

necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) of our regulations (21 CFR 111.75(a)(1)) establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Under § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to

the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower

frequency, we added to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under 21 CFR 10.30 and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95 (21 CFR 111.95). The collection of information in § 111.95 has been approved under OMB control number 0910-0606.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75(a)(1)(ii); Determining whether specifications are met	1	1	1	8	8

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

Since OMB's last approval of the information collection, we have received no petitions. We therefore retain the currently approved estimated burden, which assumes no more than one petition will be submitted annually. We further assume it would take respondents 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition, for a total of 8 burden hours annually. These figures are based on our experience with the information collection.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1201]

Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials." This draft guidance discusses the ethical and scientific issues when considering the inclusion of pregnant women in clinical trials of drugs and biological products. This draft guidance is intended to advance scientific research in pregnant women, and discusses issues that should be considered within the framework of human subject protection regulations.

DATES: Submit either electronic or written comments on the draft guidance

by June 8, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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

- For written/paper comments submitted to the Dockets Management Staff, 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-2018-D-1201 for “Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials; Draft Guidance; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/>

[fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf](https://www.fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf).

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993, 301-796-6169.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials.” Currently, collection of safety data on prescription drugs and biological products used during pregnancy usually occurs after approval, and clinicians and patients must undertake a risk-benefit analysis for the use of such products in pregnant women with limited human safety information. Historically, pregnant women have been an understudied population and there have been barriers to obtaining data from pregnant women in clinical trials, including concerns about protecting women and their fetuses from research-related risks. However, data are needed to inform safe and effective treatment during pregnancy, and in certain situations, it is ethically and scientifically appropriate to collect data in pregnant women in clinical trials conducted during drug development.

This draft guidance discusses the ethical and scientific issues when considering the inclusion of pregnant women in clinical trials of drugs and

biological products. This draft guidance is intended to advance scientific research in pregnant women, and discusses issues that should be considered within the framework of human subject protection regulations.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on scientific and ethical considerations for inclusion of pregnant women in clinical trials. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; NURSE Corps Loan Repayment Program, OMB #0915-0140—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than May 9, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to