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
Individual in-depth interviews	360	1	360	.75 (45 minutes)	270
General public focus group interviews	144	1	144	1.5 hours	216
Intercept interviews: Central location	200	1	200	.25 (15 minutes	50
Intercept interviews: Telephone	4,000	1	4,000	.08 (5 minutes)	320
Self-administered surveys	2,400	1	2,400	.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	.5 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	.17 (10 minutes)	204
Total (general public)	8,704				1,860
Physician focus group interviews	144	1	144	1.5 hours	216
Total (physician)	144				216
Total (overall)	8,848				2,076

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

Dated: October 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26044 Filed 10–27–16; 8:45 am]

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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Listing of Ingredients in Tobacco Products; Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised draft guidance for industry entitled ''Listing of Ingredients in Tobacco Products.'' The revised draft guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Family Smoking Prevention and Tobacco Control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: 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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the revised draft guidance by November 28, 2016.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–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 *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.

Submit written requests for single copies of the revised draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revised draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft guidance for industry entitled ''Listing of Ingredients in Tobacco Products.'' We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115).

The revised draft guidance document, when finalized, is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Tobacco Control Act.

The Tobacco Control Act (Pub. L. 111–31), enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health. Among its many provisions, the Tobacco Control Act added section 904 to the FD&C Act (21 U.S.C. 387d), establishing requirements for tobacco product ingredient submissions.

The revised draft guidance discusses tobacco products that are newly deemed subject to chapter IX of the FD&C Act. Cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act, including section 904, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C 387a(b)) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Under that authority, FDA issued a final rule deeming all other products that meet the statutory definition of ''tobacco product,'' set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except for accessories of those products, as subject to chapter IX of the FD&C Act (81 FR 28974, May 10, 2016). The final rule became effective on August 8, 2016. As a result, manufacturers or importers (or their agents) of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the ingredient listing requirements in section 904(a)(1).

Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products on the market as of June 22, 2009, the list of ingredients had to be submitted by December 22, 2009. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction into interstate commerce. Section 904(c) of the FD&C Act also requires submission of information whenever any additive, or the quantity of any additive, is changed.

As described in the preamble to the final deeming rule, for products other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco that are on the market as of August 8, 2016, FDA does not intend to enforce the section 904(a)(1) ingredient listing submission requirement until 6 months from the effective date of the rule or 12 months from the effective date for small-scale tobacco product manufacturers. Under this policy, FDA will not enforce the ingredient listing submission requirement until February 8, 2017, for businesses that are not considered small-scale tobacco product manufactures, and August 8, 2017, for small-scale tobacco product manufacturers. Manufacturers of tobacco products introduced into interstate commerce after August 8, 2016, must submit the ingredient information required by section 904(a)(1) at least 90 days before the product is delivered for introduction into interstate commerce, as with cigarettes, cigarette tobacco, RYO, and smokeless tobacco first marketed after June 22, 2009 (section 904(c)(1)).

II. Significance of Guidance

FDA is issuing this revised draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ingredient listing. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This revised 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 revised draft guidance includes information and recommendations for how to provide ingredient listing submissions. The collections of information in section 904(a)(1) of the FD&C Act have been approved under OMB control number 0910–0650.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the draft guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: October 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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