

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 any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance documents is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances. Submit written requests for a single hard copy of the draft guidance documents entitled "Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies" and "Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies Draft Companion Guidance Document" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Michael John, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993-0002, 301-796-6329, [Michael.John@fda.hhs.gov](mailto:Michael.John@fda.hhs.gov) or Kimberly Peters, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4314, Silver Spring, MD 20993-0002, 301-796-6350, [Kimberly.Peters@fda.hhs.gov](mailto:Kimberly.Peters@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of March 27, 2008, FDA published a notice of availability with a 120-day comment period to request comments on the draft guidances entitled "Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies" and "Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies Draft Companion Guidance Document."

The draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the current thinking of FDA on coronary drug-eluting stents—nonclinical and clinical studies. They do not establish any rights for any person and are not binding on FDA or

the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. The guidances are not subject to Executive Order 12866.

FDA is reopening the comment period to consider any new information and intends to issue revised versions of these draft guidances for further consideration. This action will help the Center for Devices and Radiological Health fulfill its commitment to finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2012 (82 FR 58429, December 12, 2017).

FDA is reopening the comment period for 90 days. The Agency believes that a 90-day extension allows adequate time for interested parties to submit comments. Previously submitted comments do not need to be resubmitted for consideration.

##### **II. Electronic Access**

Persons interested in obtaining a copy of the draft guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. The draft guidance documents are also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies" and "Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies Draft Companion Guidance Document" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 6255 to identify the guidance you are requesting.

Dated: September 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-21041 Filed 9-26-18; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2018-D-1752]

#### **Public Availability of Lists of Retail Consignees To Effectuate Certain Human and Animal Food Recalls; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry and FDA staff entitled "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls." The draft guidance, when finalized, establishes guidance for industry and FDA staff on how and when FDA intends to collect, compile, and publicize retail consignees that may have received recalled foods. While FDA intends to focus on recalls where there is a reasonable probability that the use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals (Class I recalls), FDA may also publicize retail consignee lists for other food recalls as described in the draft guidance. FDA's goal is to publicize retail consignee lists for these food recalls where providing this additional information will be of the most use to consumers to help them identify recalled food and to determine whether that food is in their possession as effectively and quickly as possible.

**DATES:** Submit either electronic or written comments on the draft guidance by November 26, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments 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-2018-D-1752 for "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls; Draft Guidance for Industry and FDA Staff." 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 any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft 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 draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Chris Henderson, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8186, [Christopher.henderson@fda.hhs.gov](mailto:Christopher.henderson@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls." The draft guidance, when finalized, establishes guidance for industry and FDA staff on how and when FDA intends to publicize retail consignees that may have received recalled foods. FDA's goal is to publicize retail consignee lists for these food recalls, especially those that are likely to be classified as Class I recalls, where providing this additional information will be of the most use to consumers to help them identify recalled food and to determine whether that food is in their possession as

effectively and quickly as possible. FDA seeks comment on this draft guidance, including scope of the term "retail consignee" as used in this document, the situations where providing retail consignee lists would be of the most use to consumers to identify recalled food in their possession, and additional information that would be of the most use to consumers to help them identify recalled food in their possession.

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 current thinking of FDA regarding publicizing retail consignees to effectuate certain food recalls. 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 draft guidance is not subject to Executive Order 12866.

##### II. 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). Any collections of information under 21 CFR 7.46, 7.49, 7.53, 7.55, and 7.59 have been approved under OMB control number 0910-0249.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Safety/Recalls/default.htm> or <https://www.regulations.gov>.

Dated: September 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0007]

### Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2019

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a rare