4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1492]

# Two-Phased Chemistry, Manufacturing, and Controls Technical Sections; Draft Guidance for Industry; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for a notice of availability of draft guidance for industry (GFI #227) entitled "Two-Phased Chemistry, Manufacturing, and Controls Technical Sections" that appeared in the Federal Register of October 20, 2014. In that notice, FDA made available for comment the draft guidance, which provides recommendations to sponsors submitting chemistry, manufacturing, and controls (CMC) data submissions. 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DATES: FDA is extending the comment period on the draft guidance. Submit either electronic or written comments on the draft guidance by February 17, 2015.

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Heather Longstaff, Center for Veterinary Medicine (HFV-145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0651, email: heather.longstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

In the Federal Register of October 20, 2014 (79 FR 62635) FDA published a notice announcing the availability of draft guidance for industry (GFI #227) entitled "Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections." It is intended to provide recommendations to industry regarding CMC data submitted to the Center for Veterinary Medicine to support approval of a new animal drug or abbreviated new animal drug. The notice invited comments on the draft guidance by December 19, 2014.

The Agency received a request for a 60-day extension of the comment period for the draft guidance.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 60 days, until February 17, 2015. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

## II. Request for 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.

Dated: December 2, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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