

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DPS

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[Docket No. 00N-1637]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human Use

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.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the Federal Register*].

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, Attn: Wendy Taylor, 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human Use

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 and Biologics for Human Use). Statutory authority for the collection of this information is provided by sections 505(a), (b), (j), and (k) and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), (b), (j), and (k) and 371(a)). Similarly, under 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 by 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's Center for Biologics Evaluation and Research (CBER) with either Form FDA 2253 or Form FDA 2567, which is a two-part transmittal form that is also used to transmit other forms of labeling, (e.g., circulars, package labels, and container labels) for CBER review when a sponsor is requesting premarket approval of a product or proposing changes to a product carton or container labeling.

The many types of promotional materials are described on Form FDA 2253 for easy reference. For example, possible submitted promotional materials could be a consumer advertisement, a professional sales aid, or a consumer broadcast advertisement. A single submission would include

two copies each of the promotional materials, Form FDA 2253, and the approved product labeling. Submissions of multiple applications are handled in a similar manner as described in the form.

In 1998, FDA revised 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 revised form had the following major changes:

1. The revised, harmonized form is now 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 it may be used by manufacturers of licensed biological products regulated by CBER who submit draft and/or final copies of promotional labeling and advertisements to the agency. The revised and harmonized Form FDA 2253 eliminated the need for sponsors to use two different forms to transmit similar materials for submission to the two centers. Although manufacturers of biological products had the option to continue to use Form FDA 2567 to transmit advertisements and promotional labeling if they wished, the other uses of Form FDA 2567 remained unchanged.

2. The revised, harmonized form updated the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or promotional labeling (e.g., consumers, professionals, news services); and it helped ensure that the submission is complete.

3. The revised form provides for sponsors to submit specimens of multiproduct promotional labeling and advertisements to only two files; to the approved product application of the sponsor's choice (generally the most frequently promoted product), and to a company name file. This revision in the form has saved sponsors time and money by eliminating the need for making multiple submissions of the same promotional materials. In addition, because the form was revised, sponsors no longer need to maintain dual inventories of both forms, and they now have multiple processing capabilities.

From October 1, 1999, through September 30, 2000, 386 sponsors submitted 12,235 postmarketing reports via Form FDA 2253 to CDER; this included 2,343 multiple submissions.

In the same time period 134 sponsors submitted 4,243 postmarketing reports via Forms FDA 2253 and 2567 to CBER.

In the **Federal Register** of December 21, 2000 (65 FR 80437), the agency requested comments on the proposed collections of information. The comments received were all unrelated to the collection of information published in the above **Federal Register** notice and may be viewed on the FDA Dockets Management Branch Web site: <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>, and by referring to the above docket number.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response ²	Total Annual Responses ³	Hours per Response	Total Hours
CBER (none)	134 ⁴	32	4,243	2	8,486
CDER § 314.81(b)(3)(i)	386 ⁵	32	12,395	2	24,790
Total					33,276

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

² Average number (rounded to the nearest whole number) of submissions submitted annually per sponsor. We note that some sponsors submit only once per year, whereas one sponsor had 893 submissions in 1999.

³ Total number of Form FDA 2253 submissions to CDER and Form FDA 2253 plus Form FDA 2567 to CBER in fiscal year (FY) 1999.

⁴ Number of sponsors that submitted establishment license applications and product license applications to CBER in FY 1999.

⁵ Number of sponsors that submitted new drug applications (including applications for new antibiotics), abbreviated new drug applications, and abbreviated antibiotic applications in FY 1999.

In FY 1999, CDER received a total of 12,395 submissions and CBER received 4,353 submissions that would require the use of this form. FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the form, collate the documentation, and send the submissions to CDER or CBER.

Electronic Submission of Promotional Materials Regarding Prescription Drugs and Biologics for Human Use

CDER and CBER are currently piloting with approximately 20 sponsors, different methods to submit postmarketing submissions of advertising and promotional labeling. FDA anticipates publishing in the **Federal Register** a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling." By using this suggested format for electronically submitting promotional materials, we anticipate that by January 2002, sponsors will submit about 20 percent of all materials electronically via Form

FDA 2253. Further, we anticipate posting a fillable electronic Form FDA 2253 on FDA's Internet site.

Applicants may then have the option to fill out the form on their computer, and with additional software, they can maintain records regarding submitted promotional materials.

Dated: 5/2/01
May 2, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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