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Current Good Manufacturing Practice Requirements for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products." The guidance describes and explains the final rule on current good manufacturing practice (CGMP) requirements for combination products, including presenting general considerations for CGMP compliance as well as analysis of hypothetical scenarios.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Current Good Manufacturing Practice Requirements for Combination Products" to the Office of Combination Products, Food and Drug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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: 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FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products."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 final rule on CGMP requirements for combination products (78 FR 4307, January 22, 2013) (21 CFR part 4) 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. 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. Throughout the guidance, reference is made to other existing guidance and additional sources of information addressing CGMP requirements for drugs,

devices, biological products, and human cells, tissues, and cellular and tissue-based products (HCT/Ps). Concurrent with publication of this draft guidance, FDA is withdrawing the draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice for Combination Products," which was issued in September 2004.

II. Significance of Guidance

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 Agency's current thinking on CGMP requirements for combination products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act

This draft 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 HCT/Ps, found at 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 the Office of Management and Budget (OMB) control number 0910-0139. The provisions of part 820 are approved under OMB control number 0910-0073. The provisions of parts 606, 640, and 660 are approved under OMB control number 0910-0116. The provisions of part 610 are approved under OMB control number 0910-0116 and

OMB control number 0910-0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910-0543.

IV. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

V. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/RegulatoryInformation/Guidances/ucm126198.htm or http://www.regulations.gov.

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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