

entitled “Suicidality: Prospective Assessment of Occurrence in Clinical Trials” issued in September 2010.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 15, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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: Thomas Laughren, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4114, Silver Spring, MD 20993-0002, 301-796-2260.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials.” The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidal ideation and behavior in clinical trials of drug and biological products. Specifically, this guidance addresses FDA’s current thinking regarding the importance of suicidal ideation and behavior assessment in psychiatric and nonpsychiatric drug trials and the general principles for how best to accomplish this assessment during drug development.

Prospective assessment of suicidal ideation and behavior involves actively querying patients about the occurrence of suicidal thinking and behavior, rather than relying on patients to report such occurrences spontaneously, followed by retrospective classification of events into appropriate categories. This guidance recommends a specific

suicidal ideation and behavior assessment instrument that can be used to conduct such prospective assessments and offers guidance on the use of alternative instruments.

This guidance is intended to serve as a focus for continued discussions among FDA, pharmaceutical sponsors, the academic community, and the public. This guidance does not address the complex analytic issues involved in the analysis of the suicidal ideation and behavior data that will be derived from prospective assessments of suicidal ideation and behavior; these issues will be addressed in separate guidances.

This guidance is a revision of the draft guidance for industry entitled “Suicidality: Prospective Assessment of Occurrence in Clinical Trials” issued September 9, 2010 (75 FR 54889). Comments we received on the draft guidance have been considered and the guidance has been revised. The revision: (1) Replaces the term “suicidality” with the terms “suicidal ideation and behavior”; (2) provides an expanded set of the Columbia Classification Algorithm for Suicide Assessment (C-CASA) categories, along with definitions and explanations; (3) revises the advice on which trials and patients would need assessments of suicidal ideation and behavior and the timing of such assessments; (4) addresses concerns about the time burden of assessments; (5) addresses questions about the possible value of the assessments providing protection for patients in the trials themselves; (6) makes it clear that use of an assessment instrument that directly classifies relevant thoughts and behaviors into C-CASA categories eliminates the need for any additional coding; (7) provides multiple additional references; and (8) revises advice on evaluation of alternative instruments.

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 prospective assessment of occurrence of suicidal ideation and behavior in clinical trials. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of

comments. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19993 Filed 8-14-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0585]

Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories.” The draft guidance identifies additional food categories to be included in food facility registrations as determined appropriate by FDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 14, 2012.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. 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 written requests for single copies of the draft guidance to the Office of Compliance, Division of Field Programs

and Guidance, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Amy Barringer, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories.” This draft guidance sets forth FDA’s determination of the necessity for additional food categories and sets forth the additional food categories to be included as mandatory fields in food facility registrations as determined appropriate by FDA.

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d). Section 415(a)(2) of the FD&C Act, as amended by section 102 of FSMA, provides in relevant part that, when determined necessary by FDA through guidance, a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in 21 CFR 170.3) or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. This draft guidance sets forth FDA’s determination of the necessity for additional food categories and the other food categories to be included in food facility registrations as determined appropriate by FDA. The inclusion of these additional food categories in food facility registrations will help FDA provide a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

FDA is interested in comments regarding including the other food categories as mandatory fields in food facility registrations. FDA intends to issue a final guidance that identifies the additional food categories that will be included as mandatory fields in food facility registration forms before the first

biennial registration renewal period, which begins on October 1, 2012.

Section 415(a)(2) of the FD&C Act provides in relevant part that a food facility is required to submit to FDA a registration containing information about the general food category (as identified listed in § 170.3 or any other food category as determined appropriate by FDA, including “by guidance”) of a food manufactured/processed, packed or held at such facility, if the Agency determines “through guidance” that such information is necessary. Because of Congress’ explicit statutory authorization in section 415(a)(2) to establish binding requirements based on actions by guidance, this document is not subject to the usual restrictions in FDA’s good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document’s nonbinding effect. (See 21 CFR 10.115(d)(i)).

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited, and the Agency’s guidances also ordinarily include language similar to the following paragraph:

This guidance represents the Food and Drug Administration’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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

FDA is not including this standard language in this draft guidance because it is not an accurate description of the effect of this guidance. This guidance contains findings that serve as the predicates for binding requirements on industry. As stated in “Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities” (2003), which implemented, in part, section 415, as added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, it contains FDA’s finding that inclusion of the food categories in § 170.3 in food

facility registrations is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency. Based in part on this finding, FDA’s regulations for the registration of food facilities in 21 CFR part 1, subpart H currently require that a food facility submit a registration to FDA containing information on applicable food product categories as identified in § 170.3 for food manufactured/processed, packed, or held at such facility. As provided in section 102 of FSMA, this draft guidance contains FDA’s finding that inclusion of other food categories in food facility registrations is also necessary to facilitate such rapid communications. In addition, this draft guidance sets forth the other food categories to be included in food facility registrations determined to be appropriate by FDA for the purposes of food facility registration. Insofar as this guidance, if finalized, modifies food categories for food facility registration under section 415 of the FD&C Act, it will have binding effect. For these reasons, FDA is not including the standard guidance paragraph in this draft guidance.

II. The Paperwork Reduction Act of 1995

This draft guidance contains a collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA intends to submit the collection of information to OMB in the near future for emergency clearance processing under 5 CFR 1320.13. The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 1.230–1.235 have been approved under OMB control number 0910-0502.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either

<http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: August 6, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20038 Filed 8–14–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic Drugs Advisory Committee.

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

DATES: *Date and Time:* The meeting will be held on October 17, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Paul Tran, 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, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 203858, lomitapide capsules, by Aegerion Pharmaceuticals, Inc. The proposed indication (use) is as an adjunct to a low-fat diet and other lipid-lowering drugs with or without low-density lipoprotein (LDL) apheresis to reduce LDL cholesterol, total cholesterol, apolipoprotein B, and triglycerides in patients with homozygous familial hypercholesterolemia. (Apheresis is a laboratory technology used to remove LDL from the bloodstream.)

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 October 2, 2012. 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 September 24, 2012. 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 September 25, 2012.

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 Paul Tran 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: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20013 Filed 8–14–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0853]

Tobacco Product Manufacturing Facility Visits

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP) is announcing an invitation for participation in its Tobacco Product Manufacturing Facility Visits. This program is intended to give FDA staff an opportunity to visit facilities involved in the manufacturing of tobacco products, including any related laboratory testing, and observe the manufacturing operations of the tobacco industry. The purpose of this notice is to invite parties interested in participating in Tobacco Product Manufacturing Facility Visits to submit requests to CTP.

DATES: Submit either an electronic or written request for participation by October 15, 2012. See section IV of this document for information on requests for participation.

ADDRESSES: If your facility is interested in participating in Tobacco Product