This document is scheduled to be published in the
Federal Register on 09/01/2015 and available online at
http://federalregister.gov/a/2015-21583, and on **FDsys.gov**

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; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI) #227 entitled "Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections." The guidance provides recommendations to sponsors submitting chemistry, manufacturing, and controls (CMC) data submissions to the Center of Veterinary Medicine (CVM) to support approval of a new animal drug or abbreviated new animal drug.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, heather.longstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2014 (79 FR 62635) FDA published the notice of availability for a draft guidance for industry #227 entitled "Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections" giving interested persons until December 19, 2014, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated October 2014.

GFI #227 provides recommendations to sponsors submitting CMC data submissions to CVM to support approval of a new animal drug or abbreviated new animal drug. The two-phased process allows for two separate CMC submissions, each with its own review clock, and each including complete appropriate CMC information that is available for review at the time of submission. The guidance specifies the technical details of how the process works, the review clocks, the information that is appropriate for each technical section submission, and the possible review outcomes. The guidance also includes CVM's recommendations for meetings between the Division of Manufacturing Technologies and the sponsor during this process to ensure concurrence with the approach used for the CMC technical section.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). This guidance represents the current thinking of FDA on two-phased CMC technical sections. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

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). The collections of information in 21 CFR part 514 and section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control numbers 0910-0032 and 0910-0669, respectively.

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 guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-21583 Filed: 8/31/2015 08:45 am; Publication Date: 9/1/2015]