimens of multi-product promotional labeling and advertisements to only two files; to the approved product application most frequently promoted, and to a company name file. This multi-product submission should cross-reference the other approved applications. The agency anticipates that the proposed revised form and revised submission will save sponsors time and money by eliminating the need for making multiple submissions and for maintaining dual inventories of both forms and multiple processing capabilities.

Under Executive Order 12866, FDA published a notice in the **Federal Register** of October 24, 1997 (62 FR 55408 through 55409), that announced an opportunity for public comment on a proposed revision of Form FDA 2253. Based on the five responses to FDA's proposal to streamline the submission of promotional labeling and advertisements via Form FDA 2253, none of the respondents objected to the agency revising the form, and two respondents had very favorable comments regarding the initiative to revise the form and streamline the submission process for multiple product submissions.

One respondent stated that it was unclear whose burden had been measured for the estimate and stated that information about methodology and assumptions was insufficient for it to comment. The agency noted in the October 24, 1997, notice that its estimate was based on contacts with industry representatives. The agency's estimate of 2 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, was obtained from an informal survey of current respondents who were asked how long it took them to prepare and submit data and materials intended to accompany Form FDA 2253. The comment did not provide an alternative estimate for the proposed burden hours. The agency's estimate, thus, will remain the same. No other comment provided an alternative estimate.

Several respondents commented on the physical layout of the form and suggested that some parts of the form be made larger or smaller. The agency agrees with some of these suggestions and will modify the layout of the form. In the section of the form that describes various submitted promotional items, some respondents suggested different descriptions for types of promotional materials (such as replace the proposed term ''profession journal ad'' with ''profession print advertisements''), and suggested combining various similar types of materials with the addition and deletion of specific promotional items. The agency agrees that the consolidation of material types will make the form easier to understand and plans to make these modifications.

Two respondents questioned whether it was necessary to identify the submission preparer, and whether it was necessary for the ''responsible official'' to actually sign the form. The agency agrees that it is not necessary to know who prepared the submission, because agency inquiries will be directed to the ''responsible official'' (contact person) either by telephone or by written correspondence. The agency considers that it would be helpful to have the ''responsible official'' sign the form to assure that the actual submission was seen or reviewed by the contact person.

One respondent commented on whether the revised Form FDA 2253 should accompany draft promotional materials intended for CBER for promoting a biologic. The respondent suggested that the revised form created an artificial distinction between drugs and biologics by requiring that draft biologic promotional materials submitted for voluntary preclearance continue to be accompanied by a form (now Form FDA 2253 in place of Form FDA 2567) because CDER does not use a form to accompany draft promotional materials. Thus, the respondent considered use of the form to be unnecessary for voluntary submissions.

CBER notes that some sponsors have submitted proposed promotional materials to CBER for comment without the Form FDA 2567, and that this has been, and continues to be, an acceptable method of submitting draft promotional materials. However, from past experience, CBER considers that the use of the Form FDA 2567 to accompany draft promotional materials makes tracking and followup of the materials more efficient and more timely. For example, the form provides a quick and efficient way of providing comments to sponsors without the need for a formal letter which would require more time. CBER also wants to emphasize that the option of using Form FDA 2253 or 2567 to accompany draft promotional materials to CBER does in no way mandate or obligate drug sponsors to use a form when submitting proposed promotional materials to CDER for comment.

Another respondent asked for clarification regarding the biologic license application (BLA) number referenced in number 3. The respondent stated that the form provided for the sponsor to identify the BLA number for biologics, but that the BLA number for the original application becomes obsolete upon approval. Later supplements are assigned new BLA numbers, and a sponsor can have multiple submissions under review at the same time, each with a different number. Therefore, the respondent requested clarification of which number would be appropriate to list in number 3. The agency agrees that further clarification of number 3 is required. We believe the least confusing and most efficient way to reference the BLA number would be for sponsors to include the ''most recent reference number'' for an application concerning a labeling change.

Four of the five respondents requested further explanation regarding the multiple submissions procedures. The agency will clearly explain the procedures regarding multiple submissions on the form, and how to submit multiple drug product promotional materials. Additionally, one respondent asked whether the ''company named file'' will be releasable under the Freedom of Information Act (FOIA). Currently, CDER's Division of Drug Marketing, Advertising, and Communications (DDMAC) maintains two types of files related to promotional materials. One file contains promotional materials submitted under the postmarketing requirements of § 314.81. These promotional materials have been submitted to the agency because they were already publicly disseminated. The agency would consider this information releasable under FOIA. The ''company named file'' for multiple submissions of Form FDA 2253-related materials would be this type of file. The other types of materials maintained by DDMAC are related to: (1) Advisory opinions (generally on proposed promotional materials) which are not

releasable, and (2) enforcement actions which are releasable.

Three respondents were not clear whether approved product labeling was still required to accompany promotional materials, and one respondent proposed an alternative method of submitting labeling. The agency presently requests that sponsors submit two copies of the approved product labeling for each referenced drug product. This has been clarified on the form. Alternative methods of submitting approved product labeling may be considered at a later time.

Three respondents proposed that the agency provide the revised Form FDA 2253 in electronic form, and accept some promotional materials via electronic means. The agency currently provides many forms on the Internet using the World Wide Web (WWW) at ''http://www.fda.gov/opacom/morechoices/fdaforms/fdaforms.html'' and intends to add the revised Form FDA 2253 shortly after it is an approved form. As for the submission of promotional materials by electronic means, DDMAC is currently reviewing a pilot project where proposed promotional materials are submitted for review via CD–ROM and in hard copy. If successful, DDMAC plans to continue the pilot project and refine the means of submitting promotional materials by electronic means.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Total Annual Responses	Hours per Response	Total Estimated Hours
FDA 2253	612	12,379	2	24,758

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In fiscal year 1995, CDER received 10,879 submissions of advertising and promotional labeling under Form FDA 2253 from an estimated 512 manufacturers. In the same period of time, CBER received 1, 034 submissions from 57 manufacturers that could have made use of revised Form FDA 2253. Prior to October 7, 1997, the submission of advertising and promotional labeling to CBER using Form FDA 2567 was a voluntary procedure. Under § 601.12(f)(4) (62 FR 39890), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i), FDA estimates that under the new regulation CBER will receive over 1,500 submissions from approximately 100 manufacturers that may use the revised Form FDA 2253. Thus, FDA estimates that there may be 12,379 submissions of advertising and promotional labeling to FDA under revised Form FDA 2253. Based on contacts with industry representatives, FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the proposed form, collate the documentation, and send the submission to CDER or CBER. Manufacturers of biological products may use the revised Form FDA 2253 or may continue to use Form FDA 2567 for the submission of advertisements and promotional labeling to CBER.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15192 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0503]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 9, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drug Application (NADA), Form FDA 356 V, 21 CFR Part 514—(OMB Control Number 0910–0032—Reinstatement)

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has the responsibility for the approval of new animal drugs that are safe and effective. Section 512(b) of the act (21 U.S.C. 360b(b)), requires that a sponsor submit and receive approval of a NADA before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under 21 CFR part 514. NADA applicants generally use a single form, FDA 356 V. The NADA must contain, among other things, safety and effectiveness data for the drug, labeling, a list of components, manufacturing and controls information, and complete information on any methods used to determine residues of drug chemicals in edible tissues. While the NADA is pending, an amended application may be submitted for proposed changes. After a NADA has been approved, a supplemental application must be submitted for certain proposed changes, including changes beyond the variations provided for in the NADA and other labeling changes. An amended application and a supplemental application may omit statements concerning which no change is proposed. This information is reviewed by FDA scientific personnel to ensure that the intended use of an animal drug, whether as a pharmaceutical dosage form, in drinking water, or in medicated feed is safe and effective. The respondents are pharmaceutical firms that produce veterinary products and commercial feed mills.

FDA estimates the burden for this collection of information as follows: