electronic access to the guidance document.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 240–276–1717, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq*.) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 904(a)(4) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.'' Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009. FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for the production of documents in a digital format, which FDA strongly encourages in order to improve the management and readability of submitted documents. Therefore, FDA does not intend to enforce the December 22, 2009, initial document submission deadline, provided that manufacturers and importers submit by April 30, 2010, all documents described in section 904(a)(4) of the act developed between June 23, 2009, and March 31, 2010. FDA is in the process of developing a draft guidance document that will explain the requirements of and recommendations for compliance with section 904(a)(4) of the act. We anticipate that the draft guidance document will be issued shortly.

II. Significance of Guidance

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). 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. This document provides guidance on statutory requirements that are due to take effect on December 22, 2009, and so it is urgent that FDA explain its enforcement policy before that date.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. 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: December 16, 2009.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning, and Budget.

[FR Doc. E9–30297 Filed 12–16–09; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Children's Study Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Children's Study Advisory Committee.

Date: January 14, 2010.

Time: 9 a.m. to 12 p.m.

Agenda: The agenda will include the following topics: an update on the current status of the Study and discussions regarding a federated IRB model, data access policies, and recruitment strategies.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room E1/E2, Bethesda, MD 20892.

Time: 12 p.m. to 5 p.m.

Agenda: This meeting is open to the public; however, registration is required since space is limited. Please visit the conference Web site for information on meeting logistics and to register for the meeting, *http://www.circlesolutions.com/ncs/ncsac/index.cfm*. For additional information about the Federal Advisory Committee meeting please contact Circle Solutions at *ncs@circlesolutions.com.*

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room E1/E2, Bethesda, MD 20892.

Contact Person: Jessica Sapienza, Executive Secretary, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 3A01, Bethesda, MD 20892, (703) 902–1339, *ncs@circlesolutions.com.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 11, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–30065 Filed 12–18–09; 8:45 am]

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