I. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases.

J. Medical Imaging Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

K. Nonprescription Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

L. Oncologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

M. Peripheral and Central Nervous System Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

N. Pharmaceutical Science and Clinical Pharmacology Advisory Committee

Reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases.

O. Pharmacy Compounding Advisory Committee

Provides advice on scientific, technical, and medical issues concerning drug compounding.

P. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

Q. Pulmonary-Allergy Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumès. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01555 Filed 2–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3548]

Public Warning and Notification of Recalls; Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry and FDA staff entitled ''Public Warning and Notification of Recalls.'' The guidance establishes guidance for industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and public notification of recalls under federal regulations. The intent of the guidance is to increase and expedite the appropriate and accurate use of public warnings and public notification and to increase public health protection by better informing the public about violative products being recalled. The guidance clarifies and supplements existing policy for industry and FDA staff regarding the use of public warnings and public notification.

DATES: The announcement of the guidance is published in the **Federal Register** on February 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–3548 for ''Public Warning and Notification of Recalls '' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on this guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: For questions or information regarding this document, contact Chris Henderson, Office of Regulatory Affairs, Office of Strategic Planning and Operational Policy, Human and Animal Food Policy Branch, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8186, *Christopher.henderson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry and FDA staff entitled ''Public Warning and Notification of Recalls under 21 CFR part 7, subpart C.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

In the **Federal Register** of January 19, 2018 (83 FR 2758), we made available a draft guidance for industry and FDA Staff entitled ''Public Warning and Notification of Recalls under 21 CFR part 7, subpart C, Draft Guidance for Industry and FDA staff'' and gave interested parties an opportunity to submit comments by March 20, 2018, for us to consider before beginning work on the final version of the guidance. We received comments on the draft guidance. We considered every comment and made changes, where appropriate. The guidance announced in this notice finalizes the draft guidance dated January 17, 2018.

The guidance establishes official guidance for industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and public notification of recalls under 21 CFR part 7, subpart C. The intent of the guidance is to increase and expedite the appropriate and accurate use of public warnings and public notification and to increase public health protection by better informing the public about violative products being recalled. The guidance clarifies and supplements existing policy for industry and FDA staff regarding the use of public warnings and public notification.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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). Any collection of information, such as a firm's public warning (21 CFR 7.42(b)(2)), has been approved under OMB control number 0910–0249.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Safety/Recalls/default.htm* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01603 Filed 2–7–19; 8:45 am]

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