ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment on a draft Level 1 guidance document entitled ''FDA Approval of Animal Drugs for Minor Uses and for Minor Species.'' The guidance document defines minor species and minor uses and sets forth suggestions for generating safety and effectiveness data to support the approval of minor use and minor species drugs. The draft Level 1 guidance document sets forth substantive changes in policy that warrant input from affected parties.

DATES: Submit written comments on the draft guidance document by December 29, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the draft guidance document to the Communications and Education Team (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Margaret R. Oeller, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1650. E-mail: moeller@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's draft guidance document entitled ''FDA Approval of Animal Drugs for Minor Uses and for Minor Species,'' is a Level 1 guidance document by definition in the Good Guidance Practices (62 FR 8961, February 27, 1997). This notice of availability for comment should not be confused with the **Federal Register** document of June 23, l997 (62 FR 33781), entitled ''Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses,'' which dealt with the same subject matter but was issued to seek comment and suggestions on legislative and regulatory options which could be utilized if adopted in the future to facilitate approval of new animal drugs for minor uses and minor species.

This draft, when finalized, will replace the previous guidance entitled ''Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Minor Use of Animal Drugs,'' (guidelines) dated April 1986. In the **Federal Register** of May 30, l986 (51 FR 19612), FDA issued a notice of availability of the guidelines. No comments were received on the guidelines. A previous version of the draft guidance document was made available in November 1996 to interested parties who requested a copy.

The draft guidance document suggests procedures that could be used to demonstrate the safety and efficacy of a minor use animal drug. Minor use animal drugs are defined as: (1) New animal drugs used in minor animal species or (2) new animal drugs used in any animal species for the control of a disease that occurs infrequently or in limited geographic areas. ''Minor species'' are defined by regulation as animals other than cattle, horses, swine, chickens, turkeys, dogs, and cats. According to current regulations, sheep are a minor species except with respect to human food safety data collection requirements, for which sheep are considered a major species. FDA intends to issue a proposed regulation in which sheep would be considered a minor species for all requirements of the drug approval process.

The procedures set forth in the draft guidance document for demonstrating the safety and efficacy of a minor use animal drug apply to production drugs as well as therapeutic drugs.

The draft guidance document has been organized in two parts. Part 1 includes general information on the document, an overview of the approval process, data extrapolation, advice on working with the Center for Veterinary Medicine (CVM), and definitions. Part 2 presents specific options for satisfying data requirements for minor uses in major species, minor avian species (gamebirds, semi-domestic waterfowl, and ratites), minor ruminants (goats, bison, semi-domestic deer), rabbits, and aquatic species (finfish, aquatic invertebrates, alligators, etc.). Each section in part 2 contains information on efficacy, target animal safety, human food safety, and environmental data requirements. The major data components, excluding manufacturing chemistry, of the animal drug approval process are represented in part 2.

When finalized, the draft guidance document will represent the agency's current thinking on the means of generating efficacy and safety data to support approval of new animal drug applications for minor use of new animal drugs. This draft guidance document will not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may, on or before December 29, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document, and with the full title of the guidance document. The comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. After review of these comments, FDA will implement the guidance document with any appropriate changes. Thereafter, interested persons may submit written comment on the guidance document directly to the CVM Communications and Education Team (address above).

III. Electronic Access

A copy of the draft guidance document may be obtained from the CVM Home Page (http://www.cvm.fda.gov) on the Internet.

Dated: September 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25667 Filed 9–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0282]

General Principles of Software Validation; Draft Guidance; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 30, 1997, the comment period for the notice announcing the availability of a draft guidance entitled ''General Principles of Software Validation'' that published in the **Federal Register** of July 25, 1997 (62 FR

40099). The draft guidance discusses how the general provisions of the Quality System Regulation apply to software and the agency's current approach to evaluating a software validation system. The agency is taking this action in response to a request for an extension to allow additional time for comment on this draft guidance document.

DATES: Written comments by December 30, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: E. Stewart Crumpler, Center for Devices and Radiological Health (HFZ–343), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 25, 1997 (62 FR 40099), FDA announced the availability of a draft guidance entitled ''General Principles of Software Validation.'' The draft guidance discusses how the general provisions of the Quality System Regulation apply to software and the agency 's current approach to evaluating a software validation system. Interested persons were given until October 1, 1997, to submit written comments on the notice. FDA received a request from the Health Industry Manufacturers Association to extend the comment period for 90 days. This would give them sufficient time to review the document and ensure quality comments on the document.

FDA is extending the comment period for 90 days to assure adequate time for preparation of comments. Accordingly, FDA finds under section 520(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360j(d)) that there is good cause for such an extension.

Interested persons may, on or before December 30, 1997, submit to the Docket Management Branch (address above) written comments regarding the notice. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25669 Filed 9–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Application and Annual Report, Maternal and Child Health Block Grant Program (OMB No. 0915–0172)—Extension and Revision

The Health Resources and Services Administration (HRSA) has revised and reformatted the Maternal and Child Health Block Grant Guidance. This guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The revisions are designed to simplify and clarify the guidance and required forms and to reduce duplication, while still allowing for clear, concise, useful, and accurate communication about the States' programs. More specifically, the revisions are designed to: (1) Make the program descriptions more readable; (2) alleviate the disconnect between the application for the next fiscal year and the annual report for the previous fiscal year that makes programmatic and data reviews difficult; (3) clarify budget and expense tables, through better design of forms and by carrying totals from form to form; (4) report objectives in a standard format, including the relationship to Healthy People 2000 goals, to facilitate year-to-year comparisons and multi-State tabulations; and, (5) incorporate uniform performance measures across all States and jurisdictions as well as State/jurisdiction-specific performance measures.

The HRSA revision also combines the current three guidance documents into one document by eliminating the separate annual application and annual report in favor of a combined document, and every fifth year explicitly including the results of the needs assessment, which would be incorporated only by reference in the intervening years. The HRSA revision efforts are intended not only to simplify and expedite the rational submission of necessary data and reports, but also to reduce the burden on States and jurisdictions by eliminating duplicative requirements and streamlining the presentation of information. Estimates of burden to complete the application and annual report are as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Application and Annual Report, 1998–99 (without needs assessment):*				
States	50	1	500	25,000
Jurisdictions	9	1	200	1,800
Five-Year Application and Annual Report, 2000 (with needs assessment): *				
States	50	1	750	37,500
Jurisdictions	9	1	400	3,600
Weighted Annual Average (over next three years):				
States	50	1	555	29,167
Jurisdictions	9	1	267	2,400

*The Annual Application and Annual Report, without needs assessment, will be submitted in FY 1998 and FY 1999. The five-year Annual Application and Annual Report will be submitted in FY 2000. The average annual response burden for the next three years is 31,567 hours.