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Current Good Manufacturing Practice Requirements for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period by 30 days to April 29, 2015, for the notice entitled "Current Good Manufacturing Practice Requirements for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability," that appeared in the Federal Register of January 27, 2015 (80 FR 4280). In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance. Submit either electronic or written comments by April 29, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled " Current Good Manufacturing Practice Requirements for Combination Products" to the Office of Combination Products, Food and Drug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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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, email: John.Weiner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 27, 2015 (80 FR 4280), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products."

The Agency received a request for a 30-day extension of the comment period for the draft guidance. The request conveyed concern that the current 60-day comment period does not allow sufficient time to respond. FDA has considered the request and is extending the comment period for the draft guidance for 30 days, until April 29, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

II. 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.

III. 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: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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