October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 76, FR 24886–24887, dated May 3, 2011) is amended to reflect the reorganization of the National Center for Injury Prevention and Control, Office of Noncommunicable Diseases, Injury and Environmental Health, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

After the title and functional statement for the Division of Violence Prevention (CUHC), delete in their entirety the title and functional statement for the Office of the Director, (CUHC1) and insert the following:

Office of the Director, (CUHC1). (1) Establishes and interprets policies and determines program priorities; (2) provides national and international leadership and guidance in policy formation and program planning, development, and evaluation; (3) provides administrative, fiscal, and technical support for division programs and units; (4) assures multi-disciplinary collaboration in violence prevention and control activities; (5) provides leadership for developing research in etiologic, epidemiologic, and behavioral aspects of violence prevention and control; (6) coordinates domestic and international activities within the division and with others involved in violence prevention; (7) prepares and monitors clearance of manuscripts for publication in scientific and technical journals and publications, including articles and guidelines published in the MMWR, and other publications for the public; (8) prepares, tracks and coordinates responses to all inquiries from Congress, the public, and the Department of Health and Human Services; (9) develops and produces communication tools and public affairs strategies to meet the needs of the division programs and mission; (10) develops health communication campaigns and guides the production and distribution of print, broadcast, and electronic materials for use in programs at the national and state levels; (11) provides technical assistance and consultation to domestic and international governmental and non-governmental organizations on violence prevention; and (12) establishes linkages and collaborates, as appropriate, with other divisions and offices in NCIPC, other CIOs throughout CDC, and with national and international prevention partners that impact on violence prevention programs.

Delete in their entirety items 10 through 13 of the functional statement for the Program Implementation and Dissemination Branch (CUHCD).

Dated: May 13 2011.

William P. Nichols,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–12570 Filed 5–23–11; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–0792] (Formerly FDA–1999–D–0792)

Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators." This draft guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators. This guidance provides FDA's responses to the most frequently asked questions regarding financial disclosure by clinical investigators.

DATES: Although comments on any guidance can be submitted at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers a comment on this draft guidance before it begins work on the final version of the guidance, electronic or written comments on the draft guidance should be submitted by July 25, 2011. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marsha Melvin, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5170, Silver Spring, MD 20993–0002, 301–796–8345.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators." This guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators, part 54 (21 CFR part 54), and to provide FDA's responses to the most frequently asked questions regarding financial disclosure by clinical investigators. When finalized, this guidance will supersede "Guidance for Industry—Financial Disclosure by Clinical Investigators" (March 20, 2001, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health).

This guidance also responds to recommendations made by the Office of the Inspector General (OIG), Department of Health and Human Services, in their report entitled "The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information."[1] The OIG's recommendations were intended to strengthen FDA's oversight

[1] OIG report OEI–05–07–00730 available at *http://oig.hhs.gov/oei/reports/oei-05-07-00730.pdf.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

and review of clinical investigators' financial disclosures. Specifically, the draft guidance will describe: (1) The sponsor's responsibility to collect the financial disclosure information prior to an investigator participating in a study and ensure that all required forms and attachments are submitted in marketing applications; (2) what is meant by "due diligence" in obtaining financial disclosures from investigators; and (3) how FDA will review financial disclosure information. The guidance will also seek comment on the circumstances under which FDA should consider public release of financial disclosure information related to an approved marketing application.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in part 54 and 21 CFR parts 312 and 812 have been approved under OMB control number 0910–0396; OMB control number 0910–0014; and OMB control number 0910–0078.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this draft guidance document. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm*.

Dated: May 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–12623 Filed 5–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0066] (Formerly Docket No. 2001D–0107)

Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance that was issued on March 9, 2001.

DATES: May 24, 2011.

FOR FURTHER INFORMATION CONTACT: Steven Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 9, 2001 (66 FR 14155), FDA announced the availability of a guidance for industry #121 entitled "Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims."

The guidance predates the enactment of the Animal Drug User Fee Act (ADUFA) of 2003, which was reauthorized by Congress in 2008. ADUFA authorized FDA to collect fees for certain animal drug applications and for the establishments, products, and sponsors associated with these and previously approved animal drug applications, in support of the review of animal drug products. As a result of these increased resources, the efficiencies of our current administrative processes, including the phased review and end review amendment processes, we have significantly reduced our review timeframes and afford sponsors a more efficient pathway to regulatory approval.

At the time the guidance was issued, FDA's review timeframes for new animal drug applications were considerably longer. As noted previously, significant changes have occurred in the Agency's processes and timeframes for reviewing new animal drug applications and the process for expedited review status contained in this guidance is outdated and no longer needed to assure the efficient review of these new animal drug applications.

Dated: *May 4, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–12624 Filed 5–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 17, 2011, from 8 a.m. to 4:30 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College (UMUC), 3501 University Blvd. East, Adelphi, MD. The conference center telephone number is 301–985–7300.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *Fax:* 301–847–8533, *e-mail: DODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about