

online screener will be asked to provide their parents' or guardians' contact information to provide parental consent for the main survey. The process of parents and guardians providing consent for eligible youth will take approximately 1 minute. For the fourth and fifth post-test surveys, we estimate that an additional 700 adults will be contacted to provide consent for eligible youth for a total of 11 additional burden

hours. Added to the original 6,000 parents and 100 burden hours, the total number of parental online screeners and consents will be 6,700 and the total burden will be 111 hours.

With these additions, the estimated number of voluntary respondents/responses for all waves of data collection for the study is 107,743, and the total burden is estimated at 15,135

hours—an estimated increase of 4,813 hours from the last approval.

In the **Federal Register** of December 26, 2017 (82 FR 61003), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, this comment was not PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Mail screener-outcome survey	23,685	1	23,685	0.0833 (5 minutes)	1,973
Cross-Sectional Youth Refresher Sample, Post-test and assent/consent process-outcome surveys 1–5.	4,920	1	4,920	0.75 (45 minutes)	3,690
Youth Pre-test and assent/consent process-outcome survey.	2,194	1	2,194	0.50 (30 minutes)	1,097
Longitudinal Youth Cohort, Post-test and assent/consent process-outcome surveys 1–5.	6,039	1	6,039	0.75 (45 minutes)	4,530
Youth Online screener-outcome survey	40,000	1	40,000	0.0833 (5 minutes)	3,332
Adult parental permission process-outcome survey	30,905	1	30,905	0.0166 (1 minute)	513
Total	107,743	15,135

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

Dated: April 12, 2018.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0913]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

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 May 17, 2018.

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 0910-0705. 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, *PRASStaff@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.

513(g) Request for Information

OMB Control Number 0910-0705—Extension

This information collection supports Agency regulations and accompanying guidance. Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request

of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device. Regulations governing medical device classification procedures are codified under 21 CFR part 860.

The guidance document entitled "FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff" establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Relatedly, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled “Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information” assists

FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910–0511.

In the **Federal Register** of November 21, 2017 (82 FR 55381) FDA published

a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

We therefore retain the currently approved burden estimate for the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH 513(g) requests	114	1	114	12	1,368
CDER 513(g) requests	4	1	4	12	48
Total					1,416

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

Respondents to the collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0524]

Listing of Ingredients in Tobacco Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised final guidance for industry entitled “Listing of Ingredients in Tobacco Products.” The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: The announcement of the guidance is published in the **Federal Register** on April 17, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2009–D–0524 for “Listing of Ingredients in Tobacco Products.” 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