efficiency of the review process. Although alternative approaches may be used, if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of October 28, 2013 (78 FR 64218), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. However, the comment was beyond the scope of the collection of information's four topics that are being solicited. Therefore, it will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part 25; Environmental impact considerations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 25.32(i)	42	1	42	1	42
§ 25.32(o)	1	1	1	1	1
§ 25.32(q)	2	1	2	1	2
Total					45

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

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested for each of these three categorical exclusions in this guidance is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30998 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1558]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information request regarding the guidance for industry and FDA staff entitled ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.''

DATES: Submit either electronic or written comments on the collection of information by February 25, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under 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, including each proposed extension of an existing 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.

Information Request Regarding Guidance for Industry and FDA Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (OMB Control Number 0910–0673—Extension)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) authorizes FDA to establish the form for the submission of information related to substantial equivalence. In a Level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act sections	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
905(j)(1)(A)(i) and 910(a)	1,000	1	1,000	360	360,000

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

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387j(a)). FDA estimates that it will receive 1,000 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 360,000 hours.

Dated: December 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30880 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Publication of a Draft of the Revised Guidebook for the National Practitioner Data Bank

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Publication of a Draft of the Revised Guidebook for the National Practitioner Data Bank.

SUMMARY: The National Practitioner Data Bank (NPDB) announces the release of a draft of the revised user Guidebook. The public is able to request a copy of the draft of the revised Guidebook and submit comments to the NPDB by the deadline below. The revised Guidebook includes expanded and improved reporting and querying examples; useful tables explaining Data Bank policies; and live links to statutes, regulations, and the Web site.

The NPDB is a confidential information clearinghouse created by Congress intended to facilitate a comprehensive review of the professional credentials of health care practitioners, health care entities, providers, and suppliers. The Guidebook is a policy manual that serves as an essential reference for Data Bank users to clarify legislative and regulatory requirements through the use of reporting and querying examples, explanations, definitions, and frequently asked questions (FAQs). The new Guidebook incorporates legislative and regulatory changes adopted since its last edition, including the merger of the NPDB with the Healthcare Integrity and Protection Data Bank. Once the comments have been reviewed, a final version of the revised Guidebook will be made available and will replace previous Guidebooks. For information on how to request a PDF copy of the draft Guidebook and instructions on how to submit comments, visit the NPDB Web site at: *http://www.npdb.hrsa.gov/news/news.jsp*.

DATES: Comments may be submitted through January 10, 2014. The comment period may be extended if needed. Information on any extensions of the review period will be posted on the Web site here: *http://www.npdb.hrsa.gov/news/news.jsp*.

FOR FURTHER INFORMATION CONTACT: Ernia P. Hughes, MBA, Acting Director of the Division of Practitioner Data Banks at: *NPDBPolicy@hrsa.gov* or 301–443–2300.

SUPPLEMENTARY INFORMATION: When submitting remarks, the NPDB requests that commenters:

- Reference the page number(s) each comment addresses; and
- Ensure comments are specific and relate to the clarity of the NPDB Guidebook's content, as regulatory or statutory concerns are beyond the scope of this comment process. Comments should be limited to content-based feedback that seeks to improve the examples and FAQs, clarify definitions, and eliminate ambiguity in the text. Comments that are not specific to content clarity and found beyond the scope of this review will not be addressed in this process.

Dated: December 19, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–31119 Filed 12–26–13; 8:45 am]

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