

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation Advisory Committee on Head Start Research and Evaluation

AGENCY: Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Administration for Children and Families (ACF). The meeting will be open to the public.

Name of Committee: Advisory Committee for Head Start Research and Evaluation.

General Function of Committee: The Advisory Committee for Head Start Research and Evaluation will provide feedback on the published final report for the Head Start Impact Study, offering interpretations of the findings, discussing implications for practice and policy, and providing recommendations on follow-up research, including additional analysis of the Head Start Impact Study data. The Committee will also be asked to provide recommendations to the Secretary regarding how to improve Head Start and other early childhood programs by enhancing the use of research-informed practices in early childhood. Finally, the Committee will be asked to provide recommendations on the overall Head Start research agenda, including—but not limited to—how the Head Start Impact Study fits within this agenda. The Committee will provide advice regarding future research efforts to inform HHS about how to guide the development and implementation of best practices in Head Start and other early childhood programs around the country.

DATES: The meeting will be held from 8:30 a.m. to 5 p.m. on January 25, 2011, and from 8:30 a.m. to 4 p.m. on January 26, 2011.

ADDRESSES: Four Points by Sheraton Hotel, 1201 K Street, NW., Washington, DC 20005, (202) 289-7600.

FOR FURTHER INFORMATION CONTACT: Jennifer Brooks, Office of Planning, Research, and Evaluation, e-mail jennifer.brooks@acf.hhs.gov or call (202) 205-8212.

Agenda: The Committee will review information on the federal Head Start program and the children and families it serves, review the design and findings

of the Head Start Impact Study, and review plans for future research on the impact of Head Start. To inform its deliberations, the Committee will also review the evidence related to Early Head Start and programs supporting children from birth through age 5, as well as evidence related to elementary school quality and how best to sustain benefits from early childhood programs through the early elementary school years.

Procedure: Interested persons may present data, information or views, in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before January 15, 2011. All written materials provided to the contact person will be shared with the Committee members.

ACF welcomes the attendance of the public at this advisory committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Brooks at least seven days in advance of the meeting. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 22, 2010.

David A. Hansell,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2010-33242 Filed 1-5-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0635]

Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.” In general, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires a premarket application and market authorization order for new tobacco products before they may be marketed; alternatively, manufacturers may submit a 905(j) report intended to demonstrate substantial equivalence to a predicate

tobacco product. The guidance provides recommendations on submitting information intended to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. Manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, must submit a report no later than March 22, 2011, or the products can no longer be legally marketed. Manufacturers of a new tobacco product first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007 and before March 22, 2011, who submit a substantial equivalence report before March 23, 2011, may continue to market the tobacco product unless FDA issues an order finding that the product is not substantially equivalent. Because it is important that FDA’s recommendations on submitting a substantial equivalence reports be available to assist new tobacco product manufacturers in preparing substantial equivalence reports in advance of March 23, 2011, this guidance document will be implemented immediately. This guidance, however, remains subject to comment in accordance with the Agency’s good guidance practices (GGPs).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit electronic comments on the guidance, including comments regarding the proposed collection of information, to <http://www.regulations.gov>. Submit written comments on the guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the guidance document entitled “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for

information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, annette.marthaler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance that provides recommendations related to reports under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)), as amended by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31). Section 905(j) authorizes FDA to establish the form for the submission of information related to substantial equivalence. The guidance is intended to assist persons submitting reports under section 905(j) of the FD&C Act. It explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence, and provides recommendations on the form and content of section 905(j) reports. The guidance also provides information on FDA's review of 905(j) reports.

II. Significance of Guidance

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's GGP's (§ 10.115 (21 CFR 10.115)). The guidance discusses premarket statutory requirements that include certain submissions to be made to FDA no later than March 22, 2011. This guidance document is being implemented immediately without prior public comment under § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline.

Manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, must submit the report no later than March 22, 2011, or the tobacco product can no longer be legally marketed. If a 905(j) report is submitted prior to March 23, 2011, the tobacco product may continue to be marketed unless FDA issues an order that the tobacco product is not substantially equivalent to the predicate tobacco product (section 910(a)(2)(B) of the FD&C Act (21 U.S.C. 387j(a)(2)(B)), as

amended by the Tobacco Control Act). It is important that this guidance be available in advance of March 23, 2011, to assist manufacturers in preparing 905(j) reports.

For 905(j) reports for tobacco products first marketed between February 15, 2007, and March 22, 2011 (many of which are from small manufacturers) that are submitted prior to March 23, 2011, FDA intends to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their initial submissions, provided these manufacturers submit a 905(j) report by the statutory deadline. FDA intends to determine what constitutes a reasonable period of time on a case-by-case basis.

This guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0673.

IV. Comments

This guidance document is being implemented immediately without prior public comment under § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline. You may submit written comments to FDA on this guidance at any time for Agency consideration; in addition, we request that you submit any comments regarding any significant oversight in this guidance within 30 days of the issuance of this guidance (refer to the title page of the guidance for the issue date). Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m.

and 4 p.m., Monday through Friday. FDA will review any comments we receive and revise the guidance document when appropriate.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-35 Filed 1-5-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1950-DR; Docket ID FEMA-2010-0002]

Arizona; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Arizona (FEMA-1950-DR), dated December 21, 2010, and related determinations.

DATES: *Effective Date:* December 21, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated December 21, 2010, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Arizona resulting from severe storms and flooding during the period of October 3-6, 2010, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Arizona.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.