Field name	Comments
Record Identifier	Enter 'T4' for W4 data. Enter 'TQ' for Quarterly Wage data. Enter 'TU' for Unemployment Insurance data.
Data Record Count	Enter the total number of records transmitted in this data set, including the header and trailer records. This will be used to verify that all records are received and processed.
Filler	Spaces. To be used for future versions of the system.

Data Record

Each of the data records for W4, Quarterly Wage, and UI is different in several ways. Following is further explanation of some of the data elements in those record layouts. See the Record Layout specifications for detailed information on all data elements.

Field name	Comments
Record Identifier	Enter 'W4' for the W4 record. Enter 'QW' for the Quarterly Wage record. Enter 'UI' for the Unemployment Insurance record.
Foreign Address Data Elements	If an address supplied for the employee or employer is outside the United States, include the Foreign Country Code for the address, the Foreign Country Name, and the Foreign Zip Code.
Employee Wage Amount (QW)	For Quarterly Wage data, provide the gross amount paid to the employee during the quarter, regardless of when the amount was earned.
Reporting Period	Use the quarters that correspond to the calendar year rather than quarters that correspond to fiscal accounting periods. Use the format QYYYY where: Q = 1 for January–March. Q = 2 for April–June. Q = 3 for July–September. Q = 4 for October–December.
Benefit Amount (UI)	The UI Benefit Amount is the gross amount paid within the reporting quarter before any withholding offsets are applied. This amount should be the sum of benefits received from all programs tracked electronically by the State. However, only include those benefits that are housed in the same hardware environment. Do not include benefits from sources that must be translated or imported to the mainframe environment.

Output Records

FPLS will return records to the data transmitters when errors were detected. The states can elect to have these records returned for error resolution or not as they choose. Federal agencies, however, will receive all error records from each transmittal.

The record formats for the error records are identical to the input record provided by the submitter except that error codes will be appended that explain the nature of the error. Errors can occur at the transmission level and at the individual record level.

Transmission Control Records: This is the output equivalent of the input TRANSMITTER RECORD and includes counts of records received, records rejected, error records returned, records posted to the National Director of New Hires, records posted to the Suspense File, and up to five Error Codes pertaining to the transmission level error conditions encountered.

Data Records: Each output version of the input DATA RECORD had appended to it up to five record level error codes that indicate the nature of the error encountered during editing. It also contains a Social Security Number Verification Indicator that indicates whether multiple valid SSNs were encountered during the SSN verification process. In addition, a corrected SSN is returned if during the SSN verification process the supplied SSN was determined to be incorrect and the verification procedure was able to provide the correct SSN.

Total Records: No transmission total records will be returned to the submitting State or federal agency.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

In addition, comments may also be forwarded to ACF at the following address: The Administration for Children and Families, Office of Information Services, Division of Information Resources, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: Reports Clearance Officer, Internet address: rjdriscoll@acf.dhhs.gov.

Dated: September 23, 1997.

Robert Driscoll,

Reports Clearance Officer.

[FR Doc. 97–25769 Filed 9–26–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0389]

FDA Approval of Animal Drugs for Minor Uses and Minor Species; Draft Guidance Document; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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