

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.

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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