such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 044'' will be available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

Dated: July 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17570 Filed 7–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

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 August 25, 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 0910–0671. 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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act (OMB Control Number 0910–0671)—Extension

The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA.

This information collection-the submission to FDA of warning plans for smokeless tobacco products is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended.

Based on the Federal Trade Commission's (FTC's) previous experience with the submission of warning plans and FDA's experience, FDA estimates that there are 52 companies affected by this information collection. To account for the entry of new smokeless tobacco companies that may be affected by this information collection, FDA is conservatively estimating the total number of annual respondents to this collection of information to be 100.

When the FTC requested an extension of their approved warning plan information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of rotational plans for health warning statements	100	1	100	60	6,000	$1,200

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

FDA estimates a total of 100 respondents will respond to this collection of information and take 60 hours to complete a rotational warning plan for a total of 6,000 burden hours. In addition, capital costs are based on 100 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to FDA to be $1,200.

In the **Federal Register** of February, 19, 2016 (81 FR 8505), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was PRA related comment was received.

(Comment) The comment believes that warning plans should not be renewed every year, but should remain in force as long as necessary after their approval

(Response) FDA does not require that a previously FDA-approved warning plan be resubmitted. FDA reviews and approves warning plans only once, unless a submitter seeks to change the distribution or display of warnings on packages or rotation of warnings in advertisements, in which case the submission would be considered a supplement. The purpose of FDA's proposed extension is to account for the entry of new smokeless tobacco product brands and advertising onto the market place.

Dated: July 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17569 Filed 7–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1853]

Unique Device Identification System: Form and Content of the Unique Device Identifier; 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 ''Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI).'' When finalized, this draft document will define the expected content and forms of the unique device identifier (UDI), to assist both labelers and FDA-accredited issuing agencies better ensure the UDIs developed under systems for the issuance of UDIs are in compliance with the unique device identification system rule (UDI Rule). 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 comment of 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 26, 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–1853 for ''Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI).'' 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