## The Federal Register Online Via GPO Access; Public Meeting for Federal, State and Local Agencies, and Others Interested in a Demonstration of GPO Access, the Online Service Providing the Federal Register and Other Federal Databases

The Superintendent of Documents will hold a public meeting for Federal, state, and local government agencies, and others interested in an overview and demonstration of the Government Printing Office's online service *GPO Access,* provided under the Government Printing Office Electronic Information Access Enhancement Act of 1993 (Public Law 103–40).

The session is available on Wednesday, April 5, 1995, from 1 p.m. to 2:30 p.m. The training session will be held at the Dallas Public Library, Library Auditorium, 1515 Young Street, Dallas, Texas 75201.

The online **Federal Register** Service offers access to the daily issues of the **Federal Register** by 6 a.m. on the day of publication. All notices, rules and proposed rules, Presidential documents, executive orders, separate parts, and reader aids are included in the database as ASCII text files, with graphics provided in TIFF format. The online **Federal Register** is available via the Internet or as a dial-in service. Historical data is available from January 1994 forward.

Other databases currently available online through *GPO Access* include the *Congressional Record; Congressional Record Index,* including the *History of Bills;* Congressional Bills; Public Laws; and *U.S. Code.*

Individuals interested in attending the training session should contact the GPO's Office of Electronic Information Dissemination Services, John Berger, Product Manager, on 202–512–1525; (FAX) 202–512–1262; or by Internet e-mail at help@eids05.eids.gpo.gov. Seating reservations will be accepted through Friday, March 31, 1995.

**Michael F. DiMario,**

*Public Printer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 92D–0039]**

## Animal Drug Manufacturing; Revised Guideline; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the revised four-part guideline entitled, ''Animal Drug Manufacturing Guidelines, 1994'' prepared by the Center for Veterinary Medicine (CVM). These guidelines describe the data and information for the manufacturing portions of abbreviated new animal drug applications, new animal drug applications, and supplements for pharmaceutical dosage forms.

**DATES:** Written comments on these guidelines may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the revised guidelines entitled, ''Animal Drug Manufacturing Guidelines, 1994: I. Pilot Batch Manufacture, II. Tentative Expiration Dates, III. Manufacturing Sites, and IV. New Animal Drug Substance Sources'' to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the revised guidelines to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the revised guidelines and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** William G. Marnane, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

**SUPPLEMENTARY INFORMATION:** The Food and Drug Administration (FDA) is announcing the availability of the revised four-part guideline entitled, ''Animal Drug Manufacturing Guidelines, 1994: I. Pilot Batch Manufacture, II. Tentative Expiration Dates, III. Manufacturing Sites, and IV. New Animal Drug Substance Sources'' prepared by CVM. These guidelines are intended to be used by both pioneer and generic manufacturers of veterinary drug products so that they are informed of the type of information that FDA believes will provide an acceptable submission to support the manufacturing requirements for new animal drug applications, abbreviated new animal drug applications, and supplemental applications for pharmaceutical dosage forms. In the **Federal Register** of August 21, 1992 (57 FR 37979), FDA issued a notice of availability of the four CVM guidelines entitled, ''Animal Drug Manufacturing Guidelines, 1992.'' Comments by the public were requested to be submitted at any time so that future revisions of the guidelines could be developed in consideration of the remarks.

The agency received three comments on the 1992 guidelines. The comments came from two drug manufacturers and one trade association. The 1992 guidelines have been revised as a result of these comments and from internal discussions within CVM.

Many editorial comments were made about all four guidelines. The editorial comments were adopted in the revised guidelines when the agency deemed that they were appropriate and provided clarification. Technical comments about ''Guideline I. Pilot Batch Manufacture'' focused on the CVM recommendations for the size of the test batch and the type of equipment or production facility that is appropriate for manufacturing test lots. A suggestion was made to allow bridging data in cases where the recommendations for batch size, production facility, equipment, and standard operating procedures are not practicable. Technical comments about ''Guideline II. Tentative Expiration Dates'' centered on a clarification of the definition of exaggerated storage conditions for different dosage forms and the application of expiration dating to all manufacturing sites for one drug product. Technical comments about ''Guideline III. Manufacturing Sites'' included criticisms of the definitions of the different types of manufacturing sites, the option for the agency to request bioequivalence data, and the appropriate location of sterile process validation data in the drug application. Technical comments about ''Guideline IV. New Animal Drug Substance Sources'' were made regarding the definitions of primary and alternate sources of the new animal drug substance, test batch and stability data for supplemental applications, and bioequivalence data requirements for mastitis products. All of these comments were considered in the revision of the manufacturing guidelines.

One of the most significant changes to the 1992 guidelines is to allow bridging data to be submitted when the recommendations for batch size, production facility, equipment, and standard operating procedures for pilot