developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3998), FDA announced the availability of final guidances on the content and format of the ''Adverse Reactions'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075057.pdf*) and ''Clinical Studies'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075059.pdf*) sections of labeling. In the **Federal Register** of October 19, 2009 (74 FR 53507), FDA announced the availability of final guidance on determining established pharmacologic class for use in the Highlights of Prescribing Information (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM186607.pdf*). In the **Federal Register** of March 23, 2010 (75 FR 13766), FDA announced the availability of final guidance on the content and format of the ''Dosage and Administration'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075066.pdf*). In the **Federal Register** of October 12, 2011 (76 FR 63303), FDA announced the availability of final guidance on the content and format of the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf*) and in the **Federal Register** of March 3, 2009 (74 FR 9250), FDA announced the availability of draft guidance on the content and format of the ''Clinical Pharmacology'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM109739.pdf*). The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

On January 24, 2006, FDA announced the availability of draft guidance entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements'' to obtain public comment (71 FR 3998). FDA received a number of comments, most of which sought clarifications and illustrations of the issues discussed in individual sections of the guidance. FDA reviewed all received comments carefully during the finalization of the guidance and made clarifying changes based on input from these comments and comments from FDA reviewers with labeling expertise.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on implementing the PLR content and format requirements for labeling for human prescription drug and biological products. 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 either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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.*

III. Paperwork Reduction Act of 1995

This 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 §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

IV. Electronic Access

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

Dated: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04195 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0409] (formerly 2006D–0169)

Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a guidance entitled ''Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act,'' dated April 2006, that was announced in the **Federal Register** on May 2, 2006. The guidance explained FDA's then current thinking on the labeling of certain uses of lecithin derived from soy under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and was part of FDA's implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA). We are taking this action because the policy stated in the guidance regarding FDA's consideration of the exercise of enforcement discretion no longer reflects our current thinking.

DATES: The withdrawal is effective February 25, 2013.

FOR FURTHER INFORMATION CONTACT: Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1056.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 2, 2006 (71 FR 25844), we announced the availability of a guidance entitled ''Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act.'' The guidance explained that, consistent with the need to establish enforcement priorities, we would consider the exercise of enforcement discretion for a food labeled on or after January 1, 2006, in which lecithin derived from soy is used solely as a component of a release agent and the label for such food does not declare the presence of soy consistent with the requirements of section 403(w) of the FD&C Act (21 U.S.C. 343(w)). In that guidance, the

term ''release agent'' referred to an agent used to facilitate the release of foods from food contact surfaces, where the agent has been applied directly to the food contact surface, rather than incorporated into the food. In that guidance, we also stated our intention to reconsider our enforcement priorities with regard to the labeling of lecithin derived from soy used as a component of a release agent approximately 18 months after the issuance of the guidance. Further, we stated our expectation that, during the period in which we considered the exercise of our enforcement discretion, manufacturers of foods that use lecithin derived from soy as a component of a release agent would revise as necessary the labels of their relevant food products to comply with FALCPA and begin to label their products using the FALCPA-compliant labels by the end of the enforcement discretion period.

We believe that there has been sufficient time for all manufacturers of foods that use lecithin derived from soy as a component of a release agent to revise the labels for such foods to be consistent with the requirements of section 403(w) of the FD&C Act. Therefore, we no longer believe it is appropriate to consider the exercise of our enforcement discretion with regard to foods that use lecithin derived from soy as a component of a release agent. For these reasons, we are withdrawing the April 2006 guidance entitled ''Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act.''

Dated: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04251 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Joint Meeting of the Medical Imaging Drugs Advisory Committee and the Oncologic 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 Committees: Medical Imaging Drugs Advisory Committee and the Oncologic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on May 3, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (rm. 1503), 10903 New Hampshire Ave., 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: Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *MIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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/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: On May 3, 3013, the committees will discuss the safety and efficacy of currently approved leukocyte growth factors (LGFs) as potential treatments for radiation-induced myelosuppression associated with a radiological/nuclear incident. (Myelosuppression is a reduction of blood cell production, which can be caused by radiation exposure.) Currently approved LGFs are licensed under biological license applications (BLAs): 103353, NEUPOGEN (filgrastim, Amgen, Inc.), 125031, NEULASTA (pegfilgrastim, Amgen, Inc.), 103362, LEUKINE, (sargramostim, Genzyme, Inc.), and 125294, TBO–FILGRASTIM (tbo-filgrastim, Sicor Biotech, UAB). The National Institute of Allergy and Infectious Diseases (NIAID) has submitted efficacy data for filgrastim, based on treatment in an animal model of radiation-induced myelosuppression. Safety and other supportive information are currently described in the labeling for LGFs.

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 meeting 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 April 19, 2013. 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 April 11, 2013. 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 April 12, 2013.

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 Diane Goyette 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/Advisory*