

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.

1. International Programme on Chemical Safety, "Environmental Health Criteria 240, Principals and Methods for the Risk Assessment of Chemicals in Food," 2009. (<http://www.who.int/foodsafety/publications/chemical-food/en/>). Accessed on February 11, 2016.
2. FDA, "Draft Guidance for Industry #232: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD), VICH GL54," (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM448430.pdf>), June 2015. Accessed on February 11, 2016.

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:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

§ 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 revised on December 5, 2012 (77 FR 72254), continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 360ccc, 371.

- 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 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.

DATES: The new comment closing date for the September 8, 2016, NPRM (FR Doc No. 2016-20968, 81 FR 62322), is November 22, 2016.

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:

Technical Information: Trish Maskew, (202) 485-6024.

Legal Information: Carine L. Rosalia, (202) 485-6092.

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 R. Coley,

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

[FR Doc. 2016-26094 Filed 10-27-16; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 50, 55, 58, and 200

[Docket No. FR-5717-P-01]

RIN 2501-AD62

Floodplain Management and Protection of Wetlands; Minimum Property Standards for Flood Hazard Exposure; Building to the Federal Flood Risk Management Standard

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise HUD's regulations governing floodplain management to require, as part of the decision making process established to ensure compliance with Executive orders on Floodplain Management and Federal Flood Risk Management, that a HUD assisted or financed (including mortgage insurance) project involving new construction or substantial improvement that is situated in an area subject to floods be elevated or floodproofed between 2 and 3 feet above the base flood elevation as determined by best available information.

The proposed rule would also revise HUD's Minimum Property Standards for one-to-four unit housing under HUD

mortgage insurance and low-rent public housing programs. Building to the proposed standards will, consistent with the Executive orders, increase resiliency to flooding, reduce the risk of flood loss, minimize the impact of floods on human safety, health, and welfare, and promote sound, sustainable, long-term planning informed by a more accurate evaluation of flood risk that takes into account possible sea level rise and increased development associated with population growth.

This document also proposes to revise a categorical exclusion available when HUD performs the environmental review under the National Environmental Policy Act (NEPA) and related Federal laws by making it consistent with changes to a similar categorical exclusion that is available to HUD grantees or other responsible entities when they perform these environmental reviews. This change will make the review standard identical regardless of whether HUD or a grantee is performing the review.

DATES: *Comment Due Date:* December 27, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410-0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410-0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at www.regulations.gov. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the www.regulations.gov Web site can be viewed by other commenters and interested members of the public. Commenters should follow the

instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202-708-3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800-877-8339. Copies of all comments submitted are available for inspection and downloading at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Danielle Schopp, Director, Office of Environment and Energy, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7250, Washington, DC 20410-8000, telephone number 202-402-4442. For inquiry by phone or email, contact Elizabeth Zepeda, Environmental Review Division, Office of Environment and Energy, Office of Community Planning and Development, at 202-402-3988 (this is not a toll-free number), or email to: Elizabeth.G.Zepeda@hud.gov. For questions regarding the Minimum Property Standards, Robert L Frazier, Housing Program Policy Specialist, Office of Housing, Home Valuation Division, 202-708-2121. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, floods caused 4,586 deaths from 1959 to 2005.¹ With climate change and associated sea-level rise, flooding risks have increased over time, and are anticipated to continue increasing. The National Climate Assessment (May 2014), for example,

¹ "Flood Fatalities in the United States," Sharon T. Ashley and Walker S. Ashley, *Journal of Applied Meteorology and Climatology*. Available at: <http://journals.ametsoc.org/doi/pdf/10.1175/2007JAMC1611.1>.