4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket Nos. FDA-2017-N-5092, FDA-2017-N-5093, FDA-2017-N-5094, FDA-2017-N-5095, FDA-2017-N-5101, FDA-2017-N-5104, and FDA-2017-N-5105]

Review of Existing Regulatory and Information Collection Requirements; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Requests for comments and information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the Requests for Comments and Information that appeared in the *Federal Register* of September 8, 2017. In the Requests for Comments and Information, FDA requested comments and information from interested parties to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the Requests for Comments and Information documents published September 8, 2017 (82 FR 42492, 82 FR 42494, 82 FR 42497, 82 FR 42499, 82 FR 42501, 82 FR 42503, and 82 FR 42506). Submit either electronic or written comments by February 5, 2018.

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 February 5, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of February 5, 2018. 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): 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 document number and title (see SUPPLEMENTARY INFORMATION). 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 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.

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 a 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.

FOR FURTHER INFORMATION CONTACT: Megan Velez, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830, megan.velez@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 8, 2017, FDA published seven Requests for Comments and Information with a 90-day comment period to request comments and information from interested parties to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations.

Docket No.	Title of Document
FDA-2017-N-5092	Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements
FDA-2017-N-5093	Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration
FDA-2017-N-5094	Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements
FDA-2017-N-5095	Review of Existing Center for Tobacco Products Regulatory and

	Information Collection Requirements
FDA-2017-N-5101	Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements
FDA-2017-N-5104	Review of Existing Center for Veterinary Medicine Regulatory and Information Collection Requirements
FDA-2017-N-5105	Review of Existing Center for Devices and Radiological Health Regulatory and Information Collection Requirements

The Agency has received requests for a 60-day extension of the comment period for the Requests for Comments and Information. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the Requests for Comments and Information.

FDA has considered the requests and is extending the comment period for the Requests for Comment and Information for 60 days, until February 5, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying work on these important issues.

Dated: November 30, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-26199 Filed: 12/5/2017 8:45 am; Publication Date: 12/6/2017]