

to the draft recommendations. Please limit comments to six pages.

**III. Potential Responders**

HHS invites input from a broad range of individuals and organizations that have interests in vaccines and vaccine safety. Some examples of these organizations include but are not limited to the following:

- General public;
- Advocacy groups and public interest organizations;
- State and local governments;
- State and local public health departments;
- Vaccine manufacturing industry, distributors and other businesses;
- Health care professional societies and organizations.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. All comments submitted will be made publicly available. Anonymous submissions will not be considered and will not have their comments posted.

Written comment submission should not exceed six pages. Any information you submit will be made public. Consequently, do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public.

Public Access: Comments on the draft report and draft recommendations will be available to the public on the NVAC Web site at <http://www.hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html>. You may access public comments received by going to the above Web site.

Dated: May 4, 2011.

**Wanda K. Jones,**

*Principal Deputy Assistant Secretary for Health.*

[FR Doc. 2011-11401 Filed 5-9-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* Request for Assistance for Child Victims of Human Trafficking.  
*OMB No.:* 0970-0362.

*Description:* The William Wilberforce Trafficking Victims Protection Reauthorization Act (TVPPRA) of 2008, Public Law 110-457, directs the U.S. Secretary of Health and Human Services (HHS), upon receipt of credible information that a non-U.S. citizen, non-Lawful Permanent Resident (alien) child may have been subjected to a severe form of trafficking in persons and is seeking Federal assistance available to victims of trafficking, to promptly determine if the child is eligible for interim assistance. The law further directs the Secretary of HHS to determine if a child receiving interim assistance is eligible for assistance as a victim of a severe form of trafficking in persons after consultation with the Attorney General, the Secretary of Homeland Security, and nongovernmental organizations with expertise on victims of severe forms of trafficking.

In developing procedures for collecting the necessary information from potential child victims of trafficking, their case managers, attorneys, or other representatives to allow HHS to grant interim eligibility, HHS devised a form. HHS has determined that the use of a standard form to collect information is the best way to ensure requestors are notified of their option to request assistance for child victims of trafficking and to make prompt and consistent determinations

about the child's eligibility for assistance.

Specifically, the form asks the requestor for his/her identifying information, for information on the child, information describing the type of trafficking and circumstances surrounding the situation, and the strengths and needs of the child. The form also asks the requestor to verify the information contained in the form because the information could be the basis for a determination of an alien child's eligibility for federally funded benefits. Finally, the form takes into consideration the need to compile information regarding a child's circumstances and experiences in a non-directive, child-friendly way, and assists the potential requestor in assessing whether the child may have been subjected to trafficking in persons.

The information provided through the completion of a Request for Assistance for Child Victims of Human Trafficking form will enable HHS to make prompt determinations regarding the eligibility of an alien child for interim assistance, inform HHS' determination regarding the child's eligibility for assistance as a victim of a severe form of trafficking in persons, facilitate the required consultation process, and enable HHS to assess and address potential child protection issues.

*Respondents:* Representatives of governmental and nongovernmental entities providing social, legal, or protective services to alien persons under the age of 18 (children) in the United States who may have been subjected to severe forms of trafficking in persons.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for Assistance for Child Victims of Human Trafficking .....	200	1	1	200

Estimated Total Annual Burden Hours: 200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and

comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0422]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Information From United States Firms and Processors That Export to the European Community

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Information From United States Firms and Processors That Export to the European Community" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 23, 2010 (75 FR 71444), 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 0910-0320. The approval expires on February 28, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-11360 Filed 5-9-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0631]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

**DATES:** Fax written comments on the collection of information by June 9, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0638. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**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.

#### Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices—(OMB Control Number 0910-0638)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. As a result of this provision, the guidance explains the importance of making available to health care providers the most current information regarding susceptibility test interpretive criteria for antibacterial drug products. To address concerns about antibacterial drug product labeling with out-of-date information on susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods, the guidance describes procedures for FDA, applications holders, and antimicrobial susceptibility testing device manufacturers to ensure that updated susceptibility test information is available to health care providers. Where appropriate, FDA will identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. The FDA recognized standards will be available to application holders of approved antibacterial drug products for updating their product labeling.

Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: Submit a labeling supplement that relies upon a standard recognized by FDA in a **Federal Register** notice or submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the "Microbiology" subsection of their product labeling is current or whether changes are needed. This information collection is already approved by OMB under control number 0910-0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and control number 0910-0001 (the requirement in 21 CFR