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.