

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.

**State Petitions for Exemption From Preemption—21 CFR 100.1(d)**

OMB Control Number 0910-0277—  
Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343-1(b)), States may petition FDA for exemption from

Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

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

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

21 CFR 100.1(d)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form of petition .....	1	1	1	40	40

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, we have received one new petition for exemption from preemption; therefore, we estimate that one or fewer petitions will be submitted annually.

Dated: June 12, 2017.

**Anna K. Abram,**

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-2683]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 17, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910—NEW and “Data to Support Social and Behavioral Research as Used by the Food and Drug Administration.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Data To Support Social and Behavioral Research as Used by the Food and Drug Administration—OMB Control Number 0910—NEW**

Understanding patients, consumers, and health care professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decisionmaking processes and communications impacting various stakeholders. The methods to be

employed to achieve these goals include individual indepth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and focus group interviews. The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative and quantitative research tool, and have two major purposes:

(1) To obtain information that is useful for developing variables and measures for formulating the basic objectives of social and behavioral research; and

(2) To assess the potential effectiveness of FDA communications, behavioral interventions, and other materials in reaching and successfully communicating and addressing behavioral change with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop communication and behavioral strategies research, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and potentially other Agency components will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions, beliefs, attitudes, behaviors, and use of

drug and biological products and related materials, including, but not limited to, social and behavioral research, decisionmaking processes, and communication and behavioral change strategies.

Annually, FDA estimates about 45 social and behavioral studies using the variety of test methods listed in this

document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of September 19, 2016 (81 FR 64166), FDA published a 60-day notice requesting public

comment on the proposed extension of this collection of information. No comments were received in response to the notice.

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

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys .....	2,520	14.6	36,792	0.25 (15 minutes) ...	9,198

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

Dated: June 12, 2017.

**Anna K. Abram,**  
Deputy Commissioner for Policy, Planning,  
Legislation, and Analysis.

[FR Doc. 2017-12446 Filed 6-14-17; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-D-0329]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 collection in the guidance on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**DATES:** Submit either electronic or written comments on the collection of information by August 14, 2017.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 14, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 14, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2014-D-0329 for "Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the Federal Food, Drug, and Cosmetic Act." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management 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