DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0499]

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice to Extend Expiration Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of expiration date.

SUMMARY: The Food and Drug Administration (FDA) is extending the expiration date of the compliance policy guide (CPG) entitled ''Sec. 400.210—Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs'' to December 31, 2008.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of the Commissioner, Office of Policy, Planning, and Preparedness (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION: On November 17, 2004, FDA announced the availability of the CPG entitled ''Sec. 400.210—Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs.'' FDA has identified RFID as a promising technology to be used in the various efforts to combat counterfeit drugs. The CPG describes how the agency intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs. The goal of the CPG is to facilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the U.S. drug supply.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. Section 913 of FDAAA addresses pharmaceutical safety and creates section 505D of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355D). Section 505D(b) of the act requires the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) of the act states that these new standards shall address promising technologies, which may include RFID technology.

As FDA considers the overlapping and complementary issues raised in the CPG and section 505D of the act, as well as the experience of stakeholders and the agency under the CPG, and whether to amend, revoke, or further extend the CPG, the CPG will remain in effect until December 31, 2008.

Dated: November 15, 2007.

David Horowitz,

Assistant Commissioner for Regulatory Affairs.

[FR Doc. E7–22818 Filed 11–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0439]

Draft Guidance for Industry on Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention; 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 entitled ''Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention.'' In this draft guidance, FDA provides recommendations on the development of drugs to be used to treat or prevent smallpox (variola) infection. This guidance is intended to help sponsors plan and design appropriate studies during the development of these drugs.

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 written or electronic comments on the draft guidance by January 22, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Debra B. Birnkrant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6332, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention.'' This guidance provides recommendations on the development of drugs to be used to treat or prevent smallpox (variola) infection. The study of smallpox drug development poses special challenges in drug development because of the unique attributes of the pathogen. Therefore, this guidance focuses on the importance of pre-investigational new drug application interactions between sponsors and FDA, appropriate approaches to nonclinical studies in early drug development, generation and use of supporting data from related poxviruses, design and characterization of animal models, approaches to clinical trials including safety studies, advance preparation of protocols for potential use in emergency settings, and use of combinations of animal and human data.

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 developing drugs to treat or prevent smallpox (variola) infection. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

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). The collections of information in 21 CFR part 312 have been approved under OMB Control No. 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22884 Filed 11–21–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0139]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (#73) entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision) VICH GL3(R).'' This revised guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This revised document is intended to provide guidance regarding the development of stability testing data for new animal drug applications (referred to as registration applications in the guidance) submitted to the European Union (EU), Japan, and United States.

DATES: Submit written or electronic 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 (CVM), 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 written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. Submit electronic comments on the guidance via the Internet at *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. VICH is a parallel initiative for veterinary medicinal products. VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH steering committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

II. Revised Guidance on Stability Testing of New Veterinary Drug Substances and Medicinal Products

In the **Federal Register** of April 14, 2006 (71 FR 19525), FDA published a notice of availability for a draft revised guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'', VICH GL3(R) giving interested persons until May 15, 2006, to comment on the draft revised guidance. No comments were received. The revised guidance announced in this notice finalizes the draft revised guidance announced on April 14, 2006. The revised guidance is a product of the quality expert working group of the VICH. The revised guidance seeks to exemplify the core stability data package to be included in registration applications for new veterinary drug substances and medicinal products.