

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 Specifically, the draft guidance will describe: (1) The sponsor's responsibility to collect the financial disclosure information prior to an investigator participating in a study and ensure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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic.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This draft guidance refers to previously approved collections of information found in FDA regulations.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may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this draft guidance document.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

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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.

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

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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

possible modifications before coming to the meeting.

Agenda: On June 17, 2011, the committee will discuss biologics license application (BLA) 125387, aflibercept ophthalmic solution, proposed trade name EYLEA, sponsored by Regeneron Pharmaceuticals, Inc., indicated for the treatment of neovascular age-related macular degeneration (wet AMD).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. *Background material is available at: <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 3, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 25, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the

speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 26, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings 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 Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. *Please visit our Web site at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm>* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-12741 Filed 5-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request; Web-Based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment)

SUMMARY: In compliance with the requirement of Section 3506(c) (2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the

National Institute on Drug Abuse, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Web-based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment).

Type of Information Collection

Request: New.

Need and Use of Information

Collection: The project aims to increase the provision of screening, brief intervention, and referral to treatment (SBIRT) for substance use in primary care by developing an engaging, interactive case-based training program that will be delivered over the Internet, providing convenient access to screening and brief intervention skills training and resources for busy PCPs. The goal of this study is to evaluate the effectiveness of this training on provider behavior and/or patient outcome and the program's utility as a training tool in a real-world medical setting. The training is named SBIRT-PC. Study participants will be randomly assigned to complete SBIRT-PC or a control training, consisting of online reading materials. Effectiveness will be evaluated in terms of differential SBIRT-related knowledge, attitudes, self-efficacy, self-reported clinical practices, skills as measured by virtual standardized patient evaluations (VSPE) and a telephone-based standardized patient (SP) interaction. Participants in each condition will also complete a training satisfaction questionnaire.

Frequency of Response: On occasion.

Affected Public: Private Sector; Businesses or other for-profit.

Type of Respondents: Primary Care Providers.

The annual reporting burden is as follows:

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per set of responses | Estimated total annual burden hours requested |
|------------------------------|---------------------------------|--|---|---|
| Primary Care Providers | 94 | 1 | 2.0 | 188 |

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper

performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.