response to Program Announcement: RFA OH–01–008.

Contact Person for More Information: Pervis C. Major, PhD., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, M/S B228, Morgantown, West Virginia 26505, telephone 304–285–5979.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 20, 2001.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–11509 Filed 5–7–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1599]

Agency Information Collection Activities; Announcement of OMB Approval; Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 7, 2001 (66 FR 13769), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0182. The approval expires on April 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11451 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0393]

Agency Information Collection Activities; Announcement of OMB Approval; MedWatch: The FDA Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''MedWatch: The FDA Medical Products Reporting Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 16, 2000 (65 FR 69314), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0291. The approval expires on April 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11453 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 June 7, 2001.

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 BURDEN[1]

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: May 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11452 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0006]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Animal Drug Application, Form FDA 356 V

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 June 7, 2001.

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

New Animal Drug Application, Form FDA 356 V— 21 CFR Part 514 (OMB Control No. 0910–0032)—Extension

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act) 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 new animal drug application (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 an 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 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
514.1 and 514.6	190	8.33	1,582	211.6	334,751
514.8	190	8.33	1,582	30	47,460
514.11	190	8.33	1,582	1	1,582
Total					383,793

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

The estimate of the burden hours required for reporting are based on fiscal year 1999 data. The burden estimate includes original NADAs, supplemental NADAs, and amendments to unapproved applications.

Dated: May 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11454 Filed 5–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0194]

Draft Guidance for Industry on the Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals.'' The purpose of this document is to provide guidance to sponsors on the design of animal carcinogenicity experiments, methods of statistical analysis of tumor data, interpretation of study results, presentation of data and results in reports, and the submission of tumor data to FDA statistical reviewers in the Center for Drug Evaluation and Research (CDER).

DATES: Submit written comments on the draft guidance by August 6, 2001. General comments on agency guidance documents are welcome at any time.