regulation is issued, except that, for good cause, we may establish an earlier effective date if we determine an earlier date to be in the public interest. 15 U.S.C. 1471n. Because it could take up to 1 year to produce a new package for some companies, we intend that any final rule become effective 1 year after the publication of a final rule in the **Federal Register**.

XIII. References

Please see all citing references in the staff's briefing package, available at *http://www.cpsc.gov/library/foia/foia12/brief/imidazolines.pdf.*

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission proposes to amend 16 CFR part 1700 as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670–74, 15 U.S.C. 1471–76. Secs. 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

2. Section 1700.14 is amended to add paragraph (a)(33) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

(33) *Imidazolines.* Any over-the-counter or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline (tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package, must be packaged in accordance with the provisions of § 1700.15(a), (b), and (c).

Dated: January 20, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–1446 Filed 1–24–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 20, 25, and 510

[Docket No. FDA–2001–N–0075 (formerly Docket No. 2001N–0284)]

RIN 0910–AF78

Import Tolerances for Residues of Unapproved New Animal Drugs in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish procedures by which a person may request that the Agency establish or amend tolerances for unapproved new animal drugs where edible portions of animals imported into the United States may contain residues of such drugs (import tolerances), as well as procedures to revoke an existing import tolerance. Such import tolerances provide a basis for legally marketing food of animal origin that is imported into the United States and contains residues of unapproved new animal drugs.

DATES: Submit either electronic or written comments on the proposed rule by April 24, 2012. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 24, 2012, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2001–N–0075 and RIN 0910–AF78, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* (301) 827–6870.
- *Mail/Hand delivery/Courier (for paperor CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA–2001–N–0075, and RIN 0910–AF78 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Scott Melton, Center for Veterinary Medicine (HFV–232), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8666, email: *scott.melton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative and Rulemaking Background

The President signed into law the Animal Drug Availability Act of 1996 (ADAA) on October 9, 1996. Section 4 of the ADAA amended section 512(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(a)) by adding the following: ''(6) For purposes of section 402(a)(2)(D) (now section 402(a)(2)(C)(ii) as a result of the Food Quality Protection Act), a use or intended use of a new animal drug shall not be deemed unsafe under this section if the Secretary establishes a tolerance for such drug (import tolerance) and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance. In establishing such tolerance, the Secretary shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Secretary to establish tolerances for applications for new animal drugs filed under subsection (b)(1). The Secretary may consider and rely on data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used or data available from a relevant international organization, to the extent such data are not inconsistent with the criteria used by the Secretary

to establish a tolerance for applications for new animal drugs filed under subsection (b)(1). For purposes of this paragraph, 'relevant international organization' means the Codex Alimentarius Commission or other international organization deemed appropriate by the Secretary. The Secretary may, under procedures specified by regulation, revoke a tolerance established under this paragraph if information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe.'' [1]

A residue is any compound present in edible tissues that results from the use of a drug, and includes the drug, its metabolites, and any other substance formed in or on food because of the drug's use (title 21 of the *Code of Federal Regulations* § 530.3(f) (21 CFR 530.3(f))).

Any amount of residue in imported, animal-derived food from a new animal drug not approved or conditionally approved in the United States and for which no import tolerance exists, even a level of residue considered safe by a country where the new animal drug is lawfully used, would cause the imported, animal-derived food to be adulterated under section 402(a)(2)(C)(ii) of the FD&C Act (21 U.S.C. 342(a)(2)(C)(ii)) because the drug would be deemed unsafe under section 512 of the FD&C Act. Such food could be denied entry into the United States under section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)).

Thus, it is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved or conditionally approved in the United States, unless a tolerance has been established for the residues of that new animal drug in imported, animal-derived food (import tolerance) and the residue of the new animal drug in the imported, animal-derived food does not exceed the import tolerance. It should be noted that the establishment of an import tolerance for an unapproved new animal drug does not provide for the lawful use of the drug in the United States, and such use would cause the drug to be deemed unsafe within the meaning of section 512 of the FD&C Act and adulterated within the meaning of section 501(a)(5) of the FD&C Act (21 U.S.C. 351(a)(5)).

This import tolerance proposed regulation, if finalized, will be FDA's last action to fully implement the ADAA. This proposed regulation describes procedures by which a person could request that the Agency establish or amend an import tolerance for a new animal drug not approved or conditionally approved for use in the United States. This proposed regulation would also establish procedures to revoke an existing import tolerance as provided in section 512(a)(6) of the FD&C Act. This regulation does not preclude the Commissioner from establishing or amending an import tolerance on his or her own initiative under § 10.25(b) (21 CFR 10.25(b)).

Public and Advisory Committee Input Prior To Rulemaking

In the **Federal Register** of August 10, 2001 (66 FR 42167), the Agency published an advance notice of proposed rulemaking (ANPRM) to discuss issues pertaining to the development of regulations regarding import tolerances. FDA solicited comments on four specific issues and for any other issues relating to import tolerances. In January 2002, FDA's Center for Veterinary Medicine (CVM, the Center) held a public meeting with the Veterinary Medicine Advisory Committee (VMAC) to discuss import tolerances. The Center presented the four specific issues that were included in the previously published ANPRM. These questions, as well as a summary of VMAC's responses and public comments to the ANPRM, follow:

Issue 1: Approaches the Agency Could Use To Find a Safe Import Tolerance

There are different approaches the Agency could use to find a safe import tolerance. It could look at toxicity and residue data and build in a conservative safety factor. Alternatively, it could also review conditions of use such as good agricultural practices, route of administration, and dose, which may result in a different safety factor or factors. Additionally, it could consider manufacturing information such as that required for a domestic application, which also could result in a different safety factor or factors. Which approach is preferable?

The consensus of VMAC was that import tolerances should be based on a food safety approach similar to that currently employed by FDA to establish tolerances for new animal drugs for which applications are filed under section 512(b)(1) of the FD&C Act. The committee noted that there should be some assurance that drugs covered by import tolerances are manufactured under good manufacturing practices (GMP)-like conditions.

Comments received from the public on this issue were similar to the comments that were received from VMAC.

Issue 2: Analytical Techniques

Only the drug marker residue for the drug substance, not the product formulation or the sponsor of the import tolerance, can be determined by the type of analytical method that is typically used to assay imports. Are there analytical techniques or other approaches that would allow the Agency to determine whether a residue is due to use of the drug product for which the tolerance is approved?

The consensus of VMAC was that they were not aware of a practical methodology to accomplish this task.

Issue 3: Agency Disclosure to the Public

- Should the Agency disclose to the public that it is considering an import tolerance for a new animal drug?
- If so, when (e.g., upon request, upon filing)?
- How should the Agency do so (e.g., **Federal Register**, Internet)?
- How much detail should the Agency provide, keeping in mind that it cannot disclose trade secrets or confidential commercial information?

The consensus of VMAC was that FDA should do an initial review of each request to establish or amend an import tolerance to determine the completeness of the submission package. If the requester's package is complete, then the public should be made aware that the Agency is considering establishing the requested import tolerance. This public notification should occur via publication in the **Federal Register**, the CVM Web site and other avenues, as appropriate. This notification should occur in a timely manner in order to allow for adequate public feedback and consideration of public concerns prior to a decision on the establishment of an import tolerance.

Public comments on this issue included suggestions that requests to establish import tolerances should be disclosed to the public early in the process. Commenters also indicated that submitted data should have the same confidentiality protections as that provided to data submitted as part of a new animal drug application (NADA). Most commenters felt that a Freedom of Information (FOI) summary should be made publicly available following establishment of the import tolerance.

[1] The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of Food and Drugs (the Commissioner) the functions vested in the Secretary under the FD&C Act and therefore, the authority under section 512(a)(6) of the FD&C Act is exercised by the Commissioner.

Issue 4: Import Tolerances Effect on the Environment

FDA is considering amending the regulations at 21 CFR 25.33 to allow a categorical exclusion for import tolerances under the National Environmental Policy Act, if there is information that shows that establishing import tolerances does not have a significant effect on the environment. The Agency is seeking information on whether import tolerances will have a significant effect on the environment.

The consensus of VMAC was that they could not think of any instance relative to residues within animal-derived food products that would have a significant environmental impact.

Other public comments on this issue included that categorical exclusion from the requirement to submit an environmental assessment would be appropriate for import tolerances on a case-by-case basis, if no extraordinary circumstances exist.

Issue 5: Please Comment on Any Other Aspects of Import Tolerances You Wish To Raise

There were no additional comments from VMAC.

Other public comments on this issue included that FDA should not establish an import tolerance for a new animal drug not allowed to be used in food animals in the United States or prohibited in the United States from extra-label use in food producing animals. Another comment suggested that an import tolerance for an unapproved new animal drug should apply to domestically-produced animal-derived food. Some commenters questioned whether the Agency would have the resources for residue testing.

B. Current Process for Establishing New Animal Drug Tolerances

1. Overview of the Approval Process for NADAs Submitted Under Section 512(b)(1) of the FD&C Act

Before FDA can approve an NADA submitted under section 512(b)(1) of the FD&C Act, the Agency must, among other things, determine that there is substantial evidence that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling, and that the NADA contains full reports of investigations including adequate tests by all methods reasonably applicable to show whether the new animal drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling (21 U.S.C. 360b(d)(1)(A) and (d)(1)(E)). In addition, for new animal drugs intended for use in food-producing animals, in determining whether a new animal drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling, FDA must consider, among other factors, the probable consumption of such drug by humans due to its presence in or on animal-derived food and the effect of such drug on humans (21 U.S.C. 360b(d)(2)). As a part of that determination, FDA may set tolerances for new animal drug residues that occur in the food (21 U.S.C. 360b(d)(1)(F)).

2. Human Food Safety Data Requirements To Establish New Animal Drug Tolerances

The human food safety requirements for approval of an NADA are broadly described in 21 CFR part 500, subpart E and in 21 CFR 514.1(a)(7) and (a)(8). The sponsor of a new animal drug is required to furnish FDA with evidence demonstrating that the residues of the new animal drug in the edible products of treated animals are safe. FDA has developed a number of guidance documents, which are available on the FDA Web site (*http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm123817.htm*), to inform sponsors of the scientific data FDA believes could provide an acceptable basis for determining the human food safety of a new animal drug.

Human food safety data are generated by conducting studies to assess the nature and quantity of residues in foods derived from animals treated with a new animal drug. The human food safety studies fall into three general categories: Toxicity studies; residue chemistry studies; and, for antimicrobial new animal drugs, microbial safety studies.

The toxicity studies are designed to evaluate the oral toxicity of a new animal drug to humans, who may be exposed to the drug through the consumption of food derived from animals treated with the new animal drug. The goal of the toxicity studies is to determine an acceptable daily intake (ADI). The ADI is used to calculate the amount of total residues permitted in each edible tissue, also known as the safe concentration.

The residue chemistry studies are designed to determine the concentration of drug residue actually appearing at the time of slaughter of the target animal in the edible tissues of that animal species as a result of treatment with the proposed new animal drug. Data from studies that investigate the metabolism of the veterinary drug are used to establish a relationship between the residue selected for assay (marker residue) and the concentration of the total residue in the target tissue. These residue chemistry data are used to calculate the tolerance. Tolerances are the maximum concentration of a new animal drug residue that can legally remain in an edible tissue from animals treated with the new animal drug. When a tolerance is assigned for an approved or conditionally approved new animal drug, a practicable regulatory analytical method is also established to quantify and confirm residues of the new animal drug to monitor the safety of the food supply.

For antimicrobial new animal drugs, typically data are generated that support the conduct of a qualitative risk assessment that addresses the release, exposure, and consequence of the effects of the new animal drug on the development of resistant bacteria in or on the target animal and the potential impact on human health.

C. International Harmonization of Food Safety Standards

FDA works toward international harmonization of food safety standards, including food safety controls such as veterinary drug tolerances.

Under the proposed regulation, FDA intends to harmonize its import tolerances with the Maximum Residue Limits (MRLs) established by the Codex Alimentarius Commission of the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Food Standards Program (Codex MRL), provided that the Codex Alimentarius Commission has established a permanent Codex MRL and that the Agency has sufficient information to make a determination that the permanent Codex MRL will protect the U.S. public health and will meet the standards of the FD&C Act. If the Codex Alimentarius Commission has established a permanent Codex MRL for a new animal drug, the Agency would allow the submission of human food safety information in the form of monographs and reports from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and/or the Joint Expert Committee on Food Additives of the FAO and the WHO (JECFA) to support the requested import tolerance. The JMPR and/or JECFA monographs and reports provide an evaluation of human food safety data; these data are then used to derive the ADI and the recommended MRL. If FDA review of the committee reports and monographs raises additional scientific concerns that merit more detailed review, the Agency

proposes to require submission of the complete toxicology and residue chemistry study reports, including the underlying data.

If the Codex Alimentarius Commission has not established a permanent Codex MRL for a new animal drug, the Agency proposes to require submission of the complete toxicology and residue chemistry study reports, including the underlying data. In addition, in the absence of a permanent Codex MRL, the Agency proposes that the requester should provide full reports of investigations made with respect to the human food safety of the new animal drug, including data submitted to the appropriate regulatory authority in any country where the new animal drug is lawfully used.

II. Summary of the Proposed Rule

A. Scope (Proposed § 510.201)

Proposed § 510.201 establishes and restricts proposed subpart C to procedures by which the Agency may establish, amend, or revoke an import tolerance for residues of a new animal drug not approved or conditionally approved for use in the United States but lawfully used in other countries and present in imported, animal-derived food and food products, as well as procedures to reconsider or stay actions regarding an import tolerance. Under section 512(a)(6) of the FD&C Act, the Secretary may consider and rely on data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used. In addition, the Secretary may use data available from a relevant international organization to the extent such data are not inconsistent with the criteria used to establish a tolerance for new animal drug applications submitted under section 512(b)(1) of the FD&C Act. For purposes of section 512(a)(6) of the FD&C Act, ''relevant international organization'' means the Codex Alimentarius Commission or other international organization deemed appropriate by the Secretary.

When evaluating the residue of a new animal drug as part of the determination of a tolerance, FDA considers the conditions of use including dose, duration, and formulation. The conditions of use can affect the uptake, metabolism, and distribution of the residues in the treated food animal and therefore, are a critical component of the human food safety evaluation for a tolerance of a domestic new animal drug as part of a new animal drug approval. Similarly, the Codex Alimentarius requires that a veterinary drug under evaluation for an MRL be approved in at least one member country in order to assure that the conditions of use are available as part of the scientific evaluation. FDA believes that it would also be important that the evaluation for a tolerance for residues of a new animal drug in imported food consider conditions of use. Consequently, FDA believes that the new animal drug under evaluation must be lawfully used in at least one country in a manner consistent with the conditions of use that cause the residues in the imported food, and that the information resulting from this lawful use be made available to FDA as part of the evaluation for an import tolerance.

B. Definitions (Proposed § 510.203)

Proposed § 510.203 contains definitions for the terms import tolerance and request. The proposed definition of import tolerance (''a tolerance for a residue of a new animal drug not approved or conditionally approved for use in the United States, but present in any imported edible portion of any animal'') is derived from the statutory language, which provides that a use or intended use of a new animal drug shall not be deemed unsafe under section 512 of the FD&C Act, ''if the Secretary establishes a tolerance for such drug and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance.'' 21 U.S.C. 360b(a)(6). The proposed definition for request (''a request to establish or amend an import tolerance'') sets forth the meaning of the term, as it is used in proposed subpart C.

C. Requests To Establish or Amend an Import Tolerance (Proposed § 510.205)

1. Initiation of a Request To Establish or Amend an Import Tolerance (Proposed § 510.205(a))

Proposed § 510.205(a) provides that any person could request that the Commissioner establish or amend an import tolerance and that such a request would have to be in the form specified in proposed § 510.205, which is described in this section of the document. Proposed § 510.205(a) also provides that the Commissioner could initiate a proceeding to establish or amend an import tolerance on his or her own initiative under 21 CFR 10.25(b).

2. Content and Administration of a Request (Proposed § 510.205(b))

Under this proposed section, a request to establish or amend an import tolerance would have to include the following information: (1) The established name and all pertinent information concerning the new animal drug, including chemical identity and composition of the new animal drug, and its physical, chemical, and biological properties; (2) the conditions of use for the new animal drug, including the route of administration and dosage, together with all labeling, directions, and recommendations regarding the uses in countries in which the new animal drug is lawfully used; (3) the proposed import tolerance(s) for the new animal drug; (4) human food safety information to support the proposed import tolerance(s); and (5) a complete description of a practicable validated method for measuring the residue level in imported edible portions of any animal treated with the new animal drug.

The contents of the request would have to include data sufficient to demonstrate that a proposed tolerance is safe based on similar human food safety criteria used by the Commissioner to establish tolerances for applications for new animal drugs filed under section 512(b)(1) of the FD&C Act. Consistent with section 512(a)(6) of the FD&C Act, information to support the establishment of an import tolerance for a new animal drug could include data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used, or data available from a relevant international organization, such as the Codex Alimentarius Commission, to the extent such data are not inconsistent with the criteria used by the Commissioner to establish a tolerance for applications for new animal drugs filed under section 512(b)(1) of the FD&C Act.

Under the proposed rule, human food safety information to support the proposed import tolerance could be submitted in two possible forms. First, if a permanent Codex MRL has been established, the requester would provide the permanent Codex MRL and monographs and reports from the JECFA and/or monographs and reports from the JMPR that support the development of the permanent Codex MRL. FDA could request additional information as needed. If no permanent Codex MRL has been established, or upon notification by FDA, the requester would have to provide full reports of investigations made with respect to the human food safety of the new animal drug.

Should full reports be required by the rule or requested by FDA, a request to establish or amend an import tolerance could be regarded as incomplete unless it includes full reports of adequate tests,

by all methods reasonably applicable, to show whether or not any edible portion of any animal receiving the new animal drug would be safe for human consumption. The reports would have to include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. Under the proposed rule, the request would have to include either a statement that all such reports have been submitted or an explanation of why such reports were not submitted. With respect to each nonclinical laboratory study contained in the request, the requestor would have to submit either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in 21 CFR part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance, and an explanation of how the noncompliance may have impacted the study.

Furthermore, a request to establish or amend an import tolerance would have to include any other information that could be deemed necessary by the Commissioner to address particular human food safety concerns that may be associated with certain new animal drugs or classes of new animal drugs. For example, for certain antimicrobial new animal drugs, the Agency could consider information regarding antimicrobial resistance concerns in making its determination that a proposed import tolerance is safe.

A request to establish or amend an import tolerance would also have to include information on where the new animal drug is lawfully used. Such information includes the conditions of use for the new animal drug, including the route of administration and dosage; labeling; directions; and recommendations. When an import tolerance is established, it would be available to any importer into the United States of the same food product(s) containing the unapproved drug product that is subject to the import tolerance.

The request would also have to include a complete description of a practicable validated method for measuring the residue level of the new animal drug in the imported edible product derived from animals treated with the new animal drug. The availability of such a method is important for monitoring compliance with the import tolerance.

Under this proposed rule, if finalized, a requester would be required to submit an environmental assessment, as described in 21 CFR 25.40, to facilitate the Agency's assessment of potential environmental impacts under the National Environmental Policy Act; Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions,'' of January 4, 1979 (44 FR 1957, January 9, 1979); and 21 CFR 25.60. As previously discussed in this document, the Agency solicited comments on the issue of whether import tolerances will have a significant effect on the environment in the August 2001 ANPRM and January 2002 VMAC. Although categorical exclusions are not addressed in this proposed rule, the Agency is still considering the comments received in response to the August 2001 ANPRM and January 2002 VMAC. If, in the future, the Agency determines it to be appropriate, FDA will consult with the Council on Environmental Quality (CEQ) regarding the establishment of categorical exclusions for certain import tolerance requests. FDA reiterates its previous requests for comments and supporting information relevant to the issue of whether import tolerances will have a significant effect on the environment in the United States or abroad.

Proposed § 501.205(b) provides that requests for an import tolerance would have to be submitted to FDA in triplicate. By prior arrangement, requests could be submitted in an electronic format.

Pertinent information previously submitted to and currently retained in the files of FDA could be incorporated in, and would be considered as part of, a request to establish or amend an import tolerance on the basis of specific reference to such information. If the requester refers to any nonpublic information other than its own, the requester would have to obtain a written right of reference to that nonpublic information and submit such right of reference with the request. Any reference to published information would have to be accompanied by reprints or copies of such references. If a part of the material submitted is in a foreign language, it would have to be accompanied by a complete and accurate English translation. Translations of literature printed in a foreign language would have to be accompanied by copies of the original publication.

Furthermore, the request would have to be dated and signed by the requester or by his or her authorized representative. If the requester or such authorized representative does not reside or have a place of business within the United States, the requester would also have to furnish the name and post office address of, and the request would have to be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States.

A request to amend an established import tolerance would have to contain information to support each proposed change. The request could omit statements made in the original request for which no change is proposed.

The requester could withdraw a request to establish or amend an import tolerance at any time before the notification provided for in proposed § 510.205(d)(2) has been made publicly available.

3. Review of Information Submitted in a Request (Proposed § 510.205(c))

In establishing an import tolerance or amending an existing import tolerance, the Commissioner would rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar human food safety criteria used by the Commissioner to establish tolerances for applications for new animal drugs filed under section 512(b)(1) of the FD&C Act. In establishing or amending an import tolerance, the Commissioner would give appropriate consideration to the residue concentrations and conditions of use of the animal drug in the import tolerance request.

4. Disclosure of Information Submitted in a Request (Proposed § 510.205(d))

FDA intends to be as transparent as possible about requests to establish, amend, or revoke import tolerances, as well as the basis for establishing, amending, or revoking import tolerances. This transparency is in response to the VMAC consensus that disclosure of import tolerance requests be made to the public early in the review process. The rule proposes that when a request to establish or amend an import tolerance has been filed, this request would be made publicly available. In addition, the decision to establish, amend, or revoke an import tolerance would be made publicly available. A summary of the basis for the decision would also be publicly released. All information and safety data submitted with, or incorporated by reference in, the request would be available for public disclosure, in accordance with the provisions of part 20 (21 CFR part 20). Trade secrets and confidential commercial or financial information would be exempted from release under § 20.61.

5. Establishment or Amendment of an Import Tolerance (Proposed § 510.205(e))

The rule proposes that when a request to establish or amend an import tolerance is granted, a copy of the public notification would be sent to the requestor. Similarly, when a request to establish or amend an import tolerance is denied, a copy of the notification of the denial would be sent to the requestor as well as made publicly available,. This proposed section also makes clear that if a tolerance is established as part of an approval of a new animal drug application under section 512(b)(1) of the FD&C Act (21 U.S.C. 360b(b)(1)), or conditional approval under section 571 of the FD&C Act, (21 U.S.C. 360ccc), the approved new animal drug tolerance would supersede any existing import tolerance for that new animal drug. A notification that the existing import tolerance has been superseded by a tolerance for that new animal drug would be made publicly available and a copy of th*is* notification would be sent to the requester.

In the event that the conditionally approved application for a new animal drug is not renewed or is withdrawn, or such drug does not achieve full approval under section 512 of the FD&C Act within 5 years following the date of the conditional approval, the Agency would reinstate the import tolerance and a notification would be made available to the public, and copy of this public notification would be sent to the original requestor.

D. Revoking an Import Tolerance (Proposed § 510.207)

Proposed § 510.207 specifies the procedures by which an established tolerance for residues of an unapproved new animal drug in food products of animal origin imported into the United States could be revoked. Section 512(a)(6) of the FD&C Act authorizes this action if information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe. The Commissioner, on his or her own initiative or on the petition of an interested person, under part 10 (21 CFR part 10), could revoke an import tolerance. The grounds for revocation of the import tolerance would be made publicly available.

E. Reconsideration of Action (Proposed § 510.209)

Proposed § 510.209 specifies the process for an interested person to petition that the Commissioner reconsider a decision to establish, amend, or revoke an import tolerance and also provides that the Commissioner could reconsider a decision on his or her own initiative. The section proposes that a petition for reconsideration of such a decision would have to be filed with the Division of Dockets Management under § 10.20, and be in the form set out in § 10.33. Under proposed § 510.209, an interested person would have to petition for reconsideration no later than 30 days after public notification of the decision, although the Commissioner could, for good cause, permit a petition to be filed more than 30 days after public notification of the decision. The petition for reconsideration would have to demonstrate that the Commissioner did not adequately consider relevant information and views that are in the administrative record. No new information could be included in a petition for reconsideration.

F. Administrative Stay of Action (Proposed § 510.211)

Proposed § 510.211 specifies the process for an interested person to petition that the Commissioner stay or extend the effective date of a decision to establish, amend, or revoke an import tolerance. It also provides that the Commissioner, on his or her own initiative, could stay or extend the effective date of a decision to establish, amend, or revoke an import tolerance. The proposed section would specify that a petition for a stay or for an extension of the effective date of such a decision be filed with the Division of Dockets Management in accordance with § 10.20, and be in the form set out in § 10.35. Under proposed § 510.211, an interested person would have to petition the Commissioner stay or extend the effective date of a decision with respect to establishing, amending, or revoking an import tolerance no later than 30 days after the date of public notification, although the Commissioner could, for good cause, permit a petition to be filed more than 30 days after the date of public notification of the decision.

III. Conforming Changes

FDA is proposing conforming changes to certain applicable sections of the Code of Federal Regulations (CFR) that would add a reference to the processes for establishing or amending import tolerances and revoking such tolerances listed under section 512 of the FD&C Act. The affected sections in title 21 of the CFR are:

- § 10.25 Initiation of administrative proceedings.
- § 20.100 Applicability; cross-reference to other regulations.
- § 25.20 Actions requiring preparation of an environmental assessment.

IV. Legal Authority

FDA is proposing this rule under the authority of section 512(a)(6) of the FD&C Act, which states that ''a use or intended use of a new animal drug shall not be deemed unsafe * * * if the Secretary establishes a tolerance for such drug and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance.'' Furthermore, ''the Secretary may, under procedures specified by regulation, revoke a tolerance established under this paragraph if information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe.'' FDA is also proposing these regulations under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which authorizes the issuance of regulations for the efficient enforcement of the FD&C Act.

V. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA anticipates most requests will rely on data already gathered, analyzed, and summarized in publicly available dossiers supporting a

permanent Codex MRL, and because FDA has received only two requests to establish import tolerances since 1996, both from large manufacturers of new animal drugs, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. The Proposed Rule

FDA is proposing procedures to establish or amend a tolerance for a new animal drug that has not been approved or conditionally approved for use in the United States where edible portions of animals imported into the United States may contain residues of such drugs (import tolerance), as well as procedures to revoke an existing import tolerance. Import tolerances will provide a basis for legally marketing food of animal origin that is imported into the United States containing residues of unapproved new animal drugs. The proposed rule sets forth the information that a requester would need to submit to support the establishment or amendment of an import tolerance. This information may include data submitted by the requester, including data submitted to appropriate regulatory authorities in any country where the new animal drug is used legally, or data available from a relevant international organization such as the Codex Alimentarius Commission. The proposed rule would also require that requests to establish or amend an import tolerance include a practical validated method for measuring the residue level of the new animal drug in the imported edible product derived from animals treated with the new animal drug. The proposed rule also allows for the public notification of requests to establish or amend an import tolerance, information supporting such requests, and for public notification when establishing, amending, or revoking import tolerances. In addition, the proposed rule describes procedures for revoking an existing import tolerance if scientific evidence shows the tolerance to be unsafe or if information demonstrates that use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance.

C. Need for the Proposed Rule

While interested parties may currently submit requests for the establishment of import tolerances under the authority of the statutory provision (21 U.S.C. 360b(a)(6)), this proposed rule, if finalized, will provide a more efficient method for the submission of requests to establish import tolerances since the regulation would set forth the information required to be submitted in such a request. In addition, under section 512(a)(6) of the FD&C Act, in order to be able to revoke existing import tolerances, the Agency must specify, by regulation, procedures to revoke an import tolerance. This proposed rule, if finalized, would establish such procedures.

D. Benefits of the Proposed Rule

As stated previously in this document, this proposed rule, if finalized, would set forth procedures by which interested parties may submit requests for the establishment, amendment or revocation of an import tolerance. In doing so, the proposed rule, if finalized, should initially increase the number of requests to establish, amend, or revoke an import tolerance the Agency would otherwise expect to receive. Under the new procedures, FDA estimates that it will receive 2.2 requests to establish import tolerances per year. At this time FDA does not expect the number of annual requests to increase any further in future years. FDA currently does not have the data to estimate the value of these import tolerances should they be established. FDA assumes, however, that profits earned importing animal-derived food containing allowable residues of unapproved new animal drugs that are the subject of established import tolerances would be greater than the marginal costs of requesting the establishment of such import tolerances.

E. Costs of the Proposed Rule

1. Requesters

Those who choose to request the establishment, amendment, or revocation of an import tolerance will voluntarily incur compliance costs. These costs are expected to be composed of labor costs for organizing the pertinent information that will be submitted with a request to establish, amend, or revoke an import tolerance.

FDA expects to receive two requests annually to establish import tolerances for unapproved new animal drugs for which a permanent Codex MRL has been established. In these cases, FDA estimates that a requester would expend about 50 hours to locate and review the toxicology and residue chemistry reports from the Codex MRL dossier and to prepare and submit the request to FDA. The median compliance officer wage rate for the pharmaceutical industry (NAICS 325400—Pharmaceutical and Medicine Manufacturing), adjusted 35 percent for benefits, is about $42 per hour. The annual compliance cost for petitioners requesting the establishment of an import tolerance for unapproved new animal drugs with permanent Codex MRLs would be about $4,000 (2 requesters times 50 hours times $42 per hour), or about $2,100 per request.

FDA estimates that it would receive 0.2 requests annually to establish import tolerances for unapproved new animal drugs for which a permanent Codex MRL has not been established. FDA estimates that a requester would expend about 80 hours to prepare such a request. Using the same $42 per hour rate for wages and benefits, the cost to prepare a request of this type would be about $3,300. Since FDA expects only one of these requests every 5 years, the average annual cost would be about $650.

Total annual industry costs for the 2.2 requests to establish an import tolerance are estimated at about $4,800 (2 requests that cost $2,100 each plus one request that costs $650).

Requests to revoke or amend an import tolerance are expected to be extremely infrequent events. FDA believes that these requests are likely to be submitted significantly less than even once every 5 years. FDA recognizes that requesters may incur some administrative costs for time spent in preparing a request to amend or revoke an import tolerance. While FDA has not added such costs to the total compliance cost estimates, due to the relative infrequency of these requests FDA concludes that the annual cost for each of these types of requests would be insignificant. Even in the rare year in which FDA receives one of these requests, at an estimated burden of about 32 labor hours, the marginal cost would amount to about $1,300. This would add about 28 percent to the very low annual costs of the proposed rule.

FDA projects the compliance costs of this rule to industry over a 10-year period at $42,400 using a 3 percent

discount rate, and at $36,300 using a 7 percent discount rate.

2. Government

FDA estimates that each request to establish, amend, or revoke an import tolerance would require up to 100 hours of total time spent in review and document preparation by mid-level FDA employees. Assuming a GS–13, Step-1 hourly pay rate of about $43, with a 35 percent increase for benefits, the 100 hours of labor for each review are estimated to cost about $5,800. This equates to about $12,800 annually for the 2.2 reviews. Over a 10-year period, the administrative costs to the Government are projected at $112,200 using a 3 percent discount rate, and at $96,000 using a 7 percent discount rate.

F. Regulatory Alternatives

Section 4 of the ADAA, which provides for the establishment and revocation of import tolerances, requires FDA to make determinations on requests to establish, amend or revoke import tolerances based on human food safety criteria similar to those used to establish tolerances for new animal drug applications. FDA consulted VMAC at a public meeting in 2001 to discuss issues pertaining to the development of regulations regarding import tolerances. The ADAA language and VMAC recommendations provided a framework for the proposed import tolerance procedures that did not allow for the development of alternative procedures significant enough to have led FDA to estimate a substantially larger or smaller number of annual requests to establish import tolerances than the 2.2 requests previously described.

G. Impacts on Small Entities

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant economic impact on a substantial number of small entities. Although the Agency believes it is very unlikely that significant economic impacts would occur, the Agency cannot rule out this possibility completely because of some uncertainty in the type or size of entities that may request the establishment, amendment, or revocation of import tolerances.

The Regulatory Flexibility Act requires a description of the small entities that would be affected by the rule, and an estimate of the number of small entities to which the rule would apply. FDA believes that manufacturers of new animal drugs will make all or nearly all requests to establish import tolerances. Manufacturers of new animal drugs are classified in the North American Industrial Classification System (NAICS) under industry code 325412—Pharmaceutical Preparation Manufacturing. Census data in this category from 2007 show that 744 companies with 963 establishments manufacture pharmaceuticals in the United States. FDA requests public comment on the probability that any entities other than pharmaceutical manufacturers would request the establishment, amendment, or revocation of an import tolerance.

The Small Business Administration defines those entities within NAICS code 325412 as small entities if they employ less than 750 employees. Census data shows that 711 of the 963 establishments within NAICS code 325412, or 74 percent, had less than 100 employees in 2007. Available Census data from 2007 identifies the number of establishments in NAICS code 325412 with 100 or more employees, but does not identify those with 100 to 749 employees. The 2002 Census data, however, indicates that up to 97 percent of all establishments in NAICS code 325412 have less than 750 employees. The existence of some multi-establishment companies in this NAICS code would likely decrease the number of companies that would meet the definition of a small entity. Regardless, FDA acknowledges that it is likely that a substantial number of pharmaceutical manufacturers would meet the criteria to be considered small entities.

For those establishments with one to four employees and five to nine employees, the average annual value of shipments ranges from $825,000 to $3.37 million in 2002, the latest year for which value of shipments for establishments differentiated by employee size is available. For all establishments with 10 or more employees, it is much greater. If a manufacturer composed of only one establishment of one to four employees requested the establishment of one import tolerance for an unapproved new animal drug that was not the subject of a permanent Codex MRL, the one-time cost of this effort would represent about 0.40 percent of average annual revenues. If this manufacturer requested the establishment of one import tolerance for an unapproved new animal drug that was the subject of a permanent Codex MRL, the one-time cost of this effort would represent about 0.25 percent of average annual revenues. Those establishments with more than 10 employees would incur compliance costs that represent significantly less than 0.1 percent of average revenues from requesting the establishment of an import tolerance for an unapproved new animal drug with or without a permanent Codex MRL. Further, requests to amend or revoke an established import tolerance, which the Agency expects to be submitted significantly less frequently than once every 5 years, would result in compliance costs that represent even smaller percentages of average annual revenues for the establishment sizes listed previously in this document. Accordingly, FDA believes that this proposed rule would not have a significant impact on a substantial number of small entities.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these requirements is given in table 1 of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Import Tolerances for Residues of Unapproved New Animal Drugs in Food.

Description: FDA is proposing procedures by which a person may request that the Agency establish or amend tolerances for unapproved new animal drugs where edible portions of animals imported into the United States may contain residues of such drugs (import tolerance). The Agency is also proposing procedures to revoke an existing import tolerance, as well as procedures for reconsideration of action or an administrative stay of action to establish, amend, or revoke an import tolerance. The ADAA amended the FD&C Act to authorize FDA to establish and revoke import tolerances. Import

tolerances will provide a basis for legally marketing food of animal origin that is imported into the United States and contains residues of unapproved new animal drugs.

If there is a permanent Codex MRL for a new animal drug, the proposed rule provides that the requester should provide, in addition to the requirements outlined in proposed § 510.205(b)(5)(i), (b)(5)(ii), (b)(5)(iii), (b)(5)(v), and (b)(5)(vi), the permanent Codex MRL and monographs and reports from the JECFA and/or the JMPR that support the development of the Codex MRL.

If there is not a permanent Codex MRL, or upon notification by FDA, the proposed rule provides that the requester should provide, in addition to the requirements outlined in proposed § 510.205(b)(5)(i), (b)(5)(ii), (b)(5)(iii), (b)(5)(v), and (b)(5)(vi), full reports of investigations made with respect to the human food safety of the new animal drug including data submitted to the appropriate regulatory authority in any country where the new animal drug is lawfully used. A request may be regarded as incomplete unless it includes full reports of adequate tests by all methods reasonably applicable to show whether or not food derived from animals receiving the new animal drug will be safe for human consumption.

Description of Respondents: We anticipate that most requests to establish or amend an import tolerance will come from the manufacturer of the unapproved new animal drug at issue in the request. Requests may also be submitted by trade associations of foreign producers who use the unapproved new animal drug or by importers of animal-derived food bearing or containing residues of the unapproved new animal drug. At this time since the Agency has not established an appreciable number of import tolerances, we are unable to estimate the number of requests to revoke an established import tolerance we may receive.

Burden: Interested persons are required to submit human food safety data and other information similar to that used to establish a tolerance under an NADA. The collection of information required for submission of NADAs has been reviewed under the Paperwork Reduction Act of 1995. The Agency has proposed extension of this existing collection most recently in 2007 (72 FR 37240, July 9, 2007). A proportion of the time estimated in that proposed extension for the paperwork associated with the human food safety technical section of an NADA was used to estimate the time (hours per response) presented in table 1 of this document for the preparation of a request to establish or amend an import tolerance not based on a permanent Codex MRL. We believe a request to establish or amend an import tolerance based on a permanent Codex MRL will be less burdensome. Based on the Agency's experience with establishing tolerances for approved new animal drugs, the Agency believes that requests to revoke an import tolerance, as well as petitions for reconsideration of an action or for an administrative stay of an action will be infrequent occurrences.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
510.205(b)(5)(i), (b)(5)(ii), and (b)(5)(iii)	2.2	1	2.2	1	2.2
510.205(b)(5)(iv)(A) (request to establish an import tolerance based on permanent Codex MRL)	2	1	2	50	100
510.205(b)(5)(iv)(B) (request to establish an import tolerance not based on permanent Codex MRL)	0.2	1	0.2	80	16
510.205(b)(6) (request to amend an import tolerance)	0.1	1	0.1	32	3
510.207, 510.209, and 510.211 (request to revoke an import tolerance, for reconsideration of an action or for administrative stay of an action)	0.1	1	0.1	10	1

[1] There are no capital costs or operating costs associated with this collection of information.

The number of respondents and number of responses per respondent listed in table 1 of this document are an estimate based on the Agency's experience since the passage of the ADAA and actual requests received. The average burden per response is an estimate based on the review of the human food safety technical section of an NADA as discussed previously in this document. The number of respondents and number of responses per respondent for §§ 510.207, 510.209 and 510.211 are based on the expectation that such responses will occur infrequently and that the Agency anticipates the average burden per response will require much less time than a request to establish or amend a tolerance.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to fax comments regarding information collection to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, fax: (202) 395–5806.

VII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 10, 20, 25, and 510 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. In § 10.25, revise paragraph (a)(1) to read as follows:

§ 10.25 Initiation of administrative proceedings.

* * * * *

(a) * * *

(1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1 of this chapter, for a food additive petition in §§ 171.1 or 571.1 of this chapter, for a new drug application in § 314.50 of this chapter, for a request to establish or amend an import tolerance in § 510.205 of this chapter, for a new animal drug application in § 514.1 of this chapter, or

* * * * *

PART 20—PUBLIC INFORMATION

3. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

4. In § 20.100, add new paragraph (c)(45) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(45) Requests to establish or amend import tolerances, in § 510.205 of this chapter.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

5. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

6. In § 25.20, add new paragraph (o) to read as follows:

§ 25.20 Actions requiring preparation of an environmental assessment.

* * * * *

(o) Establishment, amendment, or revocation of an import tolerance in accordance with subpart C of part 510 of this chapter.

PART 510—NEW ANIMAL DRUGS

7. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

8. Revise subpart C to read as follows:

Subpart C—Import Tolerances for Residues of Unapproved New Animal Drugs in Food

Sec.
510.201 Scope.
510.203 Definitions.
510.205 Request to establish or amend an import tolerance.
510.207 Revoking an import tolerance.
510.209 Reconsideration of action.
510.211 Administrative stay of action.

§ 510.201 Scope.

This part applies to tolerances for residues of new animal drugs not approved or conditionally approved for use in the United States, but lawfully used in another country and present in imported animal-derived food and food products.

§ 510.203 Definitions.

The following definitions of terms apply when used in this subpart:

Import tolerance means a tolerance for a residue of a new animal drug not approved or conditionally approved for use in the United States, but present in any imported edible portion of any animal.

Request means a request to establish or amend an import tolerance.

§ 510.205 Request to establish or amend an import tolerance.

(a) *Initiation of a request.* Any person may request that the Commissioner of Food and Drugs (the Commissioner) establish or amend an import tolerance. A request must be in the form specified in this section. The Commissioner may also initiate a proceeding to establish or amend an import tolerance on his or her own initiative under § 10.25(b) of this chapter.

(b) *Content and administration of a request.* (1) Pertinent information previously submitted to and currently retained in the files of the Food and Drug Administration may be incorporated in, and will be considered as part of, a request on the basis of specific reference to such information. If the requester refers to any nonpublic information other than its own, the requester shall obtain a written right of reference to that nonpublic information and submit the right of reference with the request. Any reference to published information offered in support of a request should be accompanied by reprints or copies of such references.

(2) Requests shall be submitted in triplicate and be addressed to the Document Control Unit (HFV–199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. By prior arrangement, requests may be submitted in an electronic format.

(3) If a part of the material submitted is in a foreign language, it shall be accompanied by a complete and accurate English translation. Translations of literature printed in a foreign language shall be accompanied by copies of the original publication.

(4) The request must be dated and must be signed by the requester or by his or her authorized attorney, agent, or official and shall state the requester's correspondence address. If the requester or such authorized representative does not reside or have a place of business within the United States, the requester must also furnish the name and post office address of, and the request must be countersigned by, an authorized attorney, agent, or official residing or

maintaining a place of business within the United States.

(5) The request must include the following information:

(i) The established name and all pertinent information concerning the new animal drug, including chemical identity and composition of the new animal drug, and its physical, chemical, and biological properties;

(ii) The conditions of use for the new animal drug, including the route of administration and dosage, together with all labeling, directions, and recommendations regarding the uses in countries in which the new animal drug is lawfully used;

(iii) The proposed import tolerance(s) for the new animal drug;

(iv) Human food safety information to support the proposed import tolerance(s) in either of the following forms:

(A) If a permanent Maximum Residue Limit (MRL) has been established by the Codex Alimentarius Committee (Codex MRL), the requester shall provide the permanent Codex MRL and monographs and reports from the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations and/or monographs and reports from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) that support the development of the permanent Codex MRL. FDA may request additional information as needed.

(B) If no permanent Codex MRL has been established, or upon notification by FDA, the requester must provide full reports of investigations made with respect to the human food safety of the new animal drug. A request may be regarded as incomplete unless it includes full reports of adequate tests by all methods reasonably applicable to show whether or not any imported edible portion of any animal receiving the new animal drug will be safe for human consumption. The reports must include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth, including data submitted to the appropriate regulatory authority in any country where the new animal drug is lawfully used. The request must also include a statement that all such reports have been submitted, or contain an explanation of why such reports were not submitted. With respect to each nonclinical laboratory study contained in the request, the requestor must submit either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance, and how this may have impacted the study;

(v) Other human food safety information as deemed necessary by the Commissioner; and

(vi) A description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use.

(6) A request to amend an established import tolerance must contain information to support each proposed change. The request may omit statements made in the original request for which no change is proposed.

(7) The requester may withdraw the request at any time before the notification provided for in paragraph (d)(3) of this section has been made publicly available.

(c) *Review of information submitted in a request.* In establishing or amending an import tolerance, the Commissioner shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Commissioner to establish tolerances for applications for new animal drugs filed under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act. In establishing or amending an import tolerance, the Commissioner will give appropriate consideration to the anticipated residue concentrations and conditions of use of the new animal drug specified.

(d) *Disclosure of information submitted in a request.* (1) When a request is determined to be complete for FDA's consideration, the Commissioner will provide public notification of the request containing the name of the requester and a brief description of the request in general terms. A copy of the notification will be sent to the requester at the time the information is made available to the public.

(2) A notification establishing, amending, or revoking an import tolerance will be made publicly available. A summary of the basis for the decision will be publicly released in accordance with the provisions of part 20 of this chapter. All information and safety data submitted with the request, or previously submitted information incorporated in, and considered as part of, a request on the basis of specific reference to such information, shall be available for public disclosure, also in accordance with the provisions of part 20 of this chapter. Trade secrets and confidential commercial or financial information are exempted from release under § 20.61 of this chapter.

(e) *Establishment or amendment of an import tolerance.* (1) If a request to establish or amend an import tolerance is granted, the Commissioner will provide public notification establishing or amending an import tolerance, which will be effective from the date of public notification. A copy of the notification will be sent to the requestor at the time the information is made available to the public.

(2) If a request to establish or amend an import tolerance is denied, a notification of the denial will be made publicly available, and a copy of the denial letter, including the reasons for such action, will be sent to the requester.

(3) A tolerance established in an approved new animal drug application submitted under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act or a conditionally approved application for conditional approval submitted under section 571 of the Federal Food, Drug, and Cosmetic Act, will supersede an existing import tolerance and a notification of such action will be made publicly available and a copy of the notification will be sent to the requester. In the event that the conditionally approved application for a new animal drug is not renewed or is withdrawn, or such drug does not achieve full approval under section 512 of the Federal Food, Drug, and Cosmetic Act within 5 years following the date of the conditional approval, the Agency will reinstate the import tolerance unless § 510.207(a)(1) or (a)(2) applies. A notification of such action will be made publicly available and a copy of the notification will be sent to the original requestor.

§ 510.207 Revoking an import tolerance.

(a) The Commissioner, on his or her own initiative or on the petition of an interested person, under § 10.25 of this chapter, may revoke an import tolerance based upon:

(1) Scientific evidence showing an import tolerance to be unsafe; or

(2) Information demonstrating that the use of a new animal drug results in food being imported into the United States with residues exceeding the import tolerance.

(b) The Commissioner will provide public notification under § 510.205(d)(2) that will specify which of these grounds upon which he or she is acting and will be effective at the time the information is made available to the public.

(c) A petition for revocation must be submitted in the form specified in § 10.30 of this chapter.

§ 510.209 Reconsideration of action.

(a) The Commissioner, on his own initiative or on the petition of an interested person under part 10 of this chapter, may at any time reconsider part or all of a decision to establish, amend, or revoke an import tolerance.

(b) A petition for reconsideration must be submitted in accordance with § 10.20 of this chapter and in the form specified in § 10.33 of this chapter no later than 30 days after the date of public notification of the decision involved. The Commissioner may, for good cause, permit a petition to be filed more than 30 days after public notification of the decision. The grounds must demonstrate that relevant information contained in the administrative record was not previously or not adequately considered by the Commissioner. No new information may be included in a request for reconsideration. An interested person who wishes to rely on information not included in the administrative record shall submit either a request to amend an import tolerance under § 510.205 or a petition to revoke an import tolerance under § 510.207 and § 10.25 of this chapter.

§ 510.211 Administrative stay of action.

(a) The Commissioner, on his or her own initiative or on the request of an interested person under part 10 of this chapter, may at any time stay or extend the effective date of a decision to establish, amend, or revoke an import tolerance.

(b) A request for stay must be submitted in accordance with § 10.20 of this chapter and in the form specified in § 10.35 of this chapter no later than 30 days after public notification of the decision involved. The Commissioner may, for good cause, permit a petition to be filed more than 30 days after public notification of the decision.

Dated: January 19, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1430 Filed 1–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1138]

RIN 1625–AA09

Drawbridge Operation Regulation; Sacramento River, CA

AGENCY: Coast Guard, DHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Coast Guard is seeking comments and information on how best to address a proposal to change the operating regulation for the Freeport Drawbridge, mile 46.0, over the Sacramento River. The bridge owner has proposed to change the 6 a.m. and 10 p.m., summer time ''on demand'' bridge opening hours to a new timeframe between 9 a.m. and 5 p.m.; and to extend the annual winter operating schedule to include the month of October, due to a documented decrease in drawbridge openings compared to other nearby bridges. The proposed change is to address the issue of misalignment between drawbridge staffing and actual usage of the drawbridge that currently appears to be resulting in unnecessary staffing of the drawbridge during periods of navigational inactivity. In addressing this issue, the Coast Guard will continue to ensure the reasonable needs of navigation and maritime users are met. We will use your comments to help determine the best means to resolve this issue.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before March 26, 2012 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2011–1138 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* (202) 493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329. To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone (510) 437–3516, email *David.H.Sulouff@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to respond to this notice by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this notice (USCG–2011–1138), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* inserting USCG–2011–1138 in the ''Keyword'' box, and then clicking ''Search.'' If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all