

- Report on Subcommittee Meetings and Activities.
- Medicare Outreach, Education, and Partnering Activities Update.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102-3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: July 17, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7-16168 Filed 8-23-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[C.F.D.A. Number: 93.598]

Notice To Award a Grant

AGENCY: Office of Refugee Resettlement, HHS.

SUMMARY: The Office of Refugee Resettlement, Anti-Trafficking in Persons Office, will award a non-competitive grant to Polaris Project, P.O. Box 77892, Washington DC, 20013, in the amount of \$394,452 in Fiscal Year 2007 due to urgent and compelling circumstances. The award will be used to improve the systemic response to protect victims of human trafficking in the United States through the Training,

Technical Assistance, and Strategic Planning (TTASP) Program.

The specific goal of the TTASP program is to raise the standards of the anti-trafficking field through the development of new and cutting edge strategies, best practices, improved national levels of coordination and strategic planning, and capacity building for the field through practitioner-based training and technical assistance. The services obtained are intended to increase levels of victim identification through the creation of improved direct outreach strategies, enable localized best practice strategies to be shared on a national scale, provide around the clock technical assistance from leading human trafficking experts, and be a resource for strategic planning assistance at the local, State and Federal levels. Services will be provided via a centralized online clearinghouse of training and technical assistance resources, a dedicated technical assistance telephone hotline, on-site training and consulting services, and a peer-to-peer training and strategic planning event.

Grant and Cooperative Agreement Program Authority for this activity is contained in section 106(b) and section 107(b)(1)(B) of the Trafficking Victims Protection Act of 2000 (TVPA), Public Law 106-386, Division A, 114 Stat. 1464 (2000) and in section 412(c)(1)(A) of the Immigration and Nationality Act (INA), (8 U.S.C. 1522(c)(1)(A)).

The Recipient will:

1. Develop anti-trafficking materials covering topics not currently in circulation;
2. Create an online clearing house of training and technical assistance resources, including all TTASP training manuals, briefing materials, model strategic plans, sample outreach materials, user-driven worksheets, and summaries of best practices and model programs;
3. Provide targeted training and technical assistance on effective anti-trafficking strategies to anti-trafficking coalitions, task forces, direct outreach organizations, service providers, and others as needed;
4. Provide around the clock technical assistance via telephone on an emergency or on-demand basis for service providers or law enforcement officials that encounter trafficking victims;
5. Create a comprehensive strategic planning document for use by new and existing anti-trafficking coalitions that consolidates national best practices for implementing anti-trafficking activities at the local level;

6. Provide technical review of third-party materials, including, but not limited to client service protocols and forms, outreach protocols and materials, and organizational training documents; and

7. Provide consulting services to ORR in areas of strategic planning, staying abreast of the latest trends in the field, and any other technical assistance requested.

After the appropriate reviews, it has been determined that the need to improve the systemic response to protect victims of human trafficking in the United States through the training, technical assistance, and strategic planning is urgent and compelling. The project period is September 30, 2007 to September 29, 2010.

FOR FURTHER INFORMATION CONTACT:

Vanessa Garza, Office of Refugee Resettlement, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447, telephone (202) 401-2334.

Dated: August 14, 2007.

Martha E. Newton,

Director, Office of Refugee Resettlement.

[FR Doc. E7-16842 Filed 8-23-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0246]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Manufactured Food Regulatory Program Standards" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 18, 2006 (71 FR 75760), 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 0910-0601. The approval expires on May 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>. The standards can be viewed on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gdl0002-vol1.pdf>.

Dated: August 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-16708 Filed 8-23-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0323]

Agency Information Collection Activities: Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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 requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

DATES: Submit written or electronic comments on the collection of information by October 23, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—21 CFR Part 207 (OMB Control Number 0910-0045—Extension)

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207).

Under current¹ 21 CFR 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute, under their own label or trade name, a drug product manufactured by a registered establishment are not required either to register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under current §§ 207.21 and 207.22, establishments, both domestic and foreign, must register with FDA by submitting Form FDA-2656 (Registration of Drug Establishment) within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually by returning, within 30 days of receipt from FDA, Form FDA-2656e (Annual Update of Drug Establishment) (Note: This form is no longer mailed to registrants by FDA; updating registration information is estimated in table 1 of this document by the information submitted annually on Form FDA-2656). Changes in individual ownership, corporate or partnership

¹This notice requests comments on the information collection in current part 207. In the **Federal Register** of Augst 29, 2006 (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally also require the electronic submission of all registration and most listing information. The August 29, 2006, proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the information collection for revised part 207 will replace the information collection in this notice.