

revised burden estimates for the proposed changes and solicited public comment. In response to requests, the comment period was extended to January 21, 2017 (81 FR 75351, October 31, 2016). In the interim, FDA is seeking an extension of OMB approval for the

current regulations so that we can continue to collect information while the proposal is pending.

*Description of Respondents:* The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or government agencies.

In the **Federal Register** of April 25, 2017 (82 FR 19054), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
58.35(b)(7); Quality assurance unit .....	300	60.25	18,075	1	18,075
58.185; Reporting of nonclinical laboratory study results ...	300	60.25	18,075	27.65	499,774
<b>Total</b> .....					517,849

<sup>1</sup> There are no capital costs or operating maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
58.29(b); Personnel .....	300	20	6,000	.21 (13 minutes) .....	1,260
58.35(b)(1)–(6), and (c); Quality assurance unit .....	300	270.76	81,228	3.36 .....	272,926
58.63(b) and (c); Maintenance and calibration of equipment.	300	60	18,000	.09 (5 minutes) .....	1,620
58.81(a)–(c); SOPs .....	300	301.8	90,540	.14 (8 minutes) .....	12,676
58.90(c) and (g); Animal care .....	300	62.7	18,810	.13 (8 minutes) .....	2,445
58.105(a) and (b); Test and control article characterization.	300	5	1,500	11.8 .....	17,700
58.107(d); Test and control article handling .....	300	1	300	4.25 .....	1,275
58.113(a); Mixtures of articles with carriers .....	300	15.33	4,599	6.8 .....	31,273
58.120; Protocol .....	300	15.38	4,614	32.7 .....	150,878
58.195; Retention of records .....	300	251.5	75,450	3.9 .....	294,255
<b>Total</b> .....					786,308

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

The annual burden for the information collection requirements in these regulations is estimated at 1,304,157 burden hours (517,849 + 786,308 = 1,304,157). The hours per response estimates are based on our experience with similar programs and information received from industry.

Dated: December 13, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-27255 Filed 12-18-17; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-D-6535]

**Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff.” The draft guidance document

recognizes the value of standards and encourages the use of appropriate standards to facilitate the evaluation of products regulated by the Center for Biologics Evaluation and Research (CBER). The guidance describes CBER’s recommendations on the use of standards in product development and the use of such standards in CBER’s managed review process. The draft guidance does not endorse the activities of specific Standards Development Organizations or recommend specific standards for use in regulatory submissions.

**DATES:** Submit either electronic or written comments on the draft guidance by March 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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-2017-D-6535 for "Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff." 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Angela Moy, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft document entitled "Standards

Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff." The Federal Government's policies on the use of standards developed by voluntary consensus standard bodies are described in the Office of Management and Budget Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." The policies outlined in Circular A-119 were codified in the National Technology Transfer and Advancement Act of 1995 (NTTAA). The NTTAA authorizes the National Institute of Standards and Technology to coordinate standards activities for Federal Agencies.

CBER recognizes the value of standards and encourages the use of appropriate standards in the development of CBER-regulated medical products. Sponsors' use of standards can facilitate product development and a more efficient evaluation of regulatory submissions. The draft guidance describes CBER's recommendations on the use of standards in product development and the use of such standards in CBER's managed review process. It describes how standards are developed, the benefits of using standards, and CBER's policy on accepting standards used in regulatory submissions. CBER's use of, and CBER's acceptance of sponsors' use of, voluntary consensus standards do not constitute a delegation of CBER's regulatory responsibilities. Whether or not standards are used, CBER retains the ability to set, and the responsibility for setting, appropriate regulatory criteria for CBER-regulated products.

This draft guidance is being issued 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 standards development and the use of standards in regulatory submissions reviewed in CBER. 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. This guidance is not subject to Executive Order 12866.

##### II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/>

[default.htm](#) or <https://www.regulations.gov>.

Dated: December 14, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-4678]

#### Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability for public comment of modified risk tobacco product applications (MRTPAs) for six Camel Snus smokeless tobacco products submitted by R.J. Reynolds Tobacco Co.

**DATES:** Electronic or written comments on the applications may be submitted until June 18, 2018; however, FDA may modify the comment period by providing notice as described in section I.

**ADDRESSES:** You may submit comments 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-2017-N-4678 for "Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company." 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 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](https://www.regulations.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf).

*Docket:* For access to the docket to read 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:** Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA under section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in an MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (2). The applicant, R.J. Reynolds Tobacco Co., is seeking orders under section 911(g)(1) for each of the 6 products that are the subject of the submitted MRTPAs. A