provide to the docket specific proposals on what the burden estimates should be for their members for the CFR sections and headings in table 1 of this notice.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) [2]	Total hours
SOP maintenance (See list of 25 SOPs in the **SUPPLEMENTARY INFORMATION** section of this document)	4,184	1	4,184	25	104,600
New startup SOPs	100	25	2500	20	50,000
211.34	4,184	.25	1,046	30/60	523
211.67(c)	4,184	50	209,200	15/60	52,300
211.68	4,184	2	8,368	1	8,368
211.68(a)	4,184	10	41,840	30/60	20,920
211.68(b)	4,184	5	20,920	15/60	5,230
211.72	4,184	.25	1,046	1	1,046
211.80(d)	4,184	.25	1,046	6/60	105
211.100(b)	4, 184	3	12,552	2	25,104
211.105(b)	4,184	.25	1,046	15/60	262
211.122(c)	4,184	50	209,200	15/60	52,300
211.130(e)	4,184	50	209,200	15/60	52,300
211.132(c)	1,698	20	33,960	30/60	16,980
211.132(d)	1,698	.2	340	30/60	170
211.137	4,184	5	20,920	30/60	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	30/60	4,184
211.173	1.077	1	1,077	15/60	269
211.180(e)	4,184	.2	837	15/60	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	15/60	2,092
211.184	4,184	3	12,552	30/60	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368
211.194	4,184	25	104,600	30/60	52,300
211.196	4,184	25	104,600	15/60	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	30/60	20,920
Total	.....	.....	.....	.....	848,625

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Dated: September 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24991 Filed 9–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0212]

Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Applications for Premarket Review of New Tobacco Products.'' The draft guidance is intended to assist persons submitting applications for new tobacco products under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The draft guidance explains, among other things, for new tobacco product applications, who submits, when and how to submit, what information the FD&C Act requires applicants to submit, and what information FDA recommends that applicants submit.

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 draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 27, 2011.

ADDRESSES: Submit electronic comments on the draft guidance, including comments on the proposed collection of information, to *http://www.regulations.gov.*

Submit written comments on the draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance document entitled ''Applications for Premarket Review of New Tobacco Products'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive

label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance:

James Flahive or Carol Drew, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

With regard to the proposed collection of information:

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Applications for Premarket Review of New Tobacco Products.'' This guidance, when finalized, will provide industry with information on how to submit an application for premarket review of a new tobacco product as required by section 910 of the FD&C Act (21 U.S.C. 387j). On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act amends the FD&C Act and grants FDA authority to regulate the manufacture, marketing and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 910 of the FD&C Act requires that FDA issue a market authorization order before a tobacco product may be introduced into interstate commerce when the tobacco product is new or modified in any way. Where a new tobacco product is not substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or exempt from the requirement to obtain a substantial equivalence determination under regulation, applicants must submit a premarket tobacco product application (PMTA) under section 910(b) of the FD&C Act and receive a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act prior to marketing the product.

The draft guidance is intended to assist persons seeking a marketing authorization order under section 910 in submitting a PMTA. The guidance discusses, among other things, the statutory requirement to submit a PMTA, definitions, who submits a PMTA, when a PMTA should be submitted, how a PMTA should be submitted, how FDA will review a PMTA, contents of a PMTA, information to support a public health finding, exemptions for investigational use of new tobacco products, and confidentiality issues.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Applications for Premarket Review of New Tobacco Products.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (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 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.

Title: Applications for Premarket Review of New Tobacco Products (OMB Control Number 0910–NEW).

FDA is announcing the availability of the draft guidance entitled ''Applications for Premarket Review of New Tobacco Products.'' This guidance, when finalized, will provide industry with information on how to submit an application for premarket review of new tobacco products as required by section 910 of the FD&C Act.

On June 22, 2009, the President signed the Tobacco Control Act into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 910(a)(1) of the FD&C Act requires persons who either create a new tobacco product that was not commercially marketed in the United States as of February 15, 2007, or modify a tobacco product in any way after February 15, 2007, ''including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient,'' to submit a premarket tobacco product application and obtain an order from FDA authorizing the marketing of the product before the product may be introduced or delivered for introduction into interstate commerce, unless the product has been shown to be substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or exempt from a substantial equivalence determination under regulation.

The draft guidance entitled ''Applications for Premarket Review of New Tobacco Products'' explains the requirements and provides recommendations for the contents of an application for premarket review of a new tobacco product including a cover letter, an executive summary, full reports of all investigations of health risks, a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product, a full description of methods of manufacturing and processing, a listing of all manufacturing, packaging, and control sites for the product, an explanation of how the product complies with applicable tobacco product standards, samples and components; and proposed labeling. As part of the application, if an applicant does not submit information on any of

the previously mentioned items, they should include a statement indicating which information is not being submitted and an explanation of why the information is not being submitted.

FDA also encourages persons who would like to study their new tobacco product to meet with the Office of Science at the Center for Tobacco Products (CTP) to discuss their investigational plan prior to distributing the product for investigational purposes. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

FDA is required to deny a PMTA and issue an order that the product may not be introduced or delivered for introduction into interstate commerce under section 910(c)(1)(A)(ii) of the FD&C Act if FDA finds that the manufacturer has not shown that the product is appropriate for the protection of the public health, the manufacturing methods, facilities, or controls do not conform to manufacturing regulations issued under section 906(e) (21 U.S.C. 387f(e)) of the FD&C Act, the proposed labeling is false or misleading, or the manufacturer has not shown that the product complies with any tobacco product standard in effect under section 907 of the FD&C Act (21 U.S.C. 387g).

Under section 902(6)(A) (21 U.S.C. 387b(6)(A)), a tobacco product is deemed adulterated if it is a new tobacco product and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act, as necessary under section 910(a) of the FD&C Act. Under section 301(a) of the FD&C Act (21 U.S.C. 331(a)), the introduction or delivery for introduction into interstate commerce of any adulterated tobacco product is a prohibited act. Violations of section 910 are subject to regulatory and enforcement action by FDA, including, but not limited to, seizure and injunction.

Description of respondents: The respondents to this collection of information are applicants who are responsible for creating and submitting new tobacco product premarket applications and who wish to obtain an FDA order to allow them to market their product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collected and FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total burden hours
Obtaining an FDA order authorizing marketing of tobacco product (the application) Section 910(a)(1)(B)	20	1	20	5,000	100,000
Request for Meeting with CTP's Office of Science to discuss Investigational Plan	18	1	18	4	72
21 CFR 25.40 Preparation of an Environmental Assessment	20	1	20	12	240
Total Reporting Burden Hours					100,312

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

FDA estimates that each respondent will take approximately 5,000 hours to complete the information required in table 1 of this document to obtain an order from FDA allowing the marketing of a new tobacco product. FDA's estimate includes anticipated burden for the writing of an application, including intracompany edits and approvals, of approximately 200 hours. In addition, FDA expects that conducting the necessary scientific investigations for a new tobacco product will require, on average, 4,800 hours. FDA also estimates the number of PMTA applications that FDA expects to receive annually will be 20.

FDA anticipates that 18 potential respondents to this collection of information may need to meet with CTP's Office of Science to discuss their investigational plans. To request this meeting, applicants must compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 4 hours to compile this information, for a total of 72 hours additional burden (18 respondents × 4 burden hours).

FDA also estimates that 20 potential respondents will take approximately 12 hours to prepare and submit an environmental assessment under part 25 (21 CFR part 25) in accordance with the requirements of § 25.40, as referenced in 21 CFR 1107.1(b)(9).

The total burden for this collection of information is estimated to be 100,312 hours ((20 respondents multiplied by 5,000 per response) plus (18 respondents multiplied by 4 hours per response) plus (20 respondents multiplied by 12 hours per response)). These burden estimates were computed using FDA staff expertise and by reviewing comments received from recent FDA information collections for other tobacco-related initiatives.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

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

Dated: September 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24989 Filed 9–27–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as