section shall be made available for inspection and copying by FDA.

Description of Respondents: Respondents include renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2000(e)(1)(iv); written procedures ..	320	1	320	14	4,480

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

We base our estimates on our experience with similar requirements to maintain written procedures. We base our estimate of the number of recordkeepers on inspectional data. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27656 Filed 12–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4465]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection for administrative detention and banned medical devices.

DATES: Submit either electronic or written comments on the collection of information by February 19, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 19, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 19, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–4465 for ''Administrative Detention and Banned Medical Devices.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Administrative Detention and Banned Medical Devices—21 CFR 800.55(g)(1) and (g)(2), 800.55(k), 895.21(d), and 895.229(a)

OMB Control Number 0910–0114—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), on administrative detention, includes among other things certain reporting requirements (§ 800.55(g)(1) and (g)(2)) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the FD&C Act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. Section 895.21 (21 CFR 895.21), on banned devices, contains certain reporting requirements. Section 895.21(d) describes the procedures for banning a device when the Commissioner of Food and Drugs (the Commissioner) decides to initiate such a proceeding. Under 21 CFR 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Documentation of ownership—800.55(g)	1	1	1	25	25
Banned devices reporting requirements—895.21(d)(8) and 895.22(a)	26	1	26	16	416
Total					441

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records regarding device adulteration or misbranding and records of distribution of detained devices—800.55(k)	1	1	1	20	20

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27655 Filed 12–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3552]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Cigarette Warnings

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 January 22, 2019.

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–NEW and title ''Experimental Study of Cigarette Warnings.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Experimental Study of Cigarette Warnings

OMB Control Number 0910–NEW

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection 4(a)(1) of the FCLAA. Section 202(b) of the Tobacco Control Act further amends section 4 of the FCLAA by adding that the Secretary of Health and Human Services (Secretary), through notice and comment rulemaking, may adjust the text of any of the label requirements if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In the **Federal Register** of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled ''Required Warnings for Cigarette Packages and Advertisements,'' which specified nine images to accompany new textual warning statements for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violated the First Amendment. In a letter to Congress on March 15, 2013, the Attorney General reported FDA's intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act. Various phases of research have been underway since 2013. The next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning responses to health warnings placed on cigarette packages and advertisements for cigarettes.

The health risks associated with the use of cigarettes are significant and far-reaching. Cigarette smoking is the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Ref. 1). In addition to lung cancer, heart disease, and chronic obstructive pulmonary disease, smoking also causes numerous other serious health conditions including several types of cancer, premature birth, low birth weight, respiratory illnesses, clogged arteries, reduced blood flow, diabetes, and vision conditions such as age-related macular degeneration and cataracts (Ref. 2).

Approximately 37.8 million U.S. adults smoke cigarettes (Ref. 3) and 8.6 million Americans have at least one serious illness caused by smoking cigarettes (Ref. 4). Results from the 2016 National Survey on Drug Use and Health demonstrate that, each day in the United States, more than 2,300 youth under age 18 smoke their first cigarette, and nearly 400 youth become daily cigarette smokers (Ref. 5). If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking (Ref. 2). Providing the public with accurate information regarding the health consequences of cigarette use is critical in achieving FDA's mission to protect the public health.

This Experimental Study of Cigarette Warnings is a voluntary online experiment. The purpose of the study is to assess whether new cigarette health warnings increase public understanding of the negative health consequences of cigarette smoking. The study will collect data from various groups of consumers, including adolescent current cigarette smokers aged 13 to 17 years, adolescent non-smokers who are susceptible to initiation of cigarette smoking aged 13 to 17 years, young adult current cigarette smokers and non-smokers aged 18 to 24 years, and older adult current cigarette smokers and non-smokers aged 25 years and older. The results will inform the Agency's efforts to implement the mandatory color graphics to accompany health warning label statements as required by section 4 of FCLAA.

Study Overview: In this study, adolescent current cigarette smokers, adolescent non-smokers who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers and non-smokers, and older adult current cigarette smokers and non-smokers will be recruited from an existing internet panel of more than 1.2 million people and screened for inclusion into the study. Participants who meet the inclusion criteria will be randomized into 1 of 17 conditions. In each condition, respondents will view one cigarette warning. In the 16 treatment conditions, participants will view 1 cigarette health warning, containing a textual warning statement