List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–10–02 Saab AB, Saab Aeronautics (Formerly Known as Saab AB, Saab Aerosystems): Amendment 39–19641; Docket No. FAA–2018–1067; Product Identifier 2018–NM–158–AD.

(a) Effective Date

This AD is effective August 15, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Saab AB, Saab Aeronautics Model SAAB 2000 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 22, Auto flight.

(e) Reason

This AD was prompted by an event where the airplane did not respond to the flightcrew's flight control inputs because the pitch trim switches did not disconnect the autopilot. We are issuing this AD to address events where the airplane does not respond to the flightcrew's flight control inputs because the autopilot remains engaged, possibly resulting in loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Modification

Within 3,000 flight hours or 24 months after the effective date of this AD, whichever occurs first: Modify the wiring for the autopilot disconnect logic, in accordance with the Accomplishment Instructions of Saab Service Bulletin 2000–22–008, dated June 15, 2018.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (i)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Saab AB, Saab Aeronautics' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0240, dated November 7, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1067.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3220.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Saab Service Bulletin 2000–22–008, dated June 15, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Saab AB, Saab Aeronautics, SE–581 88, Linköping, Sweden; telephone +46 13 18 5591; fax +46 13 18 4874; email *saab2000.techsupport@saabgroup.com;* internet *http://www.saabgroup.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on July 3, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–14726 Filed 7–10–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 520, 522, 524, 526, 529, 556, and 558

[Docket No. FDA–2012–N–1067]

RIN 0910–AG17

New Animal Drugs; Updating Tolerances for Residues of New Animal Drugs in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to revise the animal drug regulations for tolerances for residues of approved new animal drugs. This final rule is necessary to standardize, simplify, and clarify the determination standards of tolerances and provide definitions for key terms. This final rule will enhance understanding of tolerance determination and improve the overall readability of the relevant regulations.

DATES: This rule is effective September 9, 2019.

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

FOR FURTHER INFORMATION CONTACT: Dong Yan, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0825, email: *dong.yan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Final Rule

This final rule revises the animal drug regulations regarding tolerances for residues of approved and conditionally approved new animal drugs in food. Specifically, we provide a revised scope and new section for definitions of key terms FDA uses in the regulations. Additionally, we explain the general considerations for using the tolerance information to ensure the safety of veterinary drug use in food-producing animals. Finally, we provide a uniform format for listing tolerances in part 556 (21 CFR part 556), subpart B, by removing obsolete or confusing terms and cross-referencing tolerances to the approved conditions of use for that new animal drug.

B. Summary of the Major Provisions of the Final Rule

This final rule standardizes and clarifies the standards for determining, codifying, and updating tolerances, and provides a definition section. Major provisions include:

- Establishing a new definitions section with the following definitions in § 556.3 (21 CFR 556.3):
  - Acceptable daily intake;
  - Acute reference dose;
  - Edible tissues;
  - Marker residue;
  - Not required;
  - Residue;
  - Target tissue;
  - Tolerance;
  - Total residue;
  - µg/kg; and
  - Zero.
- Revising the tolerance listings in subpart B to standardize the format of listings and to add cross references to part 520, 522, 524, 526, 529, or 558 (21 CFR part 520, 522, 524, 526, 529, or 558) that contain the approved or conditionally approved conditions of use of the drug.

C. Legal Authority

Our authority for issuing this final rule is provided by sections 512(b)(1)(G) and (H), (d)(1)(F), (d)(2), and (i), and 571(a)(2)(A) and (b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(b)(1)(G) and (H), (d)(1)(F), (d)(2), and (i), and 360ccc(a)(2)(A) and (b)(1)). These provisions relate to the information new animal drug and conditional new animal drug applicants provide with respect to proposed tolerances, withdrawal periods, and practicable methods, and the process by which FDA establishes and publishes regulations setting tolerances for residues of approved and conditionally approved new animal drugs. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

This final rule will not impose compliance costs, other than reading and understanding the final rule, on current or future sponsors of any approved and conditionally approved new animal drugs. We estimate those annualized costs to range from about $1,000 to about $1,500.

By providing a uniform format for listing tolerances, and removing obsolete and confusing terms, this final rule may provide more clarity to the listing of tolerances.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
ARfD	Acute reference dose.
ASDI	Acceptable single-dose intake.
CFR	Code of Federal Regulations.
CVM	Center for Veterinary Medicine.
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FSIS	Food Safety and Inspection Service, United States Department of Agriculture.
GFI	Guidance for Industry.
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

III. Background

A. History and Scope of This Rulemaking

We issued a proposed rule in the **Federal Register** of December 5, 2012 (77 FR 72254) (2012 proposed rule) to revise part 556 by standardizing and simplifying the codification style, revising the general considerations section, adding a scope section, and adding a definition section to define key terms used in the part. The definition section was proposed to include the terms used by FDA in the determination of tolerances. We proposed a definition section because some of the terms that had been used previously in part 556, subpart B were never defined, and some terminology that had been used was outdated or resulted in confusion to users of the part. We added a new scope section and proposed a revision to the general considerations section to provide additional information and clarification with respect to the tolerances listed in proposed subpart B.

We issued a supplemental notice of proposed rulemaking in the **Federal Register** of October 28, 2016 (81 FR 74962) (2016 supplemental proposed rule) to revise the proposed changes to part 556 to align with and clarify our current thinking. We explained our current thinking about analytical methods used to determine residue levels in tissues for new animal drugs intended for use in food-producing animals. We also explained that methods other than the ''regulatory method'' derived from the practicable method submitted by a sponsor as part of the new animal drug application can be used to determine the quantity of residue in edible tissues for surveillance and enforcement purposes. We removed the definition previously proposed in 2012 for ''regulatory method'' and an additional reference to the term to reserve the term for use with carcinogenic compounds. We also revised the previously proposed definitions for ''marker residue,'' ''tolerance,'' ''not required,'' and ''zero.'' We also removed the previously proposed definition for ''acceptable single-dose intake'' and added a proposed definition for ''acute reference dose'' to be consistent with existing international guidance.

B. General Overview of the Final Rule

This final rule revises the animal drug regulations regarding tolerances for residues of approved and conditionally approved new animal drugs in food. We are finalizing most of the provisions proposed in the 2012 proposed rule as revised by the 2016 supplemental proposed rule. This final rule also reflects revisions FDA made after considering all comments received. We have also made nonsubstantive wording changes for clarity.

This final rule amends part 556 by standardizing and simplifying the codification style and adding definitions for key terms. Specifically, we provide a revised scope and new section for definitions of key terms FDA uses in the regulations. Additionally, we explain the general considerations for using the tolerance information to ensure the safety of veterinary drug use in food-producing animals. Finally, we provide a uniform format for listing tolerances in subpart B, by removing obsolete or confusing terms and cross-referencing tolerances to the approved conditions of use for that new animal drug.

IV. Legal Authority

We are issuing this final rule under sections 512(b)(1)(G) and (H), (d)(1)(F), (d)(2), and (i), and 571(a)(2)(A) and (b)(1) of the FD&C Act. These provisions relate to the information new animal drug and conditional new animal drug applicants provide with respect to proposed tolerances, withdrawal periods, and practicable methods, and the process by which FDA establishes and publishes regulations establishing tolerances for residues of approved and conditionally approved new animal drugs. In addition, section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

V. Comments on the 2012 Proposed Rule and 2016 Supplemental Proposed Rule and FDA Response

A. Introduction

We received comments on the 2012 proposed rule and 2016 supplemental proposed rule, each containing one or more comments on one or more issues. We received comments from consumers, public health organizations, and the pharmaceutical industry.

We describe and respond to the comments in section V.B through E of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment letter and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

Some comments address issues that are outside of the scope of this rule. We do not discuss such comments in this document.

B. Comments on Scope

(Comment 1) One comment to the 2012 proposed rule asks FDA to clarify whether the proposed regulations would apply to drug residues in all foods (human and animal food), or only to human foods.

(Response 1) The regulations apply only to foods intended for human consumption. New § 556.5(c) (21 CFR 556.5(c)) states in part ''. . . the finding that the concentration of the marker residue in the target tissue from a tested animal is at or below the tolerance indicates that all edible tissues (excluding milk and eggs unless otherwise indicated) from that tested animal are safe for human consumption.''

C. Comments on Definition Section

We received several comments regarding proposed definitions.

(Comment 2) One comment to the 2012 proposed rule expresses concern that the term ''edible tissues'' as defined in the proposed rule does not include all parts of animals currently consumed as foods in the United States, and thus, residues of drugs in these foods are not included in the toxicological evaluation of new animal drugs. The comment expresses the opinion that many other tissues are eaten by humans and should be included in the toxicology evaluation and tolerance assignments. The comment suggests that to ensure safety of food for humans, the definition of edible tissue be equivalent to, and broad enough to cover, any tissue that will become a component of the food and not be limited to any specific set of tissues.

(Response 2) We typically request residue data for muscle, which is a highly consumed tissue; liver, kidney, and fat (skin with fat for poultry), which are tissues where residues have a tendency to accumulate; and milk, eggs, and honey, if applicable. The edible tissue definition, which includes all the aforementioned edible products, reflects our current thinking on how to address safety of residues in food products derived from animals treated with new animal drugs.

(Comment 3) One comment to the 2012 proposed rule suggests changes to the proposed definition of ''not required'' with respect to tolerances. In the 2012 proposed rule, we proposed that ''not required,'' in reference to tolerances, means that at the time of approval, the drug met one of the following conditions: (1) No withdrawal period (*i.e.,* zero withdrawal) 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) the drug qualified for a zero withdrawal period because it was poorly absorbed or metabolized rapidly to such an extent as to make selection of an analyte impractical or impossible. The comment proposes that conditions (1) and (2) be replaced with: ''(1) no withdrawal period (*i.e.,* zero withdrawal) was necessary for residues of the drug to deplete to or below the concentrations considered to be safe, or (2) an adequate withdrawal period was inherent in the proposed drug use, or (3) there was no concern about residues resulting from misuse or overdosing, or (4) the drug was poorly absorbed or metabolized rapidly to such an extent as to make selection of an analyte impractical or impossible.''

Additionally, a comment to the 2016 supplemental proposed rule asks FDA to explain what revisions were made to the definition for ''not required'' in reference to tolerance in the 2016 supplemental proposed rule (81 FR 74962 at 74964), and FDA's current practice with regard to the tolerance ''not required.''

(Response 3) We disagree with the comment to the 2012 proposed rule suggesting revisions because the revisions do not accurately reflect the criteria we used in the past to determine that a tolerance is ''not required.''

In the past, we did not assign a tolerance for some drugs when either of the conditions described under (1) or (2) in the 2012 proposed rule were met. However, currently and going forward, FDA generally assigns and will assign a tolerance if a tolerance can be established. There are some situations, however, under which it is not possible to establish a tolerance. For example, a tolerance cannot be established when FDA has determined that an Acceptable Daily Intake (ADI) is not needed for the approval after considering the physical, chemical, toxicological, and exposure characteristics of the drug residues, or when the drug is poorly absorbed or metabolized rapidly so as to make selection of an analyte impractical or impossible.

In the 2016 supplemental proposed rule (81 FR 74962 at 74964), FDA proposed to revise and clarify the definition for ''not required'' in reference to tolerance by separately listing the conditions described under (1) and (2) into two paragraphs, to make it clearer that if either the described conditions under (1) or (2) were met at the time of approval, a tolerance was

''not required.'' In addition, under (1), the phrase ''and there was a rapid depletion of residues'' was added before the phrase ''so there was no concern about residues resulting from misuse or overdosing'' to explain the reason (*i.e.,* rapid depletion of residues) for no concern about residues resulting from misuse or overdosing.

We received no further comment on the revised proposed definition and are finalizing as proposed in the 2016 supplemental proposed rule.

(Comment 4) A few comments to the 2012 proposed rule recommend that FDA be consistent with the terms and definitions used by international organizations, such as the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). Specifically, they recommend that FDA use the VICH definition for Acute Reference Dose (ARfD) to replace the FDA-proposed definition for Acceptable Single-Dose Intake (ASDI). One comment states that FDA should use the VICH term to avoid the confusion of having two terms that mean virtually the same thing, while another comment also recommends that we include the phrase ''microgram (µg) or milligram (mg)/kg of body weight'' in the definition for ARfD, as defined in the relevant VICH guideline background information for the definition of ARfD.

(Response 4) We agree with the comment suggesting FDA replace the proposed definition of ASDI with the VICH definition of ARfD. In the 2016 supplemental proposed rule (81 FR 74962 at 74964 and 74965), we proposed to harmonize with the VICH by removing the definition of ''acceptable single-dose intake (ASDI)'' and adding the definition of ''acute reference dose (ARfD),'' referenced in our draft guidance for industry ((GFI) #232 (VICH GL54)) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (80 FR 31041, June 1, 2015), which has since been finalized (Ref. 1 and 82 FR 40010, August 23, 2017). We proposed ARfD to be defined as ''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.'' We disagree that the phrase ''microgram (µg) or milligram (mg)/kg of body weight'' should be included in the definition for ARfD, because the VICH definition for ARfD is not limited to being reported as ''microgram (µg) or milligram (mg)/kg of body weight'' (GFI #232 (VICH GL54)). We received no further comment on these proposed revisions and are finalizing as proposed in the 2016 supplemental proposed rule.

(Comment 5) One comment to the 2012 proposed rule recommends that FDA use the term ''point of departure'' (POD) instead of ''no observed effect level (NOEL)'' for calculation of the ADI.

(Response 5) The ADI definition in the 2012 proposed rule stated that an ADI is calculated by dividing the NOEL (from the most appropriate toxicological study) by a safety factor. We agree with the comment that the term ''POD,'' or threshold, is more appropriate than the term ''NOEL'' for calculation of the ADI, because the term ''POD'' is more inclusive and reflects FDA's current and past practice for the derivation of an ADI.

However, since the publication of the 2012 proposed rule, GFI #232 (VICH GL54) has been published, which includes a different definition for ADI than the one included in the 2012 proposed rule. There are no fundamental scientific differences between the ADI definition from the 2012 proposed rule and the ADI definition found in GFI #232 (VICH GL54). As a result, we are amending the ADI definition and using the ADI definition from GFI #232 (VICH GL54) in this final rule, to be consistent with the VICH definition for ADI.

Unlike the ADI definition in the 2012 proposed rule, the ADI definition found in GFI #232 (VICH GL54) and adopted here does not include a calculation for an ADI and therefore does not use the term NOEL or POD. We note, however, that we use the term POD in the description for calculation of an ADI in the revision of guidance GFI #3 entitled ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals'' (Ref. 2 and 83 FR 27333, June 12, 2018).

(Comment 6) One comment to the 2012 proposed rule requests clarification on the proposed definition for ''regulatory method'' and on the use of the term in proposed § 556.5(d), which stated that FDA requires that a drug sponsor develop a regulatory method to measure drug residues in edible tissues of approved target species. This comment notes that a regulatory method has historically been used to refer to the ''required determinative and confirmatory procedures for regulatory surveillance of residue concentrations in meat products entering the food supply for comparison to the tolerance post-commercialization of the product.'' The comment also states the context of the proposed rule appears to be the method(s) used to collect data to support the setting of the tolerances preapproval. The comment asks if the proposed rule implies that tolerances may be established using analytical procedures other than the determinative procedure. In addition, the comment states it should be clarified if regulatory method is referring to method(s) used preapproval for setting the tolerance versus a finite method(s) used for determining post-commercialization residue to compare to the tolerance. Additionally, another comment to the 2016 supplemental proposed rule suggests that, instead of removing the term ''regulatory method'' from the definitions listed in part 556, FDA keep this term and add the term ''carcinogenic compounds'' to the definitions and specify that a regulatory method is only required for carcinogenic compounds.

(Response 6) We realized that, in the 2012 proposed rule, the term ''regulatory method'' proposed in § 556.3 and used in proposed § 556.5(d) caused some confusion; thus, the 2016 supplemental proposed rule explains our current thinking about the term and its use (81 FR 74962 at 74963). We explained in the 2016 supplemental proposed rule that an analytical method other than the practicable method, which is described in § 514.1(b)(7) (21 CFR 514.1(b)(7)), can be used for surveillance and enforcement purposes for non-carcinogenic compounds, as long as the performance criteria of that method are comparable to those of the practicable method submitted by the sponsor as part of the new animal drug application. Such an analytical method other than the practicable method can be used for surveillance and enforcement purposes for non-carcinogenic compounds, so long as the performance criteria (*e.g.,* sensitivity, specificity, accuracy, and precision) of that method are comparable to those of the practicable method submitted by the sponsor as part of the new animal drug application. In addition, we proposed a revision to the definition of ''zero'' in proposed § 556.3, in reference to tolerances, by deleting ''when using a method of detection prescribed or approved by FDA'' from the definition, because an analytical method other than the practicable method can be used for surveillance and enforcement purposes for non-carcinogenic compounds. In the 2016 supplemental proposed rule we proposed to revise § 556.5(d) to align with our current thinking and to remove the term ''regulatory method'' from this provision because we are reserving this

term for use with carcinogenic compounds (part 500, subpart E (21 CFR part 500, subpart E)). Further, the regulations under part 556 are dedicated to tolerances for non-carcinogenic compounds approved for use in food-producing animals, while those under part 500, subpart E, entitled ''Regulation of Carcinogenic Compounds Used in Food-Producing Animals,'' are dedicated to carcinogenic compounds for use in food-producing animals. FDA's intention is to clearly separate the purpose of these two parts in Title 21 of the Code of Federal Regulations and, therefore, does not agree with the recommendation. We are finalizing as proposed in the 2016 supplemental proposed rule and removing the term ''regulatory method'' from part 556.

(Comment 7) We received two comments to the 2016 supplemental proposed rule regarding the proposed changes in the tolerance definition. The comments express concern that by replacing the term ''target tissue'' with ''edible tissue'' in the definition, the focus about using target tissue to indicate safety of other edible tissues from treated animals is likely to be lost.

(Response 7) FDA's revised definition reflects the fact that we can establish tolerances for both target and non-target tissue. We intend to continue to use the target tissue tolerance to indicate safety of all of the edible tissue (excluding milk and eggs, unless otherwise specified) from treated animals.

(Comment 8) One comment to the 2016 supplemental proposed rule asks us to explain how FDA will interpret the revised definition for ''zero'' in proposed § 556.3, which reads, ''zero, in reference to tolerances in this part, means any residues detected in the tissue renders it unsafe.'' The comment states that ''zero'' is defined by the sensitivity of the testing methodology and asks what would happen if the ''testing method increases their sensitivity level that it will be chasing zero?'' The comment asks FDA to explain how this will influence zero tolerance and ''updating new withdrawal times'' and how this new information will be communicated to the industry. The comment also recommends that in the proposed definition for ''zero,'' the word ''tissue'' be replaced with ''edible tissue,'' to be consistent throughout the document.

(Response 8) We agree with the comment that ''zero'' is defined by the sensitivity of the testing methodology. As explained in the preamble of the 2012 proposed rule (77 FR 72254 at 72256), in approving certain animal drugs in the past, FDA assigned a ''zero'' tolerance, with ''zero'' meaning that no residues could be detected using the ''approved analytical method.'' Often, the analytical method chosen to determine ''zero'' represented the limit of analytical method technology at the time of the evaluation. However, we recognize that equipment, reagents, and methodology change over time and the analytical method (practicable method) submitted by the sponsor in support of drug approval may become obsolete. Therefore, we explained in the 2016 supplemental proposed rule (81 FR 74962 at 74964) that an analytical method other than the practicable method can be used for surveillance and enforcement purposes for non-carcinogenic compounds. Such an analytical method should have the same capability as the practicable method to determine the quantity of the drug residues such that the tolerance, withdrawal period, or other use restrictions continue to ensure that the use of the drug will be safe. Therefore, the assigned withdrawal periods will not need to be changed.

In response to the last part of the comment that we replace ''tissue'' with ''edible tissue'' in the definitions section, we agree and finalize the codified as the comment suggested.

(Comment 9) A comment to the 2016 supplemental proposed rule observes that new terms such as ''practicable method,'' ''analytical method,'' ''edible tissue,'' and ''acute reference dose'' were used to replace ''regulatory method,'' ''target tissue,'' and ''acute single dose intake''; however, these new terms are not present in FDA's draft revised GFI #3 (81 FR 47397, July 21, 2016) (since finalized), and the inconsistency will lead to confusion between the regulation and guidance.

(Response 9) We interpret the term, ''acute single dose intake,'' in the comment to mean ''acceptable single-dose intake.'' We disagree with the comment that the terms, ''practicable method,'' ''analytical method,'' ''edible tissue,'' and ''acute reference dose'' are not present in the guidance. Although revised GFI #3 does not have a definition section or glossary, all of these terms are used in the guidance. We do not believe there is any inconsistency in how these terms are used and therefore do not believe that will lead to confusion between the regulation and the guidance.

(Comment 10) One comment to the 2016 supplemental proposed rule observes that many of the revised terms proposed for part 556 remain as currently defined in 21 CFR 500.80. The comment expresses concern that the existence of different definitions will lead to confusion.

(Response 10) The regulations under part 500, including those terms listed under 21 CFR 500.82, implement the Diethylstilbestrol (DES) Proviso to the Delaney Clause in section 512(d)(1)(I) of the FD&C Act (21 U.S.C. 360b(d)(1)(I)), which allows cancer-causing compounds to be used in food-producing animals if, among other conditions, no residue of such drug will be found in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animals. Because there are different requirements for approving a new animal drug under these provisions than those for approving non-carcinogenic new animal drugs for use in food-producing animals, a different definition is needed for the term ''marker residue'' depending on whether the new animal drug is a carcinogenic compound or a non-carcinogenic compound. The definitions of ''residue'' and ''target tissue,'' although slightly different in wording, have the same meaning in both parts 500 and 556, and we do not believe this will lead to confusion.

(Comment 11) One comment to the 2016 supplemental proposed rule asks FDA to explain the differentiation of residue method requirements for carcinogenic and non-carcinogenic compounds.

(Response 11) Section 512(d)(1)(I) of the FD&C Act provides that an animal drug will not be approved if, among other reasons, the drug is a carcinogen, unless the Secretary of Health and Human Services finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice, that no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals. Thus, the FD&C Act requires the use of the approved regulatory method as promulgated in regulation to show ''no residues'' of carcinogens; however, there is no such requirement to use an approved regulatory method for measuring residues of non-carcinogenic compounds for post-approval residue surveillance and enforcement. Therefore, an analytical method other than the practicable method (§ 514.1(b)(7)) can be used for residue surveillance and enforcement purpose for non-carcinogenic compounds.

D. Comments on Analytical Method

We received eight comments regarding the statement in the 2016 supplemental proposed rule that an

analytical method other than the practicable method can be used for post-approval residue surveillance and enforcement (81 FR 74962 at 74964).

(Comment 12) One comment recommends that FDA modify the proposed revision to § 556.5 General Considerations by removing the phrase ''FDA uses the practicable method to determine the quantity of the drug residues that can safely remain in edible tissue (*i.e.,* the tolerance) . . .'' from the provision. The comment states that the quantity of drug residues that can safely remain in the edible tissues is based on the safe concentration derived from the ADI. In addition, the comment states that ''while the practicable method may be utilized to determine the ratio of the marker residue to the total drug residues, the work typically precedes the finalization of the official marker residue method.''

(Response 12) FDA does not agree that the phrase should be removed from the sentence under § 556.5 General Considerations and is finalizing as proposed. In proposed § 556.5(d) of the 2016 supplemental proposed rule, we said that we require a drug sponsor to submit a practicable method as part of their new animal drug application. We use 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. We think that it is clear that the phrase refers to establishment of a tolerance, which is based not only on the safe concentration derived from the ADI, but also on the marker residue or other residues measured by the practicable method.

(Comment 13) Two comments to the 2016 proposed rule express concerns that, with the implementation of the rule, an analytical method other than the practicable method may be used for post-approval residue surveillance and compliance when that other analytical method is not actually equivalent to the practicable method. The comments advocate for proper validation of the analytical method before its use for residue surveillance and compliance. One of the comments asks FDA to clarify the terms ''performance criteria'' and ''comparable'' used in the 2016 supplemental proposed rule as they relate to the requirements that an analytical method other than the practicable method must meet before it can be used for residue surveillance and enforcement. It recommends that FDA add a definition for the term ''performance criteria'' and provisions in the final rule to ensure that the original marker residue to total residue ratio is achieved with the analytical method.

(Response 13) FDA establishes tolerances using the practicable method (defined at § 514.1(b)(7)) submitted by a sponsor as part of the new animal drug application. The practicable method is used to collect data for tolerance assignment. After the drug product is approved, FDA makes the practicable method available for monitoring drug residues in the food supply. In the 2016 supplemental proposed rule, we stated that as technologies have evolved, many of the older methods have become obsolete. In addition, there is an increased reliance on multiresidue methods in the monitoring of the food supply. We also stated that an analytical method other than the practicable method can be used for residue surveillance and enforcement purposes for non-carcinogenic compounds, as long as the performance criteria (*e.g.,* sensitivity, specificity, accuracy, and precision) of the analytical method are comparable to those of the practicable method. FDA considers the performance criteria of the two methods to be ''comparable'' if the analytical method has been shown, through appropriate validation, to have the same capability as the practicable method to determine the quantity of the drug residues remaining in edible tissues of treated animals so that the tolerance, withdrawal period, or other use restrictions continue to ensure that the use of the drug will be safe. The proposal included sensitivity, specificity, accuracy, and precision as examples of the performance criteria. As a result, we do not believe additional definitions are necessary.

(Comment 14) One comment to the 2016 supplemental proposed rule asks FDA to clarify how the Food Safety and Inspection Service, United States Department of Agriculture (FSIS) (USDA) methods will be viewed by FDA and whether this supplemental proposed rule is ''intended to indicate that any multi-residue method (MRM), independent of version, can be used, and the version changes have no impact on the data.''

(Response 14) We interpret that the comment is asking whether the supplemental proposed rule is intended to indicate that any multiresidue method (MRM), independent of version, can be used for surveillance and enforcement purposes. The supplemental proposed rule is intended to indicate, as explained above, that an analytical method other than the practicable method can be used for surveillance and enforcement purposes for non-carcinogenic compounds, as long as the performance criteria *(e.g.,* sensitivity, specificity, accuracy, and precision) of that method are comparable to those of the practicable method submitted by the sponsor as part of the new animal drug application.

(Comment 15) One comment suggests that ''the availability of advanced methods that improve upon the practicable method necessarily means that the tolerance, withdrawal period, and the need for use restrictions of many drugs must be reassessed using the best available technologies.''

(Response 15) The 2016 supplemental proposed rule stated that an analytical method other than the practicable method can be used for post-approval residue surveillance and enforcement, which allows the use of evolving analytical technologies while maintaining the tolerance, withdrawal period, and other restrictions as part of the conditions of the approval. The practicable method is used to collect data for tolerance assignment. A different method may be used for surveillance and enforcement purposes as long as it has the same capability as the practicable method to measure residues to ensure the established tolerance is not exceeded. If an analytical method has the same capability as the practicable method to determine the quantity of the same marker residue in the same tissue, then the tolerance, withdrawal period, or other use restrictions for the approved drug will continue to ensure that the use of the drug will be safe.

(Comment 16) One comment suggests that, in the cases where the performance criteria of a new analytical method and a practicable method are not comparable, FDA consider implementing a strategy to correct the tolerance based on the recovery of the marker residue observed when the new analytical method is used, with the goal of ensuring that the use of the approved drug is safe while avoiding the need for new studies to update the marker to total residue ratio.

(Response 16) FDA does not think that it is necessary to change the tolerance based on the recovery of the marker residue observed with a new analytical method. The point of using an analytical method with comparable performance criteria as the practicable method is to allow newer more useful methods to be used for surveillance and enforcement purposes, as long as the newer method has the same capability as the practicable method to determine the quantity of the drug residues so that the tolerance, withdrawal period, or other use restrictions continue to ensure

that the use of the drug will be safe. Such a policy ensures a safe food supply and allows regulatory agencies to take advantages of scientific advances in analytical methodology.

(Comment 17) One comment to the 2016 supplemental proposed rule asks that, if FSIS MRMs are used prior to an active pharmaceutical ingredient (API) being approved, can the FSIS methods be used [to support a new animal drug approval] with or without modification [vis-à-vis version changes]; if the data FSIS generated for validation can be submitted to Center for Veterinary Medicine (CVM); and if a sponsor can submit a request for FSIS to provide all data on their API.

(Response 17) FDA encourages drug sponsors to take advantage of available information from government laboratories and industry for the development of an analytical method to support a new animal drug approval. The modification of a method already validated in a government laboratory may allow for a scaled down interlaboratory method trial process during the drug application review period. Although FDA does not object to a sponsor requesting information from FSIS, we defer to USDA on whether, how, and under what conditions such information is made available.

(Comment 18) A comment asks FDA to encourage sponsors to utilize the same analytical methods as those used by USDA FSIS for creation of the approved analytical method, because of the many associated benefits.

(Response 18) Although, in theory, we agree that submitting a practicable method that is in use by USDA FSIS may be beneficial, we note that continued use of such a method by USDA FSIS is not guaranteed, and as newer technologies become available and relied on, the same need to use an analytical method other than the practicable method for monitoring the food supply may appear after approval of the new animal drug application. We also note that the USDA FSIS MRMs, which are used for screening purposes, may or may not be appropriate to use to establish a tolerance, withdrawal period, and other conditions of safe use, which is the purpose behind requiring submission of a practicable method as part of the new animal drug application. Therefore, as long as a method meets the requirements of § 514.1(b)(7) for the sponsor of a new animal drug application to submit a practicable method, FDA declines the commenter's request to encourage sponsors to use USDA FSIS methods to meet those requirements. We encourage drug sponsors to reference FDA's relevant GFI documents for the method performance recommendations. We further encourage drug sponsors to use a method that is in line with the recommendations in the relevant GFIs, regardless of the method's origin.

E. Comments on Subpart B, Listing of Tolerances for Residues of Approved and Conditionally Approved New Animal Drugs

(Comment 19) We received two comments to the 2012 proposed rule about the removal of safe concentrations from part 556. One comment agrees with our decision and states this will reduce the potential for confusion. A second comment expresses concern that, for some drugs for which FDA historically listed only ADI and safe concentrations, removing the listing of safe concentrations will lead to the loss of valuable toxicological information about the drugs. The comment cites fenprostalene as an example. The comment asks that FDA keep pertinent toxicological information for these drugs for which tolerances are not required.

(Response 19) We agree with the comment that removing safe concentrations from part 556 will reduce the potential for confusion. We disagree with the comment that toxicological information about a drug is lost when listings of safe concentrations for that drug are removed, so long as the ADI for that drug is listed. Toxicological information for the residue of a drug is determined through toxicological evaluations and reflected by the assigned ADI. Safe concentrations for an edible tissue are calculated from the ADI using a formula in which the only variable is the ADI (safe concentration = ADI × Human Body Weight/Food Consumption Value) (see GFI #3 ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals'' Ref. 2 and 83 FR 27333). When there is an ADI assigned for the residue of a drug, the ADI is listed under that drug's name in part 556, together with any tolerances (if tolerances are established). Therefore, after removing safe concentrations from the listings, toxicological information about the drug is still reflected by the ADI. Listing of the ADI alone in part 556 provides sufficient toxicological information for the drug. We note that the safe concentrations remain available through the Freedom of Information Drug Summaries, available on the CVM website at *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm2006466.htm.* Additionally, safe concentrations can be calculated with the ADI in part 556 using the formula described above.

(Comment 20) One comment to the 2012 proposed rule questions why FDA's ''safe level of residue'' for the same drug is different in different food products. The commenter is concerned that FDA's decision is not based on science, but ''on rule of law.'' The comment uses carbendazim in orange juice as an example.

(Response 20) The comment uses the example of carbendazim in orange juice; however, because the proposed rule addresses tolerances for residues of drugs in edible tissues of treated animals, we assume the commenter is asking why the tolerance for the same drug may be different in different edible tissues from a treated animal.

FDA assigns one ADI to reflect the quantity of the drug residues that humans can safely consume on a daily basis. The ADI is based on the toxicological, microbiological, or pharmacological properties of the drug and represents the total amount of residues that humans can safely consume on a daily basis from the different food sources of the residue (*i.e.,* food derived from the food-producing animal species for which the drug is approved).

FDA assigns a tolerance based on not only the ADI, but also the ratio of the marker residue to total residue in the specific edible tissue, which can potentially differ as a function of pharmacokinetic properties of the drug in the food-producing animal species for which the drug is approved. The marker residue is the residue whose concentration is in a known relationship to the concentration of total residue in an edible tissue. In addition, the tolerance also takes into account the amount of the edible tissue that is consumed. Therefore, different tolerances, rather than a single tolerance, are often needed and assigned for different edible tissues of the same food-producing animal species, or for the same edible tissue from different food-producing animal species, to ensure that daily human consumption of the total drug residue in the edible tissues will not exceed the ADI.

(Comment 21) One comment to the 2016 supplemental proposed rule asks FDA to clarify the regulatory/enforcement use of available surveillance residue methods for non-target tissues in a species of livestock where a tolerance has not been established for that tissue but has been established for another tissue.

(Response 21) When CVM establishes a tolerance for a specific edible tissue as part of a new animal drug approval,

CVM provides, for surveillance and enforcement purpose, an analytical method that has been evaluated in an interlaboratory study for assay of the residue in the specific edible tissue. A tolerance assigned for a residue in a specific edible tissue or tissues as listed in part 556, subpart B applies only to the specific tissue or tissues.

(Comment 22) A comment to the 2012 proposed rule expresses concern that, as testing abilities improve over time, ''smaller and smaller'' levels of detection are attained. The end result could be ''that there will be no food naturally produced that will be totally free of detectable residues.'' The comment also observes that the proposed rule establishes that approved drugs meet established tolerance levels, but that there are drugs that are approved for use in food-producing animals that have no published tolerance levels. The comment asks where FDA stands on this, *i.e.,* when a drug is approved, but no tolerance exists for a particular tissue. The comment also questions why some new animal drugs for use in food-producing animals have been approved without a tolerance even though residues are able to be detected at very low concentrations as analytical methods improve.

(Response 22) The detection limit for the analytical methods is not a basis to determine if a tolerance needs to be assigned or if a tolerance is not required for approval of a new animal drug. However, in the past, during the new animal drug approval process FDA determined that a tolerance was not required for some drugs. As we explained in the 2016 supplemental proposed rule, ''not required'' means: (1) No withdrawal period was necessary for residues of the drug to deplete to or below the concentrations considered to be safe, or an adequate withdrawal period was inherent in the proposed drug use, and there was a rapid depletion of residues, so there was no concern about residues resulting from misuse or overdosing; or (2) No withdrawal period was necessary because the drug was poorly absorbed or metabolized rapidly so as to make selection of an analyte impractical (81 FR 74962 at 74966). Currently, FDA's general practice is to establish a tolerance for all new animal drugs we approve. However, as discussed earlier, FDA recognizes that there are some situations for which it is not possible to establish a tolerance. For example, a tolerance cannot be established when FDA has determined that an ADI is not needed for the approval after considering the physical, chemical, toxicological, and exposure characteristics of the drug residues, or when the drug is poorly absorbed or metabolized rapidly so as to make selection of an analyte impractical or impossible. Under both circumstances, FDA requires that drug sponsors provide toxicology and residue information to ensure that the approved use is safe even though a tolerance is not assigned.

(Comment 23) A comment to the 2012 proposed rule recommends that the regulation should also include tolerances for residues of ''new as well as old drugs,'' as old and/or forgotten drugs may have new or undiscovered impacts in human health, especially those drugs used in different countries from which the United States receives imported animal-derived food.

(Response 23) ''New animal drug'' is a term defined by section 201(v) of the FD&C Act (21 U.S.C. 321(v)). With very limited exceptions, drugs intended for use for animals meet the definition of ''new animal drug.'' Since 1968, FDA has had a specific statutory requirement under section 512(i) of the FD&C Act to codify any tolerance established as a consequence of the approval of a new animal drug application (NADA). Subpart B in part 556 was created to satisfy this requirement; it is a listing of tolerances assigned for ''new animal drugs'' approved or conditionally approved for use in food-producing animals in the United States. Tolerances for substances administered to food-producing animals as food additives prior to 1968 were added to this listing as appropriate if these substances became the subject of an approved NADA.

When approval of an NADA is withdrawn, section 512(i) of the FD&C Act requires that the Agency revoke the regulations that were published following the approval. That revocation includes the regulation for any tolerance listed in part 556; thus, the tolerance is removed for any drug for which approval has been withdrawn.

Regarding importation of animal-derived food, in addition to establishing tolerances for approved new animal drugs, FDA also has authority to establish import tolerances for new animal drugs not approved in the United States, but used lawfully in another country, to ensure that food imported into the United States is safe (section 512(a)(6) of the FD&C Act).

(Comment 24) A comment to the 2012 proposed rule agrees with FDA's proposal to delete salt designations and safe concentrations from the tolerance listings in part 556, subpart B. However, the comment suggests that it is not necessary to delete the word ''uncooked'' from the individual listings for tolerances in subpart B.

(Response 24) Section 556.5, General Considerations clarifies that, ''All tolerances refer to the concentrations of the marker residue, or other residue indicated for monitoring, permitted in uncooked tissues.'' Therefore, the word ''uncooked'' is not necessary in the listing of tolerances, so we are finalizing as proposed.

F. Other Comments

(Comment 25) One comment to the 2012 proposed rule expresses concern that an unintended consequence of this rule is that it would have the effect of acting as a ''non-tariff trade barrier as it does not conform and is contradictory to the practices of our trading partners.''

(Response 25) We recognize the importance of harmonizing international food safety standards to facilitate trade. We also recognize that sometimes, because of our requirement to meet applicable U.S. statutes and regulations governing food safety, our tolerances are sometimes not harmonized with international food safety standards.

FDA participates in the trilateral (European Union, Japan, United States) VICH to harmonize the technical requirements for veterinary product registration. This harmonization develops common guidelines, including the development of data to support an ADI and tolerance for a particular drug. FDA also participates in The Codex Committee on Residues of Veterinary Drugs in Foods, which determines priorities for the consideration of residues of veterinary drugs in foods and recommends maximum residue limits (MRLs) for veterinary drugs to The Codex Alimentarius Commission of the Food and Agriculture Organization and the World Health Organization of the United Nations.[1] The Codex Alimentarius Commission develops harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. Again, although FDA recognizes the value in harmonizing requirements and standards, we are required to follow U.S. law with respect to our standard setting activities.

VI. Effective/Compliance Date

The rule is effective September 9, 2019.

[1] See *http://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCRVDF.*

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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 us 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). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule would not impose compliance costs on current or future sponsors of any approved or conditionally approved new animal drugs, and because we did not receive any comments pertaining to this same assertion in the 2016 supplemental proposed rule, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

All entities affected by this final rule will incur the one-time cost for reading and understanding this rule. We use the time required to complete this activity to estimate the burden of this activity. To understand this rule, affected entities will read the preamble and codified, which together contain almost 16,800 words. If those reviewing the rule read at the average adult reading speed of approximately 200 words to 250 words per minute, the time to read and understand the regulation is about 67 to 84 minutes per person. There are currently 41 sponsors with approved applications for new animal drugs for use in food-producing animals that will read the final rule. We also estimate that approximately one sponsor per year will submit a first-time application for approval of a new animal drug for use in a food-producing animal. Thus, we estimate that about 51 firms would need to read and understand this rule over the next 10 years.

To value the time for complying with reading and understanding the rule, we use wages calculated from the Bureau of Labor Statistics' national industry-specific occupational employment and wage estimates for the pharmaceutical and medical manufacturing industry (Ref. 3).[2] [3] We use the average of the $71.06 hourly wage of management occupations (occupation code 11–0000) and the $79.52 hourly wage of legal occupations. We double this average hourly wage to account for benefits and overhead, yielding an average hourly labor cost of $150.58. We estimate the cost for the one person to read and understand the rule ranges from $169 to $211. The total costs for reading and understanding the rule over 10 years range from around $8,600 to around $10,800.

In table 1, FDA provides the Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated Information Center accounting information.

TABLE 1—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year					7 3		
Annualized Quantified					7 3		
Qualitative	Standardizing and simplifying the determination standards and codification style regarding tolerances should provide more clarity for industry members.						
Costs:							
Annualized Monetized $millions/year	$0.0011 $0.0010	$0.0010 $0.0009	$0.0013 $0.0011	2017 2017	7 3	10 10	
Annualized Quantified					7 3		
Qualitative.							
Transfers:							

[2] May 2017 National Industry-Specific Occupational Employment and Wage Estimates for the North American Industry Classification System (NAICS) 325400—Pharmaceutical and Medicine Manufacturing. We use estimates from NAICS 325400 because detailed estimates for NAICS 325412 are not available. Please see *http://www.bls.gov/oes/*.

[3] This wage is slightly higher than that of management occupations for NAICS 622110—General Medical and Surgical Hospitals, but this difference does not significantly impact of the cost of the final rule.

TABLE 1—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Federal Annualized Monetized $millions/year					7 3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7 3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: No Effect.
Small Business: The final rule will not have a significant impact on a substantial number of small entities that manufacture new animal drugs for use in food-producing animals.
Wages: No effect.
Growth: No effect.

Table 2 presents a summary of the costs, cost savings, and net costs of the final rule. We estimate that the final rule has net costs with present values that range from about $11,000 to $17,000, well below the de minimis cost threshold for Executive Order 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[In $ millions 2016 dollars, over a perpetual time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$.011	$.009	$.012	$.014	$.013	$.016
Present Value of Cost Savings	0	0	0	0	0	0
Present Value of Net Costs	.011	.009	.012	.014	.013	.016
Annualized Costs	0.0007	0.0007	0.0008	0.0004	0.0004	0.0005
Annualized Cost Savings	0	0	0	0	0	0
Annualized Net Costs	0.0007	0.0007	0.0008	0.0004	0.0004	0.0005

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(i) 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 an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does 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, we conclude that the 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.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references are on display at the Dockets Management Staff (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 *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, 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,* August 2017.

2. FDA, Guidance for Industry #3, ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used In Food-Producing Animals,'' *https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052180.pdf,* June 2018.

3. Bureau of Labor Statistics, United States Department of Labor, May 2017 National Industry-Specific Occupational Employment and Wage Estimates for the North American Industry Classification System (NAICS) 325400—Pharmaceutical and Medicine

Manufacturing. Available at *http://www.bls.gov/oes/.*

List of Subjects

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Parts 520, 522, 524, 526, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I, subchapter E, is amended as follows:

PART 500—GENERAL

■ 1. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 2. Amend § 500.82, in paragraph (b), by alphabetically adding a definition for ''No residue'' to read as follows:

§ 500.82 Definitions.

* * * * *

(b) * * *

No residue means the marker residue is below the limit of detection using the approved regulatory method. The ''no residue'' designation applies only to compounds of carcinogenic concern.

* * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 4. In § 520.462, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 520.462 Clorsulon drench.

* * * * *

(c) *Related tolerances.* See § 556.163 of this chapter.

* * * * *

■ 5. In § 520.1840, add paragraph (c) to read as follows:

§ 520.1840 Poloxalene.

* * * * *

(c) *Related tolerances.* See § 556.517 of this chapter.

* * * * *

■ 6. In § 520.2325b, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 520.2325b Sulfaquinoxaline drench.

* * * * *

(c) *Related tolerances.* See § 556.685 of this chapter.

* * * * *

■ 7. In § 520.2640, revise paragraph (c) to read as follows:

§ 520.2640 Tylosin.

* * * * *

(c) *Related tolerances.* See § 556.746 of this chapter.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 9. In § 522.150, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 522.150 Azaperone.

* * * * *

(c) *Related tolerances.* See § 556.68 of this chapter.

* * * * *

■ 10. In § 522.468, add paragraph (c) to read as follows:

§ 522.468 Colistimethate sodium powder for injection.

* * * * *

(c) *Related tolerances.* See § 556.167 of this chapter.

* * * * *

■ 11. In § 522.770, revise paragraph (c) to read as follows:

§ 522.770 Doramectin.

* * * * *

(c) *Related tolerances.* See § 556.222 of this chapter.

* * * * *

■ 12. In § 522.850, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 522.850 Estradiol valerate and norgestomet in combination.

* * * * *

(c) *Related tolerances.* See § 556.240 of this chapter.

* * * * *

■ 13. In § 522.1077, redesignate paragraphs (c) and (d) as paragraphs (d) and (e) and add new paragraph (c) to read as follows:

§ 522.1077 Gonadorelin.

* * * * *

(c) *Related tolerances.* See § 556.304 of this chapter.

* * * * *

■ 14. In § 522.1079, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 522.1079 Serum gonadotropin and chorionic gonadotropin.

* * * * *

(c) *Related tolerances.* See § 556.304 of this chapter.

* * * * *

■ 15. In § 522.1192, add paragraph (c) to read as follows:

§ 522.1192 Ivermectin.

* * * * *

(c) *Related tolerances.* See § 556.344 of this chapter.

* * * * *

■ 16. In § 522.1242, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 522.1242 Levamisole.

* * * * *

(c) *Related tolerances.* See § 556.350 of this chapter.

* * * * *

■ 17. In § 522.1662a, add paragraph (l) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(l) For related tolerances see § 556.500 of this chapter.

■ 18. In § 522.2120, redesignate paragraphs (c) and (d) as paragraphs (d) and (e) and add new paragraph (c) to read as follows:

§ 522.2120 Spectinomycin dihydrochloride injection.

* * * * *

(c) *Related tolerances.* See § 556.600 of this chapter.

* * * * *

■ 19. In § 522.2477, add paragraph (c) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(c) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

* * * * *

■ 20. In § 522.2640, revise paragraph (c) to read as follows:

§ 522.2640 Tylosin.

* * * * *

(c) *Related tolerances.* See § 556.746 of this chapter.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 21. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.770 [Amended]

■ 22. In § 524.770, in paragraph (c), remove ''§ 556.225'' and in its place add ''§ 556.222''.

■ 23. In § 524.920, revise paragraph (c) to read as follows:

§ 524.920 Fenthion.

* * * * *

(c) *Related tolerances.* See § 556.280 of this chapter.

* * * * *

■ 24. In § 524.1044e, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 524.1044e Gentamicin spray.

* * * * *

(c) *Related tolerances.* See § 556.300 of this chapter.

* * * * *

■ 25. In § 524.1600b, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone ophthalmic ointment.

* * * * *

(c) *Related tolerances.* See §§ 556.430 and 556.470 of this chapter.

* * * * *

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 26. The authority citation for part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 27. In § 526.820, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 526.820 Erythromycin.

* * * * *

(c) *Related tolerances.* See § 556.230 of this chapter.

* * * * *

■ 28. In § 526.1696d, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

* * * * *

(c) *Related tolerances.* See §§ 556.460 and 556.510 of this chapter.

* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 29. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 30. In § 529.400, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 529.400 Chlorhexidine tablets and suspension.

* * * * *

(c) *Related tolerances.* See § 556.120 of this chapter.

* * * * *

■ 31. Revise part 556 to read as follows:

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

Subpart A—General Provisions

Sec.

Subpart B—Specific Tolerances for Residues of Approved and Conditionally Approved New Animal Drugs

Sec.

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

Subpart A—General Provisions

§ 556.1 Scope.

(a) The Federal Food, Drug, and Cosmetic Act requires an applicant seeking approval or conditional approval of a new animal drug to submit a proposed tolerance as part of its new animal drug application when such a tolerance is needed to assure that the proposed use of the new animal drug will be safe (see sections 512(b)(1)(H)

and 571(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act). FDA assigns tolerances for animal drugs used in food-producing animals as part of the application approval process. Tolerances for approved and conditionally approved new animal drugs are codified in subpart B of this part.

(b) Compounds that have been found to be carcinogenic are regulated under subpart E of part 500 of this chapter.

§ 556.3 Definitions.

As used in this part:

Acceptable daily intake (ADI) means the daily intake which, during up to an entire life of a human, appears to be without adverse effects or harm to the health of the consumer. The ADI most often will be set on the basis of the drug's toxicological, microbiological, or pharmacological properties. It is usually expressed in micrograms or milligrams of the chemical per kilogram of body weight per day.

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.

Edible tissues means muscle, liver, kidney, fat, skin with fat in natural proportions, whole eggs, whole milk, and honey.

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

mg/kg means milligrams per kilogram.

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

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

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

ppb means parts per billion (equivalent to nanograms per gram (ng/g) or µg/kg).

ppm means parts per million (equivalent to micrograms per gram (µg/g) or mg/kg).

ppt means parts per trillion (equivalent to picograms per gram (pg/g) or nanograms per kilogram (ng/kg)).

Residue means 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.

Target tissue means the edible tissue selected to monitor for residues in the target animals.

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.

Total residue means the aggregate of all compounds that results from the use of an animal drug, including the drug, its metabolites, and any other substances formed in or on food because of such drug use.

µg/kg means microgram per kilogram.

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

§ 556.5 General considerations.

(a) The tolerances listed in subpart B of this part pertain only to the species and production classes of the animal for which the drug use has been approved or conditionally approved. Approved and conditionally approved conditions of use in parts 516, 520, 522, 524, 526, 529, and 558 of this chapter, including the species and production classes of animals, are referenced in each tolerance section in subpart B of this part.

(b) All tolerances refer to the concentrations of a marker residue, or other residue indicated for monitoring, permitted in uncooked tissues.

(c) After a tolerance is listed, the finding that the concentration of the marker residue in the target tissue from a tested animal is at or below the tolerance indicates that all edible tissues (excluding milk and eggs unless otherwise indicated) from that tested animal are safe for human consumption. If a listed tolerance is not expressly linked to a target tissue, then the tolerance is specific only for the named edible tissue and inferences cannot be made about the safety of the other edible tissues from the tested animal.

(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.

Subpart B—Specific Tolerances for Residues of Approved and Conditionally Approved New Animal Drugs

§ 556.34 Albendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of albendazole is 5 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for albendazole 2-aminosulfone (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 0.2 ppm.

(ii) Muscle: 0.05 ppm.

(2) *Sheep.* (i) Liver (target tissue): 0.25 ppm.

(ii) Muscle: 0.05 ppm.

(3) *Goat.* (i) Liver (target tissue): 0.25 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See §§ 520.38a and 520.38b of this chapter.

§ 556.36 Altrenogest.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of altrenogest is 0.04 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for altrenogest (marker residue) are:

(1) *Swine.* (i) Liver (target tissue): 4 ppb.

(ii) Muscle: 1 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 520.48 of this chapter.

§ 556.38 Amoxicillin.

(a) [Reserved]

(b) *Tolerances.* The tolerance for amoxicillin is:

(1) *Cattle.* Edible tissues: 0.01 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.88d, 522.88, and 526.88 of this chapter.

§ 556.40 Ampicillin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for ampicillin are:

(1) *Cattle.* Edible tissues: 0.01 ppm.

(2) *Swine.* Edible tissues: 0.01 ppm.

(c) *Related conditions of use.* See §§ 520.90e, 520.90f, 522.90a, and 522.90b of this chapter.

§ 556.50 Amprolium.

(a) [Reserved]

(b) *Tolerances.* The tolerances for amprolium are:

(1) *Cattle.* (i) Liver, kidney, and muscle: 0.5 ppm.

(ii) Fat: 2.0 ppm.

(2) *Chickens and turkeys.* (i) Liver and kidney: 1 ppm.

(ii) Muscle: 0.5 ppm.

(iii) Eggs:

(A) Egg yolks: 8 ppm.

(B) Whole eggs: 4 ppm.

(3) *Pheasants.* (i) Liver: 1 ppm.
(ii) Muscle: 0.5 ppm.
(c) *Related conditions of use.* See §§ 520.100, 558.55, and 558.58 of this chapter.

§ 556.52 Apramycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of apramycin is 25 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for apramycin (marker residue) is:
(1) *Swine.* Kidney (target tissue): 0.1 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See §§ 520.110 and 558.59 of this chapter.

§ 556.60 Avilamycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of avilamycin is 1.1 mg/kg of body weight per day.
(b) *Tolerances.* The tolerances for avilamycin are:
(1) *Chickens.* Edible tissues (excluding eggs): Not required.
(2) *Swine.* Edible tissues: Not required.
(c) *Related conditions of use.* See § 558.68 of this chapter.

§ 556.68 Azaperone.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of azaperone is 0.63 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for azaperone is:
(1) *Swine.* Edible tissues: Not required.
(2) [Reserved]
(c) *Related conditions of use.* See § 522.150 of this chapter.

§ 556.70 Bacitracin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of bacitracin is 0.05 mg/kg of body weight per day.
(b) *Tolerances.* The tolerances for bacitracin are:
(1) *Cattle.* Edible tissues: 0.5 ppm.
(2) *Chickens, turkeys, pheasants, quail.* Edible tissues: 0.5 ppm.
(3) *Swine.* Edible tissues: 0.5 ppm.
(c) *Related conditions of use.* See §§ 520.154a, 520.154c, 558.76, and 558.78 of this chapter.

§ 556.75 Bambermycins.

(a) [Reserved]
(b) *Tolerances.* The tolerances for bambermycins are:
(1) *Cattle.* Edible tissues (excluding milk): Not required.
(2) *Chickens and turkeys.* Edible tissues (excluding eggs): Not required.
(3) *Swine.* Edible tissues: Not required.
(c) *Related conditions of use.* See § 558.95 of this chapter.

§ 556.100 Carbadox.

(a) [Reserved]
(b) *Tolerances.* The tolerance for quinoxaline-2-carboxylic acid (marker residue) is:
(1) *Swine.* Liver (target tissue): 30 ppb.
(2) [Reserved]
(c) *Related conditions of use.* See § 558.115 of this chapter.

§ 556.110 Carbomycin.

(a) [Reserved]
(b) *Tolerances.* The tolerance for carbomycin is:
(1) *Chickens.* Edible tissues (excluding eggs): Zero.
(2) [Reserved]
(c) *Related conditions of use.* See § 520.1660a of this chapter.

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake and acute reference dose*—(1) *Acceptable daily intake (ADI).* The ADI for total residue of ceftiofur is 30 µg/kg of body weight per day.
(2) *Acute reference dose (ARfD).* The ARfD for total residue of ceftiofur is 0.830 mg/kg of body weight.
(b) *Tolerances.* The tolerances for desfuroylceftiofur (marker residue) are:
(1) *Cattle.* (i) Kidney (target tissue): 0.4 ppm.
(ii) Liver: 2 ppm.
(iii) Muscle: 1 ppm.
(iv) Milk: 0.1 ppm.
(2) *Chickens and turkeys.* Edible tissues (excluding eggs): Not required.
(3) *Goats.* (i) Kidney (target tissue): 8 ppm.
(ii) Liver: 2 ppm.
(iii) Muscle: 1 ppm.
(iv) Milk: 0.1 ppm.
(4) *Sheep.* Edible tissues (excluding milk): Not required.
(5) *Swine.* (i) Kidney (target tissue): 0.25 ppm.
(ii) Liver: 3 ppm.
(iii) Muscle: 2 ppm.
(c) *Related conditions of use.* See §§ 522.313a, 522.313b, 522.313c, and 526.313 of this chapter.

§ 556.115 Cephapirin.

(a) [Reserved]
(b) *Tolerances.* The tolerances for cephapirin are:
(1) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.
(ii) Milk: 0.02 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See §§ 526.363 and 526.365 of this chapter.

§ 556.118 Chloramine-T.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of chloramine-T is 5 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for *para*-toluenesulfonamide (marker residue) is:
(1) *Fish.* Muscle/skin (target tissue): 0.9 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See § 529.382 of this chapter.

§ 556.120 Chlorhexidine.

(a) [Reserved]
(b) *Tolerances.* The tolerance for chlorhexidine is:
(1) *Cattle.* Edible tissues (excluding milk): Zero.
(2) [Reserved]
(c) *Related conditions of use.* See § 529.400 of this chapter.

§ 556.150 Chlortetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for the sum of tetracycline residues are:
(1) *Cattle.* (i) Liver: 6 ppm.
(ii) Kidney and fat: 12 ppm.
(iii) Muscle: 2 ppm.
(2) *Chickens, turkeys, and ducks.* (i) Liver: 6 ppm.
(ii) Kidney and fat: 12 ppm.
(iii) Muscle: 2 ppm.
(iv) Eggs: 0.4 ppm for chlortetracycline only.
(3) *Sheep.* (i) Liver: 6 ppm.
(ii) Kidney and fat: 12 ppm.
(iii) Muscle: 2 ppm.
(4) *Swine.* (i) Liver: 6 ppm.
(ii) Kidney and fat: 12 ppm.
(iii) Muscle: 2 ppm.
(c) *Related conditions of use.* See §§ 520.441, 520.443, 520.445, 558.128, and 558.140 of this chapter.

§ 556.160 Clopidol.

(a) [Reserved]
(b) *Tolerances.* The tolerances for clopidol are:
(1) *Chickens and turkeys.* (i) Liver and kidney: 15 ppm.
(ii) Muscle: 5 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See § 558.175 of this chapter.

§ 556.163 Clorsulon.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of clorsulon is 8 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for clorsulon (marker residue) are:
(1) *Cattle.* (i) Kidney (target tissue): 1.0 ppm.
(ii) Muscle: 0.1 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See §§ 520.462 and 522.1193 of this chapter.

§ 556.165 Cloxacillin.

(a) [Reserved]
(b) *Tolerances.* The tolerance for cloxacillin is:
(1) *Cattle.* Edible tissues: 0.01 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 526.464a, 526.464b, and 526.464c of this chapter.

§ 556.167 Colistimethate.

(a) [Reserved]

(b) *Tolerances.* The tolerance for colistimethate is:

(1) *Chickens.* Edible tissues (excluding eggs): Not required.

(2) [Reserved]

(c) *Related conditions of use.* See § 522.468 of this chapter.

§ 556.168 Coumaphos.

(a) [Reserved]

(b) *Tolerances.* The tolerances for coumaphos (measured as coumaphos and its oxygen analog, O,O-diethyl O-3-chloro-4-methyl-2-oxo-2 H-1-benzopyran-7-yl phosphate) are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 1 ppm.

(ii) Milk fat: 0.5 ppm.

(2) *Chickens.* (i) Edible tissues (excluding eggs): 1 ppm.

(ii) Eggs: 0.1 ppm.

(c) *Related conditions of use.* See § 558.185 of this chapter.

§ 556.169 Danofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of danofloxacin is 2.4 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for danofloxacin (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 0.2 ppm.

(ii) Muscle: 0.2 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 522.522 of this chapter.

§ 556.170 Decoquinate.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of decoquinate is 75 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for decoquinate are:

(1) *Cattle.* (i) Muscle: 1 ppm.

(ii) Other edible tissues (excluding milk): 2 ppm.

(2) *Chickens.* (i) Muscle: 1 ppm.

(ii) Other edible tissues (excluding eggs): 2 ppm.

(3) *Goats.* (i) Muscle: 1 ppm.

(ii) Other edible tissues (excluding milk): 2 ppm.

(c) *Related conditions of use.* See §§ 520.543 and 558.195 of this chapter.

§ 556.180 Dichlorvos.

(a) [Reserved]

(b) *Tolerances.* The tolerance for dichlorvos is:

(1) *Swine.* Edible tissues: 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.596 and 558.205 of this chapter.

§ 556.185 Diclazuril.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of diclazuril is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for diclazuril are:

(1) *Chickens and turkeys.* (i) Liver: 3 ppm.

(ii) Muscle: 0.5 ppm.

(iii) Skin/fat: 1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.198 of this chapter.

§ 556.200 Dihydrostreptomycin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for dihydrostreptomycin are:

(1) *Cattle.* (i) Kidney: 2.0 ppm.

(ii) Other edible tissues (excluding milk): 0.5 ppm.

(iii) Milk: 0.125 ppm.

(2) *Swine.* (i) Kidney: 2.0 ppm.

(ii) Other edible tissues: 0.5 ppm.

(c) *Related conditions of use.* See §§ 522.650, 526.1696b, and 526.1696c of this chapter.

§ 556.222 Doramectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of doramectin is 0.75 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for doramectin (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 100 ppb.

(ii) Muscle: 30 ppb.

(2) *Swine.* Liver (target tissue): 160 ppb.

(c) *Related conditions of use.* See §§ 522.770 and 524.770 of this chapter.

§ 556.224 Efrotomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of efrotomycin is 10 µg/kg of body weight per day.

(b) *Tolerances.* The tolerance for efrotomycin is:

(1) *Swine.* Edible tissues: Not required.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.235 of this chapter.

§ 556.226 Enrofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of enrofloxacin is 3 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for enrofloxacin are:

(1) *Cattle.* Liver (target tissue): 0.1 ppm desethylene ciprofloxacin (marker residue).

(2) *Swine.* Liver (target tissue): 0.5 ppm enrofloxacin (marker residue).

(c) *Related conditions of use.* See § 522.812 of this chapter.

§ 556.227 Eprinomectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of eprinomectin is 10 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for eprinomectin B_{1a} (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 1.5 ppm.

(ii) Muscle: 100 ppb.

(iii) Milk: 12 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.814 and 524.814 of this chapter.

§ 556.230 Erythromycin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for erythromycin are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: Zero.

(2) *Chickens and turkeys.* (i) Edible tissues (excluding eggs): 0.125 ppm.

(ii) Eggs: 0.025 ppm.

(3) *Swine.* Edible tissues: 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.823, 522.820, 526.820, and 558.248 of this chapter.

§ 556.240 Estradiol and related esters.

(a) [Reserved]

(b) *Residues.* Residues of estradiol are not permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated animals:

(1) *Cattle.* (i) Muscle: 120 ppt.

(ii) Fat: 480 ppt.

(iii) Kidney: 360 ppt.

(iv) Liver: 240 ppt.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.840, 522.842, 522.850, 522.1940, 522.2477, and 522.2478 of this chapter.

§ 556.260 Ethopabate.

(a) [Reserved]

(b) *Tolerances.* The tolerances for ethopabate, measured as metaphenetidine, are:

(1) *Chickens.* (i) Liver: 1.5 ppm.

(ii) Kidney: 1.5 ppm.

(iii) Muscle: 0.5 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.58 of this chapter.

§ 556.273 Famphur.

(a) [Reserved]

(b) *Tolerances.* The tolerance for famphur including its oxygen analog is:

(1) *Cattle.* Edible tissues (excluding milk): 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.1242g, 524.900, and 558.254 of this chapter.

§ 556.275 Fenbendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of fenbendazole is 40 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for fenbendazole are:

(1) *Cattle.* (i) Liver (target tissue): 0.8 ppm fenbendazole (marker residue).
(ii) Muscle: 0.4 ppm fenbendazole.
(iii) Milk: 0.6 ppm fenbendazole sulfoxide.
(2) *Chickens.* (i) Liver (target tissue): 5.2 ppm fenbendazole sulfone (marker residue).
(ii) Eggs: 1.8 ppm fenbendazole sulfone (marker residue).
(3) *Goats.* (i) Liver (target tissue): 0.8 ppm fenbendazole (marker residue).
(ii) Muscle: 0.4 ppm fenbendazole.
(4) *Swine.* (i) Liver (target tissue): 3.2 ppm fenbendazole (marker residue).
(ii) Muscle: 2 ppm fenbendazole.
(5) *Turkeys.* (i) Liver (target tissue): 6 ppm fenbendazole sulfone (marker residue).
(ii) Muscle: 2 ppm fenbendazole sulfone.
(c) *Related conditions of use.* See §§ 520.905a, 520.905c, 520.905d, 520.905e, and 558.258 of this chapter.

§ 556.277 Fenprostalene.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of fenprostalene is 0.08 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for fenprostalene are:
(1) *Cattle.* Edible tissues (excluding milk): Not required.
(2) *Swine.* Edible tissues: Not required.
(c) *Related conditions of use.* See § 522.914 of this chapter.

§ 556.280 Fenthion.

(a) [Reserved]
(b) *Tolerances.* The tolerance for fenthion is:
(1) *Cattle.* Edible tissues (excluding milk): 0.1 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See § 524.920 of this chapter.

§ 556.283 Florfenicol.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of florfenicol is 10 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for florfenicol amine (marker residue) are:
(1) *Cattle.* (i) Liver (target tissue): 3.7 ppm.
(ii) Muscle: 0.3 ppm.
(2) *Swine.* (i) Liver (target tissue): 2.5 ppm.
(ii) Muscle: 0.2 ppm.
(3) *Catfish.* Muscle (target tissue): 1 ppm.
(4) *Freshwater-reared warmwater finfish (other than catfish) and salmonids.* Muscle/skin (target tissue): 1 ppm.
(c) *Related conditions of use.* See §§ 520.955, 522.955, 522.956, and 558.261 of this chapter.

§ 556.286 Flunixin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of flunixin is 0.72 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for flunixin are:
(1) *Cattle.* (i) Liver (target tissue): 125 ppb flunixin free acid (marker residue).
(ii) Muscle: 25 ppb flunixin free acid.
(iii) Milk: 2 ppb 5-hydroxy flunixin (marker residue).
(2) *Swine.* (i) Liver (target tissue): 30 ppb flunixin free acid (marker residue).
(ii) Muscle: 25 ppb flunixin free acid.
(c) *Related conditions of use.* See §§ 522.956, 522.970, 522.1664, and 524.970 of this chapter.

§ 556.292 Gamithromycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of gamithromycin is 10 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for gamithromycin (marker residue) are:
(1) *Cattle.* (i) Liver (target tissue): 500 ppb.
(ii) Muscle: 150 ppb.
(2) [Reserved]
(c) *Related conditions of use.* See § 522.1014 of this chapter.

§ 556.300 Gentamicin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of gentamicin is 60 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for gentamicin are:
(1) *Chickens and turkeys.* Edible tissues (excluding eggs): 0.1 ppm.
(2) *Swine.* (i) Liver: 0.3 ppm.
(ii) Kidney (target tissue): 0.4 ppm gentamicin (marker residue).
(iii) Fat: 0.4 ppm.
(iv) Muscle: 0.1 ppm.
(c) *Related conditions of use.* See §§ 522.1044a, 520.1044b, 520.1044c, and 524.1044e of this chapter.

§ 556.304 Gonadotropin.

(a) *Acceptable daily intake (ADI).* The ADI for residues of total gonadotropins (human chorionic gonadotropin and pregnant mare serum gonadotropin) is 42.25 International Units per kilogram of body weight per day.
(b) *Tolerances.* The tolerances for gonadotropin are:
(1) *Cattle.* Edible tissues (excluding milk): Not required.
(2) *Fish.* Edible tissues: Not required.
(3) *Swine.* Edible tissues: Not required.
(c) *Related conditions of use.* See §§ 522.1077, 522.1079, and 522.1081 of this chapter.

§ 556.308 Halofuginone.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of halofuginone hydrobromide is 0.7 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for halofuginone (marker residue) are:
(1) *Chickens.* Liver (target tissue): 0.16 ppm.
(2) *Turkeys.* Liver (target tissue): 0.13 ppm.
(c) *Related conditions of use.* See § 558.265 of this chapter.

§ 556.310 Haloxon.

(a) [Reserved]
(b) *Tolerances.* The tolerance for haloxon is:
(1) *Cattle.* Edible tissues (excluding milk): 0.1 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See §§ 520.1120a and 520.1120b of this chapter.

§ 556.330 Hygromycin B.

(a) [Reserved]
(b) *Tolerances.* The tolerances for hygromycin B are:
(1) *Chickens.* Edible tissues: Zero.
(2) *Swine.* Edible tissues: Zero.
(c) *Related conditions of use.* See § 558.274 of this chapter.

§ 556.344 Ivermectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of ivermectin is 1 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for 22,23-dihydroavermectin B_1a (marker residue) are:
(1) *American bison.* Liver (target tissue): 15 ppb.
(2) *Cattle.* (i) Liver (target tissue): 100 ppb.
(ii) Muscle: 10 ppb.
(3) *Reindeer.* Liver (target tissue): 15 ppb.
(4) *Sheep.* Liver (target tissue): 30 ppb.
(5) *Swine.* (i) Liver (target tissue): 20 ppb.
(ii) Muscle: 20 ppb.
(c) *Related conditions of use.* See §§ 520.1192, 520.1195, 520.1197, 522.1192, 522.1193, 524.1193, and 558.300 of this chapter.

§ 556.346 Laidlomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of laidlomycin is 7.5 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for laidlomycin (marker residue) is:
(1) *Cattle.* Liver (target tissue): 0.2 ppm.
(2) [Reserved]
(c) *Related conditions of use.* See § 558.305 of this chapter.

§ 556.347 Lasalocid.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of lasalocid is 10 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for lasalocid (marker residue) are:

(1) *Cattle.* Liver (target tissue): 0.7 ppm.

(2) *Chickens.* (i) Skin with adhering fat (target tissue): 1.2 ppm.

(ii) Liver: 0.4 ppm.

(3) *Rabbits.* Liver (target tissue): 0.7 ppm.

(4) *Sheep.* Liver (target tissue): 1.0 ppm.

(5) *Turkeys.* (i) Liver (target tissue): 0.4 ppm.

(ii) Skin with adhering fat: 0.4 ppm.

(c) *Related conditions of use.* See § 558.311 of this chapter.

§ 556.350 Levamisole.

(a) [Reserved]

(b) *Tolerances.* The tolerances for levamisole are:

(1) *Cattle.* Edible tissues (excluding milk): 0.1 ppm.

(2) *Sheep.* Edible tissues (excluding milk): 0.1 ppm.

(3) *Swine.* Edible tissues: 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.1242a, 520.1242b, 520.1242d, 520.1242e, 520.1242f, 520.1242g, 522.1242, and 524.1240 of this chapter.

§ 556.360 Lincomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of lincomycin is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for lincomycin are:

(1) *Chickens.* Edible tissues (excluding eggs): Not required.

(2) *Swine.* (i) Liver: 0.6 ppm.

(ii) Muscle: 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.1263c, 522.1260, and 558.325 of this chapter.

§ 556.370 Lubabegron.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of lubabegron is 3 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerance for lubabegron (marker residue) is:

(1) *Cattle.* Liver (target tissue): 10 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.330 of this chapter.

§ 556.375 Maduramicin.

(a) [Reserved]

(b) *Tolerances.* The tolerance for maduramicin (marker residue) is:

(1) *Chickens.* Fat (target tissue): 0.38 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.340 of this chapter.

§ 556.380 Melengestrol.

(a) [Reserved]

(b) *Tolerances.* The tolerance for melengestrol is:

(1) *Cattle.* Fat: 25 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.342 of this chapter.

§ 556.410 Metoserpate.

(a) [Reserved]

(b) *Tolerances.* The tolerance for metoserpate is:

(1) *Chickens.* Edible tissues (excluding eggs): 0.02 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 520.1422 of this chapter.

§ 556.420 Monensin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of monensin is 12.5 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for monensin are:

(1) *Cattle.* (i) Liver: 0.10 ppm.

(ii) Muscle, kidney, and fat: 0.05 ppm.

(iii) Milk: Not required.

(2) *Chickens and turkeys.* Edible tissues (excluding eggs): Not required.

(3) *Goats.* Edible tissues (excluding milk): 0.05 ppm.

(4) *Quail.* Edible tissues (excluding eggs): Not required.

(c) *Related conditions of use.* See § 558.355 of this chapter.

§ 556.425 Morantel.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of morantel tartrate is 10 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for N-methyl-1,3-propanediamine (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 0.7 ppm.

(ii) Milk: Not required.

(2) *Goats.* (i) Liver (target tissue): 0.7 ppm.

(ii) Milk: Not required.

(c) *Related conditions of use.* See §§ 520.1450a, 520.1450b, 520.1450c, and 558.360 of this chapter.

§ 556.426 Moxidectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of moxidectin is 4 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for moxidectin (marker residue) are:

(1) *Cattle.* (i) Fat (target tissue): 900 ppb.

(ii) Liver: 200 ppb.

(iii) Muscle: 50 ppb.

(iv) Milk: 40 ppb.

(2) *Sheep.* (i) Fat (target tissue): 900 ppb.

(ii) Liver: 200 ppb.

(iii) Muscle: 50 ppb.

(c) *Related conditions of use.* See §§ 520.1454, 522.1450, and 524.1450 of this chapter.

§ 556.428 Narasin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of narasin is 5 µg/kg of body weight per day.

(b) *Tolerances.* The tolerance for narasin (marker residue) is:

(1) *Chickens.* Abdominal fat (target tissue): 480 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 558.363 and 558.364 of this chapter.

§ 556.430 Neomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of neomycin is 6 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for neomycin are:

(1) *Cattle.* (i) Kidney (target tissue): 7.2 ppm.

(ii) Liver: 3.6 ppm.

(iii) Muscle: 1.2 ppm.

(iv) Fat: 7.2 ppm.

(v) Milk: 0.15 ppm.

(2) *Sheep and goats.* (i) Kidney (target tissue): 7.2 ppm.

(ii) Liver: 3.6 ppm.

(iii) Muscle: 1.2 ppm.

(iv) Fat: 7.2 ppm.

(v) Milk: 0.15 ppm.

(3) *Swine.* (i) Kidney (target tissue): 7.2 ppm.

(ii) Liver: 3.6 ppm.

(iii) Muscle: 1.2 ppm.

(iv) Fat: 7.2 ppm.

(4) *Turkeys.* (i) Skin with adhering fat: 7.2 ppm.

(ii) Liver: 3.6 ppm.

(iii) Muscle: 1.2 ppm.

(c) *Related conditions of use.* See §§ 520.1484, 524.1600b, 558.365, and 558.455 of this chapter.

§ 556.445 Nicarbazin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of nicarbazin (4,4′-dinitrocarbanilide and 2-hydroxy-4,6-dimethylpyrimidine) is 200 µg/kg of body weight per day.

(b) *Tolerances.* The tolerance for 4,4′-dinitrocarbanilide (marker residue) is:

(1) *Chickens.* Liver (target tissue): 52 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 558.364 and 558.366 of this chapter.

§ 556.460 Novobiocin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for novobiocin are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 1 ppm.

(ii) Milk: 0.1 ppm.

(2) *Chickens, turkeys, and ducks.* Edible tissues (excluding eggs): 1 ppm.

(c) *Related conditions of use.* See §§ 526.1590, 526.1696d, and 558.415 of this chapter.

§ 556.470 Nystatin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for nystatin are:

(1) *Cattle.* Edible tissues (excluding milk): Zero.

(2) *Chickens and turkeys.* Edible tissues: Zero.

(c) *Related conditions of use.* See §§ 524.1600b and 558.430 of this chapter.

§ 556.490 Ormetoprim.

(a) [Reserved]

(b) *Tolerances.* The tolerances for ormetoprim are:

(1) *Chickens, turkeys, ducks, and chukar partridges.* Edible tissues (excluding eggs): 0.1 ppm.

(2) *Salmonids and catfish.* Edible tissues: 0.1 ppm.

(c) *Related conditions of use.* See § 558.575 of this chapter.

§ 556.495 Oxfendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of oxfendazole is 7 µg/kg of body weight per day.

(b) *Tolerances.* The tolerance for fenbendazole (marker residue) is:

(1) *Cattle.* Liver (target tissue): 0.8 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.1629 and 520.1630 of this chapter.

§ 556.500 Oxytetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for the sum of tetracycline residues are:

(1) *Cattle.* (i) Muscle: 2 ppm.

(ii) Liver: 6 ppm.

(iii) Fat and kidney: 12 ppm.

(iv) Milk: 0.3 ppm.

(2) *Chickens and turkeys.* (i) Muscle: 2 ppm.

(ii) Liver: 6 ppm.

(iii) Fat and kidney: 12 ppm.

(3) *Finfish.* Muscle (with adhering skin when edible): 2 ppm.

(4) *Lobster.* Muscle: 2 ppm.

(5) *Swine and sheep.* (i) Muscle: 2 ppm.

(ii) Liver: 6 ppm.

(iii) Fat and kidney: 12 ppm.

(c) *Related conditions of use.* See §§ 520.1660a, 520.1660c, 520.1660d, 522.1660a, 522.1660b, 522.1662a, 522.1664, 529.1660, 558.450, and 558.455 of this chapter.

§ 556.510 Penicillin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for penicillin are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 0.05 ppm.

(ii) Milk: Zero.

(2) *Chickens.* Edible tissues: Zero.

(3) *Pheasants and quail.* Edible tissues: Zero.

(4) *Sheep and swine.* Edible tissues: Zero.

(5) *Turkeys.* Edible tissues (excluding eggs): 0.01 ppm.

(c) *Related conditions of use.* See §§ 520.1696b, 522.1696a, 522.1696b, 526.1696a, 526.1696b, 526.1696c, and 526.1696d of this chapter.

§ 556.513 Piperazine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for piperazine are:

(1) *Chickens and turkeys.* Edible tissues (excluding eggs): 0.1 ppm.

(2) *Swine.* Edible tissues: 0.1 ppm.

(c) *Related conditions of use.* See § 520.1807 of this chapter.

§ 556.515 Pirlimycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of pirlimycin is 0.01 mg/kg of body weight per day.

(b) *Tolerances.* The tolerances for pirlimycin (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 0.5 ppm.

(ii) Muscle: 0.3 ppm.

(iii) Milk: 0.4 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 526.1810 of this chapter.

§ 556.517 Poloxalene.

(a) [Reserved]

(b) *Tolerances.* The tolerance for poloxalene is:

(1) *Cattle.* Edible tissues (excluding milk): Not required.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.1840, 558.464, and 558.465 of this chapter.

§ 556.540 Progesterone.

(a) [Reserved]

(b) *Residues.* Residues of progesterone are not permitted in excess of the following increments above the concentrations of progesterone naturally present in untreated animals:

(1) *Cattle and sheep.* (i) Muscle: 5 ppb.

(ii) Liver: 15 ppb.

(iii) Kidney: 30 ppb.

(iv) Fat: 30 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.1940 and 529.1940 of this chapter.

§ 556.560 Pyrantel.

(a) [Reserved]

(b) *Tolerances.* The tolerances for pyrantel are:

(1) *Swine.* (i) Liver and kidney: 10 ppm.

(ii) Muscle: 1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.2045 and 558.485 of this chapter.

§ 556.570 Ractopamine.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of ractopamine hydrochloride is 1.25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for ractopamine (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 0.09 ppm.

(ii) Muscle: 0.03 ppm.

(2) *Swine.* (i) Liver (target tissue): 0.15 ppm.

(ii) Muscle: 0.05 ppm.

(3) *Turkeys.* (i) Liver (target tissue): 0.45 ppm.

(ii) Muscle: 0.1 ppm.

(c) *Related conditions of use.* See § 558.500 of this chapter.

§ 556.580 Robenidine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for robenidine are:

(1) *Chickens.* (i) Skin and fat: 0.2 ppm.

(ii) Other edible tissues (excluding eggs): 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.515 of this chapter.

§ 556.592 Salinomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of salinomycin is 5 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for salinomycin are:

(1) *Chickens.* Edible tissues (excluding eggs): Not required.

(2) *Quail.* Edible tissues (excluding eggs): Not required.

(c) *Related conditions of use.* See § 558.550 of this chapter.

§ 556.597 Semduramicin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of semduramicin is 3 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for semduramicin are:

(1) *Chickens.* (i) Liver: 400 ppb.

(ii) Muscle: 130 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.555 of this chapter.

§ 556.600 Spectinomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of spectinomycin is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for spectinomycin are:

(1) *Cattle.* (i) Kidney (target tissue): 4 ppm spectinomycin (marker residue).

(ii) Muscle: 0.25 ppm.

(2) *Chickens and turkeys.* Edible tissues (excluding eggs): 0.1 ppm.

(3) *Swine.* Edible tissues: Not required.

(c) *Related conditions of use.* See §§ 520.1265, 520.2123b, 520.2123c, 522.2120, and 522.2121 of this chapter.

§ 556.610 Streptomycin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for streptomycin are:

(1) *Cattle and swine.* (i) Kidney: 2.0 ppm.

(ii) Other edible tissues (excluding milk): 0.5 ppm.

(2) *Chickens.* (i) Kidney: 2.0 ppm.

(ii) Other edible tissues (excluding eggs): 0.5 ppm.

(c) *Related conditions of use.* See § 520.2158 of this chapter.

§ 556.620 Sulfabromomethazine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfabromomethazine are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: 0.01 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 520.2170 of this chapter.

§ 556.625 Sulfachloropyrazine.

(a) [Reserved]

(b) *Tolerances.* The tolerance for sulfachloropyrazine is:

(1) *Chickens.* Edible tissues (excluding eggs): Zero.

(2) [Reserved]

(c) *Related conditions of use.* See § 520.2184 of this chapter.

§ 556.630 Sulfachlorpyridazine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfachlorpyridazine are:

(1) *Cattle and swine.* Edible tissues (excluding milk): 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.2200 and 522.2200 of this chapter.

§ 556.640 Sulfadimethoxine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfadimethoxine are:

(1) *Catfish and salmonids.* Edible tissues: 0.1 ppm.

(2) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: 0.01 ppm.

(3) *Chickens, turkeys, ducks, and chukar partridges.* Edible tissues (excluding eggs): 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.2220a, 520.2220d, 520.2220e, 522.2220, and 558.575 of this chapter.

§ 556.650 Sulfaethoxypyridazine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfaethoxypyridazine are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: Zero.

(2) *Swine.* Edible tissues: Zero.

(c) *Related conditions of use.* See §§ 520.2240a, 520.2240b, and 522.2240 of this chapter.

§ 556.660 Sulfamerazine.

(a) [Reserved]

(b) *Tolerances.* The tolerance for sulfamerazine is:

(1) *Trout.* Edible tissues: Zero.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.582 of this chapter.

§ 556.670 Sulfamethazine.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfamethazine are:

(1) *Cattle.* Edible tissues (excluding milk): 0.1 ppm.

(2) *Chickens and turkeys.* Edible tissues (excluding eggs): 0.1 ppm.

(3) *Swine.* Edible tissues: 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.2260a, 520.2260b, 520.2260c, 520.2261a, 520.2261b, 522.2260, 558.140, and 558.630 of this chapter.

§ 556.685 Sulfaquinoxaline.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfaquinoxaline are:

(1) *Cattle.* Edible tissues (excluding milk): 0.1 ppm.

(2) *Chickens and turkeys.* Edible tissues (excluding eggs): 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.2325a, 520.2325b, and 558.586 of this chapter.

§ 556.700 Sulfomyxin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for sulfomyxin are:

(1) *Chickens and turkeys.* Edible tissues (excluding eggs): Zero.

(2) [Reserved]

(c) *Related conditions of use.* See § 522.2340 of this chapter.

§ 556.710 Testosterone.

(a) [Reserved]

(b) *Residues.* Residues of testosterone are not permitted in excess of the following increments above the concentrations of testosterone naturally present in untreated animals:

(1) *Cattle.* (i) Fat: 2.6 ppb.

(ii) Kidney: 1.9 ppb.

(iii) Liver: 1.3 ppb.

(iv) Muscle: 0.64 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 522.842 of this chapter.

§ 556.720 Tetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for the sum of tetracycline residues are:

(1) *Cattle and sheep.* (i) Kidney and fat: 12 ppm.

(ii) Liver: 6 ppm.

(iii) Muscle: 2 ppm.

(2) *Chickens and turkeys.* (i) Kidney and fat: 12 ppm.

(ii) Liver: 6 ppm.

(iii) Muscle: 2 ppm.

(3) *Swine.* (i) Kidney and fat: 12 ppm.

(ii) Liver: 6 ppm.

(iii) Muscle: 2 ppm.

(c) *Related conditions of use.* See §§ 520.2345c and 520.2345d of this chapter.

§ 556.730 Thiabendazole.

(a) [Reserved]

(b) *Tolerances.* The tolerances for thiabendazole are:

(1) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: 0.05 ppm.

(2) *Swine.* Edible tissues: 0.1 ppm.

(3) *Sheep and goats.* (i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: 0.05 ppm.

(4) *Pheasants.* Edible tissues (excluding eggs): 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.2380a, 520.2380b, 520.2380c, and 558.600 of this chapter.

§ 556.732 Tiamulin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of tiamulin is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerance for 8-alpha-hydroxymutilin (marker residue) is:

(1) *Swine.* Liver (target tissue): 0.6 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 520.2455 and 558.612 of this chapter.

§ 556.733 Tildipirosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of tildipirosin is 10 µg/kg of body weight per day.

(b) *Tolerances.* The tolerance for tildipirosin (the marker residue) is:

(1) *Cattle.* (i) Liver (the target tissue): 10 ppm.

(ii) [Reserved]

(2) [Reserved]

(c) *Related conditions of use.* See § 522.2460 of this chapter.

§ 556.735 Tilmicosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of tilmicosin is 25 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for tilmicosin (marker residue) are:
(1) *Cattle.* (i) Liver (target tissue): 1.2 ppm.
(ii) Muscle: 0.1 ppm.
(2) *Sheep.* (i) Liver (target tissue): 1.2 ppm.
(ii) Muscle: 0.1 ppm.
(3) *Swine.* (i) Liver (target tissue): 7.5 ppm.
(ii) Muscle: 0.1 ppm.
(c) *Related conditions of use.* See §§ 520.2471, 522.2471, and 558.618 of this chapter.

§ 556.739 Trenbolone.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of trenbolone is 0.4 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for trenbolone is:
(1) *Cattle.* Edible tissues (excluding milk): Not required.
(2) [Reserved]
(c) *Related conditions of use.* See §§ 522.2476, 522.2477, and 522.2478 of this chapter.

§ 556.741 Tripelennamine.

(a) [Reserved]
(b) *Tolerances.* The tolerances for tripelennamine are:
(1) *Cattle.* (i) Edible tissues (excluding milk): 200 ppb.
(ii) Milk: 20 ppb.
(2) [Reserved]
(c) *Related conditions of use.* See § 522.2615 of this chapter.

§ 556.745 Tulathromycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of tulathromycin is 15 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for CP–60,300 (marker residue) are:
(1) *Cattle.* Liver (target tissue): 5.5 ppm.
(2) *Swine.* Kidney (target tissue): 15 ppm.
(c) *Related conditions of use.* See § 522.2630 of this chapter.

§ 556.746 Tylosin.

(a) [Reserved]
(b) *Tolerances.* The tolerances for tylosin are:
(1) *Cattle.* (i) Liver, kidney, fat, and muscle: 0.2 ppm.
(ii) Milk: 0.05 ppm.
(2) *Chickens and turkeys.* (i) Liver, kidney, fat, and muscle: 0.2 ppm.
(ii) Eggs: 0.2 ppm.
(3) *Swine.* Liver, kidney, fat, and muscle: 0.2 ppm.
(c) *Related conditions of use.* See §§ 520.2640, 522.2640, 558.625, and 558.630 of this chapter.

§ 556.748 Tylvalosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tylvalosin is 47.7 µg/kg of body weight per day.
(b) *Tolerances.* A tolerance for tylvalosin in edible tissues of swine is not required.
(c) *Related conditions of use.* See §§ 520.2645 and 558.633 of this chapter.

§ 556.750 Virginiamycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of virginiamycin is 250 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for virginiamycin are:
(1) *Cattle.* Edible tissues (excluding milk): Not required.
(2) *Chickens.* Edible tissues (excluding eggs): Not required.
(3) *Swine.* (i) Kidney, skin, and fat: 0.4 ppm.
(ii) Liver: 0.3 ppm.
(iii) Muscle: 0.1 ppm.
(4) *Turkeys.* Edible tissues (excluding eggs): Not required.
(c) *Related conditions of use.* See § 558.635 of this chapter.

§ 556.760 Zeranol.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of zeranol is 1.25 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for zeranol are:
(1) *Cattle.* Edible tissues (excluding milk): Not required.
(2) *Sheep.* Edible tissues (excluding milk): 20 ppb.
(c) *Related conditions of use.* See § 522.2680 of this chapter.

§ 556.765 Zilpaterol.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of zilpaterol is 0.083 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for zilpaterol freebase (marker residue) is:
(1) *Cattle.* Liver (target tissue): 12 ppb.
(2) [Reserved]
(c) *Related conditions of use.* See § 558.665 of this chapter.

§ 556.770 Zoalene.

(a) [Reserved]
(b) *Tolerances.* The tolerances for zoalene and its metabolite 3-amino-5-nitro-*o*-toluamide are:
(1) *Chickens.* (i) Liver and kidney: 6 ppm.
(ii) Muscle: 3 ppm.
(iii) Fat: 2 ppm.
(2) *Turkeys.* Liver and muscle: 3 ppm.
(c) *Related conditions of use.* See § 558.680 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 32. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 558.68 [Amended]

■ 33. In § 558.68, in paragraph (c), remove ''556.68'' and in its place add ''556.60''.

■ 34. In § 558.95, add paragraph (c) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(c) *Related tolerances.* See § 556.75 of this chapter.

* * * * *

■ 35. In § 558.185, revise paragraph (c) to read as follows:

§ 558.185 Coumaphos.

* * * * *

(c) *Related tolerances.* See § 556.168 of this chapter.

* * * * *

■ 36. In § 558.235, revise paragraph (a), redesignate paragraph (b) as paragraph (d), and add new paragraphs (b) and (c) to read as follows:

§ 558.235 Efrotomycin.

(a) *Specifications.* Type A medicated articles containing 14.5 grams efrotomycin per pound.
(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.
(c) *Related tolerances.* See § 556.224 of this chapter.

* * * * *

■ 37. In § 558.464, revise paragraph (a), redesignate paragraph (b) as paragraph (d), and add new paragraphs (b) and (c) to read as follows:

§ 558.464 Poloxalene.

(a) *Specifications.* Dry Type A medicated articles containing 53 percent poloxalene or liquid Type A medicated articles containing 99.5 percent poloxalene.
(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
(c) *Related tolerances.* See § 556.517 of this chapter.

* * * * *

■ 38. In § 558.465, revise paragraph (a), redesignate paragraph (b) as paragraph (d), and add new paragraphs (b) and (c) to read as follows:

§ 558.465 Poloxalene free-choice liquid Type C feed.

(a) *Specifications.* Type A medicated articles containing 99.5 percent poloxalene.
(b) *Sponsor.* See No. 066104 in § 510.600(c) of this chapter.
(c) *Related tolerances.* See § 556.517 of this chapter.

* * * * *

§ 558.625 [Amended]

■ 39. In § 558.625, in paragraph (c), remove ''556.740'' and in its place add ''556.746''.

§ 558.630 [Amended]

■ 40. In § 558.630, in paragraph (c), remove ''556.740'' and in its place add ''556.746''.

Dated: June 20, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: June 25, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–14098 Filed 7–10–19; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8179]

Organizations Under Common Control; Eighty Percent Control Test for a Brother-Sister Controlled Group; Correcting Amendment

AGENCY: Internal Revenue Service.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to Treasury Decision 8179, which was published in the **Federal Register** for Wednesday, March 2, 1988. Treasury Decision 8179 issued final regulations and withdrew temporary regulations relating to organizations under common control for purposes of certain rules relating to pension, profit-sharing, and stock bonus plans. Treasury Decision 8179 was corrected on May 9, 1988; however, the corrections were not properly incorporated into the Code of Federal Regulations.

DATES:

Effective date. This correction is effective on July 11, 2019.

Applicability date: March 2, 1988.

FOR FURTHER INFORMATION CONTACT: Dara Alderman at (202) 317–5500.

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 8179) that are the subject of this correction are under section 52 of the Internal Revenue Code. Treasury Decision 8179 was corrected at 53 FR 16408, May 9, 1988; however, the Office of the Federal Register did not properly incorporate the correction into the Code of Federal Regulations at that time.

Need for Correction

As published March 2, 1988 (53 FR 6603), the final regulations (TD 8179; FR Doc. 88–4451) contain an error that needed to be corrected. Treasury Decision 8179 was corrected at 53 FR 16408, May 9, 1988; however, the Office of the Federal Register did not properly incorporate the correction into the Code of Federal Regulations.

Applicability of Correction

Generally, the amendments to the regulations under section 52 of the Code (relating to tax credits for employees) apply to taxable years beginning after December 31, 1976. However, because the May 9, 1988 correction was not properly incorporated into the Code of Federal Regulations at the time of publication, with respect to taxable years that began prior to the Effective date, the Internal Revenue Service will not challenge the application of either published version of the regulation.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.52–1 [Amended]

■ **Par. 2.** In § 1.52–1, paragraph (d)(1)(i) is amended by removing the language ''§ 1.414(c)–4(b)(1))'' and adding ''§ 1.414(c)–4'' in its place.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2019–14424 Filed 7–10–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 510

Technical Amendments to North Korea Sanctions Regulations

Correction

In rule document 2019–13652, appearing on pages 30868 through 30870, in the issue of Friday, June 28, 2019 make the following correction:

On page 30869, in the first column, in the second paragraph, on the twelfth line, ''§§ '' should read ''sections''.

[FR Doc. C1–2019–13652 Filed 7–10–19; 8:45 am]

BILLING CODE 1300–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0761; FRL–9996–38–Region 9]

Air Plan Approval; Arizona; Regional Haze Progress Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving Arizona's Regional Haze Progress Report (''Progress Report'' or ''Report''), submitted on November 12, 2015, as a revision to its state implementation plan (SIP). This SIP revision addresses requirements of the Clean Air Act (CAA) and the EPA's rules that require states to submit periodic reports describing progress toward reasonable progress goals (RPGs) established for regional haze and a determination of adequacy of the state's existing regional haze plan. The EPA is approving the Report on the basis that it addresses the progress report and adequacy determination requirements for the first implementation period for regional haze.

DATES: This rule is effective on August 12, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2018–0761. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as