DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACF/ACYF/CB–98–04]

Fiscal Year (FY) 1998 Notice of an Announcement of the Availability of Financial Assistance and Request for Applications To Support Demonstration Projects Under the Adoption Opportunities Program

AGENCY: Administration on Children, Youth and Families, ACYF, ACF, DHHS.

ACTION: Notice of Fiscal Year (FY) 1998 availability of financial assistance and request for applications to support demonstration projects under the Adoption Opportunities Program, Title II of the Child Abuse Prevention and Treatment Act, as amended, Pub. L. 104–235.

SUMMARY: The Children's Bureau, within the Administration on Children, Youth and Families announces the availability of FY 1998 funds for competing new discretionary grants under the Adoption Opportunities Program. Adoption Opportunities Program funds are designed to provide services that facilitate the elimination of barriers to adoption and to provide permanent loving homes for children who would benefit from adoption, particularly children with special needs. Specific priority areas for which grant awards are being solicited include:

98.1—National Resource Center on Special Needs Adoption
98.2—Administration of the Interstate Compact on Adoption and Medical Assistance
98.3—Achieving Increased Adoptive Placements of Children in Foster Care
98.4—Effective Collaborations for Timely Adoptions
98.5—Overcoming State and Local Barriers to Adoption
98.6—Adoption 2002 Support Project
98.7—Post-Legal Adoption Services

DATES: The date and time deadline for RECEIPT of applications by DHHS for new grants under this announcement 4:30 p.m. (Eastern Time Zone) on July 24, 1998.

FOR FURTHER INFORMATION CONTACT: Copies of the program announcement will be automatically sent to all current Adoption Opportunities Program grantees, all organizations that applied for grant awards in FY 97 and all individuals and organizations that have asked to be placed on the mailing list for FY 1998. Copies of the program announcement can be obtained the ACYF Operations Center at 1–800–351–2293. A copy of this program announcement is also located at the CB website at http://www.acf.dhhs.gov/programs/CB under Policy and Funding Announcements.

SUPPLEMENTARY INFORMATION: Grant awards of FY 1998 funds will be made by September 30, 1998. The estimated funds available for new awards is $4.9 million and the approximate number of new grants is estimated at 28.

(*Catalog of Federal Domestic Assistance.* Number 93.652, Adoption Opportunities Grants)

Dated: June 3, 1998.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 98–15284 Filed 6–8–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0373]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA Recall Regulations under 21 CFR part 7. Recall guidelines set forth procedures to be used by manufacturers and distributors or other responsible persons in notifying or alerting health professionals or other persons of an unreasonable risk of substantial harm to the public's health and describe the procedures used or required by FDA in the recall process.

DATES: Submit written comments on the collection of information by August 10, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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, when appropriate, and other forms of information technology.

FDA Recall Regulations—Part 7 (21 CFR Part 7), Subpart C—(OMB Control Number 0910–0249—Extension)

These regulations were established to provide guidance to manufacturers on recall responsibilities. These responsibilities include development of a recall strategy; providing complete details of the recall reason, risk evaluation, quantity produced, distribution information, firm's recall

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