ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
U.S. Repatriation Program Loan Waiver Request Form	100 or more	1	1	100 or more.
U.S. Repatriation Program Temporary Assistance Extension Request Form.	500 or more	1	0.20	100 or more.
U.S. Repatriation Program Individual Case Management Report	1000 or more	1 or more	0.20	200 or more.

Estimated Total Annual Burden Hours: 540.4.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–21211 Filed 8–29–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0519]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry # 108 on How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 30, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0454 and title ''Guidance for Industry # 108 on How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry # 108 on How To Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway—21 CFR 11.2 (OMB Control Number 0910–0454)—Extension

The Center for Veterinary Medicine (CVM) accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S–0251 as required by § 11.2 (21 CFR 11.2). CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled ''Guidance for Industry # 108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway'' outlines general standards to be used for the submission of any information by email. The likely respondents are sponsors for new animal drug applications.

In the **Federal Register** of May 16, 2013 (78 FR 28851), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part and Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 11.2; Form FDA 3538	65	2.4	156	.08 (5 minutes)	13 (Rounded from 12.5)

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

Dated: August 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21236 Filed 8–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0920]

Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems.'' FDA has developed this guidance to inform the coronary and peripheral stent industry about selected updates to FDA's thinking regarding certain non-clinical testing for these devices. While FDA is considering more substantial updates to the ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance (*http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071863.htm*), we are issuing this update on select sections in order to notify the industry in a timely manner of our revised recommendations. This draft guidance is not final nor is it in effect at this time.

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 September 30, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lindsay Pack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.66, Rm. 1270, Silver Spring, MD 20993–0002, 301–796–5214; or Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.62, Rm. 3226, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

FDA held a public workshop entitled ''Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching'' on March 8 and 9, 2012, that provided information on current practices for performing these tests (see *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm287535.htm*). A group of participants from industry, test facilities, and academia provided comments on practices for corrosion testing and nickel ion release testing. Based on the discussion at the workshop, this draft guidance updates a key aspect of sample conditioning for pitting corrosion testing that is less burdensome, and includes additional information on when galvanic corrosion testing may be omitted with justification, based on information gained from the workshop. This guidance provides updates only for the following topics:

- Pitting corrosion potential;
- Galvanic corrosion;
- Surface characterization; and
- Nickel ion release.

This draft guidance provides cross-references and updates to the related sections of the existing ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance. Following the close of the comment period on this guidance, FDA intends to consider the comments received, revise this draft guidance as appropriate, and publish it in final. Simultaneously, FDA will issue an update to the existing guidance to add cross-references where this selected updates guidance supersedes the existing recommendations. Subsequently, FDA will incorporate the elements of the final select updates guidance into an anticipated revision of the entire ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance.

This draft guidance also lists the relevant product codes for stents addressed in the guidance. Of note is that the product code NXP (Stent, Tibial), which is not currently listed in the existing ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance, has been added. This product code was not created until after the current guidance was published, however, the recommendations in this draft guidance are applicable to tibial stents. Further, FDA will include this product code in the anticipated revision of the entire ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance.

II. Significance of Guidance

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 certain non-clinical testing for coronary and peripheral stents. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.*

To receive ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems,'' you may either send