Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


List of Subjects

21 CFR Part 514
Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 556
Animal drugs, Foods. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I, subchapter E, be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for part 514 continues to read as follows:

§ 514.1 [Amended]

■ 2. In § 514.1(b)(7) introductory text, remove the word “regulatory” from the last sentence.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for part 556, as proposed to be revisied on May 5, 2012 (77 FR 72254), continues to read as follows:

■ 4. Amend § 556.3, as proposed to be added on December 5, 2012 (77 FR 72254), as follows:

■ a. Remove the definition of “Acceptable single-dose intake”;
■ b. Add, in alphabetical order, a definition for “Acute reference dose”;
■ c. Revise the definitions for “Marker residue” and “Not required”;
■ d. Remove the definition of “Regulatory method”; and
■ e. Revise the definitions for “Tolerance” and “Zero”.

The revisions and additions read as follows:

§ 556.3 Definitions.

* * * * * Acute reference dose (ARfD) means an estimate of the amount of residues expressed on a body weight basis that can be ingested in a period of 24 hours or less without adverse effects or harm to the health of the human consumer.

* * * * * Marker residue means the residue whose concentration is in a known relationship to the concentration of total residue in an edible tissue.

* * * * * Not required, in reference to tolerances in this part, means that at the time of approval:

(1) No withdrawal period was necessary for residues of the drug to deplete to or below the concentrations considered to be safe, or an adequate withdrawal period was inherent in the proposed drug use, and there was a rapid depletion of residues, so there was no concern about residues resulting from misuse or overdosing; or

(2) No withdrawal period was necessary because the drug was poorly absorbed or metabolized rapidly so as to make selection of an analyte impractical or impossible.

* * * * * Tolerance means the maximum concentration of a marker residue, or other residue indicated for monitoring, that can legally remain in a specific edible tissue of a treated animal.

* * * * * Zero, in reference to tolerances in this part, means any residues detected in the tissue renders it unsafe.

■ 5. Amend § 556.5, as proposed to be added on December 5, 2012 (77 FR 72254), by revising paragraph (d) to read as follows:

§ 556.5 General considerations.

* * * * *

(d) FDA requires that a drug sponsor submit a practicable method as part of their new animal drug application. FDA uses the practicable method to determine the quantity of the drug residues that can safely remain in edible tissues (i.e., the tolerance), the withdrawal period, and any other use restrictions necessary to ensure that the proposed use of the drug will be safe.

Dated: October 21, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–26043 Filed 10–27–16; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 96

[Public Notice: 9772]

RIN 1400–AD91

Intercountry Adoptions

AGENCY: Department of State.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Department of State (the Department) is extending the period of time by 15 days for the public to submit comments on the Proposed Intercountry Adoption rule, in order to give the public more time to respond.


ADDRESSES:

• Internet: You may view this Proposed rule and submit your comments by visiting the Regulations.gov Web site at www.regulations.gov, and searching for docket number DOS–2016–0056.

• Mail or Delivery: You may send your paper, disk, or CD-ROM submissions to the following address: Comments on Proposed rule 22 CFR part 96, Office of Legal Affairs, Overseas Citizens Services, U.S. Department of State, CA/OCS/L, SA–17, Floor 10, Washington, DC 20522–1710.

• All comments should include the commenter’s name and the organization the commenter represents (if applicable). If the Department is unable to read your comment for any reason, the Department might not be able to consider your comment. Please be advised that all comments will be considered public comments and might be viewed by other commenters; therefore, do not include any information you would not wish to be made public. After the conclusion of the comment period, the Secretary will publish a Final rule as expeditiously as possible in which it will address relevant public comments.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: On September 8, 2016, the Department published a notice of Proposed rulemaking (NPRM), to amend requirements for accreditation of agencies and approval of persons to provide adoption services in intercountry adoption cases. (See 81 FR 62322.) The NPRM provided a comment period of 60 days, which expires on November 7, 2016.

In response to a request for extension, the Department extends the comment period until November 22, 2016. This will provide 75 days for the public to submit comments on this rule. Further information, including the text of the Proposed rule, can be found in the NPRM.

Dated: October 19, 2016.

Theodore K. Coley,
Acting Deputy Assistant Secretary, Overseas Citizen Services, Bureau of Consular Affairs, U.S. Department of State.