4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0198]

Current Good Manufacturing Practice Requirements for Combination Products; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products." The guidance describes and explains the document on current good manufacturing practice (CGMP) requirements for combination products, which published in the Federal Register of January 22, 2013, and includes general considerations for CGMP compliance as well as analysis of hypothetical scenarios.

DATES: Submit either electronic or written comments on this guidance at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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-2015-D-0198 for "Current Good Manufacturing Practice Requirements for Combination Products; Final Guidance for Industry and FDA Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://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 for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance document entitled "Current Good Manufacturing Practice Requirements for Combination Products" to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns or John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products." The guidance provides background on combination products, including an overview of the document on CGMP requirements for combination products, which published in the Federal Register of January 22, 2013 (78 FR 4307), and the role of the lead center and other Agency components with respect to combination product CGMP issues. The guidance addresses general considerations for CGMP requirements for combination products and the purpose and content of specific CGMP provisions addressed in part 4 (21 CFR part 4). The guidance also contains hypothetical scenarios intended to clarify how to comply with certain CGMP requirements addressed in part 4 by presenting compliance considerations for specific types of combination products.

FDA carefully considered the comments received on the draft guidance, and, where possible, has incorporated into the final guidance additional detailed discussion of how the requirements apply and acceptable CGMP compliance approaches. FDA encourages combination product manufacturers to contact the lead Center for their combination product and/or the Office of Combination Products if they have questions on CGMP compliance or approaches they are considering for meeting CGMP requirements.

II. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM429304.pdf.

III. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). We note that the information collected under the underlying CGMP regulations for drugs, devices, and biological products, including current good tissue practices for human cells, tissues, and cellular and tissue-based products, found at parts 211, 820, 600 through 680, and 1271 (21 CFR parts 211, 820, 600 through 680, and 1271), have already been approved and are in effect. The provisions of part 211 are approved under OMB control number 0910-0139. The provisions of part 820 are approved under OMB control number 0910-0073. The provisions of parts 606 and 640 are approved under OMB control number 0910-0116. The provisions of part 610 are approved under OMB control numbers 0910-0116 and 0910-0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910-0543.

Dated: January 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00411 Filed: 1/10/2017 8:45 am; Publication Date: 1/11/2017]