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]

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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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