Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of “List of Highest Priority Devices for Human Factors Review” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500052 to identify the guidance you are requesting.

IV. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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). The collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” are approved under OMB control number 0910–0756.

Dated: January 28, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–01889 Filed 2–2–16; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

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 March 4, 2016.

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 0910–0731. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, 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 on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

OMB Control Number 0910–0731—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate. This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. The guidance has been revised to provide clarity.

In the guidance, the Agency discusses, among other things:

• What information FDA recommends persons include in a meeting request;

• How and when to submit a request; and

• What information FDA recommends persons submit prior to a meeting.

This guidance describes two collections of information: (1) The submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance as a level 2 guidance consistent with FDA’s good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA’s recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name and FDA-assigned Submission Tracking Number (if applicable);

2. Product category (e.g., cigarettes, smokeless tobacco) (if applicable);

3. Product use (indicate for consumer use or for further manufacturing);

4. Contact information for the authorized point of contact for the company requesting the meeting;

5. The topic of the meeting being requested (e.g., a new tobacco product application, an application for permission to market an MRTP, or investigational use of a new tobacco product);

6. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;

7. A preliminary list of the specific objectives/outcomes expected from the meeting.
Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers

67
1
67
10
670

Meeting Information Packages

Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers

67
1
67
18
1,206

Total

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1,876

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
that it will take respondents 1,206 hours of time (67 respondents × 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is 1,876 hours (670 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–02000 Filed 2–2–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0199]

Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry and FDA staff entitled “Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices.” When finalized, this draft document will describe the Agency’s intent to continue enforcement, before September 24, 2021, the prohibition against providing National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and device packages, with respect to certain finished devices manufactured and labeled prior to September 24, 2018. In addition, when finalized, this draft guidance will describe the Agency’s intent to continue considering requests for continued use of FDA labeler codes under a system for the issuance of unique device identifiers (UDIs) until September 24, 2018. This draft guidance is not the final version of the guidance 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 comments 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 April 4, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–0199 for “Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the draft guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, 105431, Silver Spring, MD 20939-0002. Alternatively, you may submit written