

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 Specifically, the draft guidance will describe: (1) The sponsor's responsibility to collect the financial disclosure information prior to an investigator participating in a study and ensure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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic.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This draft guidance refers to previously approved collections of information found in FDA regulations.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may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this draft guidance document.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.

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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.

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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