4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0566]

Residual Solvents in Animal Drug Products; Questions and Answers; 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 #211 entitled "Residual Solvents in Animal Drug Products; Questions and Answers." The questions and answers guidance addresses the United States Pharmacopeia (USP) General Chapter <467> Residual Solvents that applies to both human and veterinary drugs and to compendial and non-compendial drug products. This document answers questions regarding the Center for Veterinary Medicine's (CVM) implementation of USP <467> Residual Solvents.

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 Communications Staff (HFV-12), 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 request. 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 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, email: heather.longstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 3, 2010 (75 FR 75482), FDA published the notice of availability for a draft guidance entitled "Residual Solvents in Animal Drug Products; Questions and Answers" giving interested persons until February 1, 2011, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. Two of the questions and answers were revised, in addition to a few editorial changes made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2, 2010.

On July 1, 2008, the USP implemented a requirement for the control of residual solvents in drug products marketed in the United States. Once implemented, the requirement, USP General Chapter <467> Residual Solvents, became a statutory requirement under section 501(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(b)). This document answers questions regarding CVM's implementation of USP <467> Residual Solvents.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Residual

Solvents in Animal Drug Products; Questions and Answers." 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 have been approved under OMB control number 0910-0032; the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C. 360k) have been approved under OMB control number 0910-0669.

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: March 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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