TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	70	10	700	3	2,100
25.40(a) and (c)	10	1	10	2,160	21,600
Total					23,700

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

Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drugs, and Cosmetic Act (21 U.S.C. 387, 387j, and 387k), product applications and supplements (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. In 2015, FDA estimated it will receive approximately 5 premarket review of new tobacco PMTAs from 5 respondents, 509 reports intended to demonstrate the substantial equivalence of a new tobacco product (SEs) from 509 respondents, 15 exemption from substantial equivalence requirements applications (SE Exemptions) from 15 respondents, and 3 modified risk tobacco product applications (MRTPAs) from 3 respondents. FDA is not accepting claims for categorical exclusions at this time, and estimates that there will be 532 EAs from 532 respondents as required under §§ 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 532 respondents will submit an average of 1 application for environmental assessment. Part of the information in the EA will be developed while writing other parts of a PMTA, SE, Exemption from SE, or MRTPA. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	532	1	532	80	42,560

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

Dated: August 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22507 Filed 9–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0147]

Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; Second Edition; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a second edition of the guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions''. FDA is issuing the second edition to provide further information on demonstrating substantial equivalence (SE) of a new tobacco product, including demonstrating SE when the new tobacco product has: A modified label that renders it distinct from, but has identical characteristics to, a valid predicate product; or a change in product quantity from, but where the per weight composition is identical to, a valid predicate product.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA–2011–D–0147. Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 1–877–287–1373, *CTPRegulations@fda.hhs.gov,* or *annette.marthaler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the second edition of the guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' (second edition SE FAQ guidance). We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115).

In September 2011, FDA issued draft guidance responding to frequently asked questions covering a range of topics on demonstrating the SE of a new tobacco product (September 9, 2011, 76 FR 55927). In March 2015, FDA issued a final guidance on many of the topics included in the September 2011 draft ((March 5, 2015, 80 FR 12011) (March 2015 FAQ guidance)). In May 2015, FDA announced that an interim enforcement policy would be in effect while it considered comments submitted on the March 2015 FAQ guidance. This interim enforcement policy will continue to be in effect for 30 days from the date of issuance of the

second edition SE FAQ guidance. Based on the comments received on the September 2011 draft guidance and the March 2015 final guidance, we are now issuing the second edition FAQ final guidance.

The second edition FAQ guidance describes FDA's current thinking on whether and when a change to a tobacco product's label, product quantity in the package, additives, or specifications renders that product a ''new tobacco product'' subject to premarket review. It explains that a manufacturer may submit streamlined SE reports for certain modifications to labels and changes to product quantity. The guidance also explains FDA's plans and processes for review of the streamlined SE reports. Finally, this guidance responds to several questions that have been raised about the SE process more generally.

The guidance represents the current thinking of FDA on this topic. 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved information collections. 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 collections of information in sections 905(j) and 910 of the FD&C Act (21 U.S.C. 387e(j) and 387j, respectively), as amended by the Tobacco Control Act (Pub. L. 111–31), have been approved under OMB control number 0910–0673; the collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322.

III. Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on *http://www.regulations.gov.* This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *http://www.regulations.gov.* For this document, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

IV. Electronic Access

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

Dated: August 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22494 Filed 9–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than November 9, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System.

OMB No. 0906–xxxx—New

Abstract: The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), administered by HRSA in partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States and Tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities.