TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Pre-test	5	1	5	1.5	7.5
Interviews	339	1	339	1.5	508.5
Total					516

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. FDA estimates that up to 339 respondents will take part in the interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 508.5 hours. Thus, the total estimated annual burden is 516 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21038 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–2008–D–0180]

Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies and Companion Guidance Document; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice of availability, published in the **Federal Register** of March 27, 2008. In that document, FDA requested comments on two draft guidance documents entitled ''Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies'' and ''Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies Draft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.'' The Agency is reopening the comment period to allow interested persons to provide updated comments and any new information.

DATES: FDA is reopening the comment period on the notice of availability published March 27, 2008 (73 FR 16311). Submit either electronic or written comments on the draft guidances by December 26, 2018, to ensure that the Agency considers your comment on the draft guidances before it begins work on the final version of the guidances.

ADDRESSES: You may submit comments on any guidance 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–2008–D–0180 for ''Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies'' and ''Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies Draft Companion Guidance Document.'' 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)).

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* 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.*

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* 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]

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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,