

**(g) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4119; fax: (816) 329-4090; email: [albert.mercado@faa.gov](mailto:albert.mercado@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements*: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

**(h) Related Information**

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2012-0202, dated October 1, 2012; and Reims Aviation S.A. Service Bulletin No. F406-74, dated September 26, 2012, for related information. For service information related to this AD, contact Reims Aviation Industries, Aérodrome de Reims Prunay, 51360 Prunay, France; telephone + 33 3 26 48 46 65; fax + 33 3 26 49 18 57; email: [stephan.lapagne@reims-aviation.fr](mailto:stephan.lapagne@reims-aviation.fr); Internet: [www.geciaviation.com/en/f406.html](http://www.geciaviation.com/en/f406.html). You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on November 29, 2012.

**Earl Lawrence**,

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2012-29395 Filed 12-4-12; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF COMMERCE****Minority Business Development Agency****15 CFR Part 1400**

[Docket No. 121130667-2667-01]

**Petition for Inclusion of the Arab-American Community in the Groups Eligible for MBDA Services**

**AGENCY:** Minority Business Development Agency, Commerce.

**ACTION:** Notice of proposed rulemaking and request for comments; amendment.

**SUMMARY:** The Minority Business Development Agency (MBDA) publishes this notice to extend the date on which it plans to make its decision on a petition from the American-Arab Anti-Discrimination Committee requesting formal designation as a group eligible for MBDA's services from November 30, 2012 to March 1, 2013.

**FOR FURTHER INFORMATION CONTACT:** For further information about this Notice, contact Josephine Arnold, Minority Business Development Agency, 1401 Constitution Avenue NW., Room 5053, Washington, DC 20230, (202) 482-5461.

**SUPPLEMENTARY INFORMATION:** On May 30, 2012, the Minority Business Development Agency (MBDA) published a notice of proposed rulemaking and request for comments regarding a petition received on January 11, 2012 from the American-Arab Anti-Discrimination Committee (ADC) requesting formal designation of Arab-Americans as a minority group that is socially or economically disadvantaged pursuant to 15 CFR part 1400. MBDA has published several notices in the **Federal Register** to extend the date for making a decision on the merits of the petition. On September 4, 2012, MBDA published an amendment to extend the deadline for the decision until November 30, 2012. The Agency has determined that an additional ninety (90) day period for consideration of the policy implications associated with the petition is necessary. Therefore, the Agency has determined that the time in which it will make its decision on the petition will be on or before March 1, 2013. This extension will not prejudice the petitioner.

Minority Business Development Agency.

**David Hinson**,

*National Director.*

[FR Doc. 2012-29431 Filed 12-4-12; 8:45 am]

**BILLING CODE 3510-21-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 500, 520, 522, 524, 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:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revise the animal drug regulations regarding tolerances for residues of approved and conditionally approved new animal drugs in food by standardizing, simplifying, and clarifying the determination standards and codification style. In addition, we are proposing to add definitions for key terms. The purpose of the revision is to enhance understanding of tolerance determination and improve the readability of the regulations.

**DATES:** Submit either electronic or written comments by March 5, 2013. See section VI of this document for the proposed effective date of a final rule based on this proposed rule.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2012-N-1067 and RIN number 0910-AG17, by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

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

**Written Submissions**

Submit written submissions in the following ways:

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

*Instructions:* All submissions received must include the Agency name, Docket

No. FDA-2012-N-1067, and Regulatory Information Number (RIN) 0910-AG17 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

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

**FOR FURTHER INFORMATION CONTACT:** Dong Yan, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8117, email: [dong.yan@fda.hhs.gov](mailto:dong.yan@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sections 512(b)(1)(H), 512(i), and 571(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(1)(H), 360b(i), and 360ccc(a)(2)(A)) provide the authority for the Secretary of Health and Human Services (the Secretary) to establish and publish regulations setting tolerances for residues of approved and conditionally approved new animal drugs. The Secretary delegated this authority to the Commissioner of Food and Drugs. FDA's regulations setting forth the tolerances for residues of new animal drugs in food are codified in part 556 of Title 21 of the Code of Federal Regulations (21 CFR part 556) (40 FR 13802 at 13942, March 27, 1975). The part 556 regulations describe general considerations regarding tolerances for residues of new animal drugs in food in subpart A and specific tolerances for residues of new animal drugs in subpart B. Subpart B has been amended frequently as new animal drugs have been approved for use in food-producing animals. Food from treated animals with new animal drug residues that exceed established tolerances is adulterated under section 402(a)(2)(C)(ii) of the FD&C Act (21 U.S.C. 342(a)(2)(C)(ii)).

FDA's human food safety evaluation of residues of new animal drugs has evolved over the past 50 years. Before the mid-1970s, FDA based tolerances primarily on a small number of toxicity studies, typically 90-day feeding studies in laboratory animals. From the results

of these studies, FDA determined the "no-observed-effect-level" (NOEL). The acceptable daily intake (ADI) for total residue of a drug was calculated by dividing the NOEL by the appropriate safety factor to adjust for the differences between test animals and humans. To calculate the safe concentrations, FDA considered food consumption values and human body weight. Consumption was estimated as a total dietary exposure of 1,500 grams of food per day. Historically, FDA used an average human weight of 50 or 60 kilograms. Because these toxicology studies did not assess lifetime effects (which could only be observed in long-term feeding studies), FDA applied a 2,000-fold safety factor to the NOELs. FDA generally set the tolerance for "negligible" residues of these drugs at 0.1 part per million (ppm) in muscle and 10 parts per billion in milk, even if the computed tolerance exceeded the calculated values.

In later years, FDA assigned what it called "finite tolerances." Finite tolerances were calculated using procedures similar to those described previously, except, unlike tolerances set for "negligible" residues, finite tolerances were set at the calculated level. Finite tolerances had to be supported, at a minimum, by lifetime feeding studies in two rodent species, a 6-month or longer study in a non-rodent mammalian species, and a three-generation reproduction study. Because finite tolerances were based on more extensive studies, FDA generally applied a lower (100-fold) safety factor in calculating the ADI.

The earliest established tolerances generally referred to the parent drug. Consequently, residue chemistry studies, including residue depletion studies that served as the basis for assigning withdrawal periods for tissues and for milk (milk discard time), and the analytical methods used to measure residue levels focused on the parent drug.

From the mid-1970s to the present, FDA's human food safety evaluation of animal drug residues has evolved with advancements in science. As a result, the procedures described in the existing § 556.1 for setting drug tolerances no longer accurately reflect current regulatory science. In addition, current part 556 employs a patchwork of various styles for listing tolerances that have evolved over the past 40 years. As a result, the listings in part 556 are not uniform in format, and, in some instances, do not provide all relevant information in a consistent manner. For example, the regulations provide the ADI and safe concentrations for some,

but not all, drugs. In addition, the regulations list some tolerances as being for "negligible" residue, and others as "no residue," "zero," or "not required," but they do not explain what these important terms mean. The proposed rule addresses these inconsistencies by simplifying and standardizing the determination standards and codification style and by adding definitions for key terms.

**II. Description of Proposed Rule**

FDA proposes to revise part 556 by standardizing and simplifying the codification style and adding definitions for key terms. First, proposed § 556.1 provides a revised scope for part 556. Second, proposed § 556.3 provides definitions of key terms FDA uses in the regulations. Third, proposed § 556.5 explains the general considerations for using the tolerance information for veterinary drug residues. Finally, FDA proposes a uniform format for listing tolerances in subpart B, by, among other things, removing obsolete or confusing terms and cross-referencing tolerances to the approved conditions of use for that new animal drug.

*A. Subpart A—General Provisions*

1. Scope (Proposed § 556.1)

FDA proposes to delete existing § 556.1 ("General considerations; tolerances for residues of new animal drugs in food") and replace it with a description of the scope. FDA proposes to discuss general considerations for setting tolerances in new § 556.5.

Proposed § 556.1 reiterates the requirement in sections 512(b)(1)(H) and 571(a)(2)(A) of the FD&C Act that applicants seeking approval or conditional approval of new animal drugs must submit a proposed tolerance as part of new animal drug applications when necessary to assure that the proposed use of the new animal drug will be safe. The proposed section states that FDA assigns tolerances for animal drugs used in food-producing animals as part of the application approval process and then codifies them in subpart B of part 556. Proposed § 556.1 also clarifies that compounds that have been found to be carcinogenic are regulated under subpart E of part 500 (21 CFR part 500).

2. Definitions (Proposed § 556.3)

FDA proposes to define in § 556.3 certain key terms used in animal drug residue chemistry and some terms frequently used in part 556. In the proposed rule, the definitions appear in alphabetical order. In this preamble, the definitions are discussed in an order

that facilitates the explanation of the interrelated concepts the terms represent.

a. *Terms related to determining tolerances.* FDA's human food safety evaluation focuses on residues of new animal drugs in the edible tissues of the treated animal. FDA proposes to define "edible tissues" as muscle, liver, kidney, fat, skin with fat in natural proportions, whole eggs, whole milk, and honey. FDA proposes to define "residue," as it is defined in 21 CFR 530.3, to mean 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. Under the proposed rule, the "total residue" includes every residue of a given drug. FDA proposes to define total residue as the aggregate of all compounds that result 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.

Under the proposal, the definition of a NOEL means the highest dose level of a drug tested that produces no observable effects. ADI means the amount of total residue that can safely be consumed per day over a human's lifetime. The ADI is calculated by dividing the NOEL (from the most appropriate toxicological study) by a safety factor. The safety factor reflects, among other things, the extrapolation of long-term effects from shorter-term exposures, extrapolation of animal data to humans, and variability in sensitivity among human populations. Sometimes, the concept of an "acceptable single-dose intake" or "ASDI" is used to calculate tolerances. FDA is proposing to define "ASDI" as the amount of total residue that may safely be consumed in a single meal. The ASDI may be used to derive the tolerance for residues of a drug at an injection site where the drug is administered according to the label.

Under the proposed rule, a "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. A "marker residue" means the residue selected for assay by the regulatory method. In general, the marker residue is a subset of the total residue; for example, the marker residue could be the parent drug, a metabolite, or a combination of residues. The concentration of the marker residue in the target tissue is in a known relationship to the concentration of the total residue in the target tissue. The "regulatory method" means the

aggregate of all experimental procedures for measuring and confirming the presence of the marker residue in the target tissue of the target animal. The "target tissue" means the edible tissue selected to monitor for residues in the target animals. When the marker residue or other residue indicated for monitoring is at or below the tolerance in the target tissue, the total drug residues in all the edible tissues (excluding milk and eggs unless otherwise specified) should be at or below the safe concentration.

b. *Terms used to characterize tolerances.* In the past, FDA has used several terms to characterize tolerances in part 556, including "zero," "no residue," "not required," and "not needed" but has not included clear definitions in part 556 for these important terms. Because the differences in these terms has not always been evident, FDA is proposing to amend part 556 by eliminating redundant terminology and adding definitions for the terms that the Agency intends to continue using to help ensure that going forward the terms will be uniformly applied by the Agency and understood by the public.

First, over the years, many people have mistakenly believed the term "zero" with respect to tolerances to mean there could be no residue remaining in an edible tissue. However, FDA acknowledges that some residue will remain in the animal, even if below a detectable level, and that a complete lack of drug residue is not achievable. In approving certain animal drugs, FDA assigned a "zero" tolerance, with "zero" meaning that no residues could be detected using the approved analytical method to detect residues of that drug. Often, the analytical method chosen to determine "zero" represented the limit of technology at the time. FDA no longer assigns "zero" tolerances for new approvals, but instead assigns a tolerance for a drug based on a toxicological and residue chemistry evaluation (see proposed § 556.5). However, FDA is not proposing to remove the previously assigned "zero" tolerances from the regulations at this time.

Second, FDA uses the term "no residue" to apply specifically to compounds of carcinogenic concern. Under section 512(d)(1)(I) of the FD&C Act, "no residue" of any drug that induces cancer when ingested by man or animal is allowed in any edible tissue of a food-producing animal, when tested using methods of examination prescribed or approved by FDA. FDA historically has interpreted the term "no residue" to mean that any residue in the

target tissue must be non-detectable or below the limit of detection of the approved regulatory method (67 FR 78172, December 23, 2002). Consistent with this interpretation, FDA is proposing to define "no residue" to mean that the marker residue is below the limit of detection using the approved regulatory method. FDA is proposing to add this definition to § 500.82 under subpart E entitled "Regulation of Carcinogenic Compounds Used in Food-Producing Animals."

Third, FDA previously approved some animal drugs with a waiver of the requirement for a tolerance (*i.e.*, a tolerance was "not required" or "not needed") because they met two conditions in place at the time they were evaluated by FDA. The first condition was an assurance that residues would deplete to or below safe levels by zero-day withdrawal (*i.e.*, no withdrawal period was needed), or that an adequate withdrawal period was inherent in the proposed conditions of drug use. The second condition was a rapid depletion of residues, so there was no concern about residues resulting from misuse or overdosing. Sometimes the codified tolerance listings described these situations as ones where a tolerance was "not needed"; other times the phrase "not required" was used to convey the same meaning. To ensure consistency, FDA proposes to revise part 556 to delete descriptions of tolerances as "not needed" and replace such designations with the term "not required."

Fourth, in the past, when a drug was approved with a zero withdrawal period, FDA would not set a tolerance for the particular drug. Historically, FDA generally recommended that a sponsor of a drug seeking a zero withdrawal period conduct a total residue depletion study in which target animals were dosed with 1.5 to 2 times the recommended maximum dose of drug to simulate overdosing. If a zero withdrawal period was approved, FDA would not set a tolerance for the drug.

Currently, FDA continues to recommend these total residue depletion studies when sponsors propose zero withdrawal periods, but, when possible, FDA sets a tolerance for these drugs. Infrequently, circumstances preclude FDA from setting a tolerance. For example, some drugs may be poorly absorbed and/or metabolized rapidly to such an extent as to make selection of an analyte impractical or impossible. In these uncommon cases, FDA proposes to use the term "not required" when describing the tolerance.

FDA is proposing to define “not required” with respect to tolerances as indicating 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.

### 3. General Considerations (Proposed § 556.5)

Proposed § 556.5(a) states that tolerances published in subpart B of part 556 pertain only to the species and production classes of the animal for which the drug use has been approved or conditionally approved. The proposed rule provides the approved use and conditionally approved use conditions, including species and production classes, in each tolerance listing under “(c) *Related conditions of use.*” Tolerances are not provided for extralabel (*e.g.*, use in species or production classes in which the drug is not approved for use.) Extralabel use resulting in any residue above an established safe level or tolerance is unlawful and renders the drug product adulterated under section 501(a)(5) of the FD&C Act (21 U.S.C. 351(a)(5)), in that it is unsafe within the meaning of section 512 of the FD&C Act.

Proposed § 556.5(b) states that all tolerances refer to the concentrations of a marker residue, or other residue indicated for monitoring, permitted in uncooked tissues.

Proposed § 556.5(c) states that a finding that the concentration of a marker residue is at or below the tolerance in the target tissue from a tested animal indicates that all edible tissues (excluding milk and eggs unless otherwise specified) from that animal are safe. In the proposed listing format, if a listed tolerance is linked to a target tissue, the phrase “target tissue” will appear in parentheses immediately after the identified tissue. If a listed tolerance is not expressly linked to a target tissue, then the tolerance is meant to apply only to the named edible tissue, and inferences cannot be made about the safety of the other edible tissues from the target animal.

Proposed § 556.5(d) states that FDA requires that a drug sponsor develop a regulatory method to measure drug residues in edible tissues of approved

target species at concentrations around the tolerance as provided in § 514.1(b)(7) of this chapter. The tolerance is directly tied to the approved regulatory method because FDA determines the tolerance using data collected with that method.

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

FDA proposes a uniform format for the individual drug tolerance listings in subpart B. FDA would list the ADI and ASDI if they are available. If the ADI and ASDI are both unavailable, FDA would reserve paragraph (a) for future use. FDA would list tolerances in paragraph (b) for each edible tissue for each species, as appropriate. When a tolerance listing states “edible tissues,” it would mean all edible tissues of that species unless otherwise specified. FDA intends the revised paragraph (c) to help readers locate approved or conditionally approved uses of each drug and to identify the form of the drug (*e.g.*, free acid or base, salt, hydrate).

FDA proposes to revise subpart B by deleting tolerances for certain drugs (or species of animals) whose approvals have been withdrawn, but the corresponding tolerances were not removed from the part 556 listing; and adding tolerances for approved drugs not previously listed in this subpart. Specifically, FDA proposes to delete the tolerances for clopidol for all species other than chickens and turkeys (§ 556.160) and nystatin for swine (§ 556.470). FDA proposes to add tolerance listings for: Azaperone, bambamycins, coumaphos, efrotomycin, fenprostalene (swine), fenthion, flurogestone, and poloxalene.

Note that some listings provide more than one tolerance. For example, tilimicosin in cattle (§ 556.735(b)(1)) includes the following information: A marker residue (tilimicosin), a target tissue (liver), a tolerance of 1.2 ppm for tilimicosin in liver of cattle, and a tolerance of 0.1 ppm for tilimicosin in muscle of cattle.

This means that if the concentration of tilimicosin in the liver of a treated animal is at or below 1.2 ppm, all the edible tissues (excluding milk and eggs unless otherwise specified) from the animal are considered to be safe if ingested daily by humans over a lifetime. If the concentration of tilimicosin is assayed for only the muscle tissue and the concentration is at or below 0.1 ppm, the muscle tissue from the animal is considered to be safe if ingested daily by humans over a lifetime. Because muscle is not the

target tissue, the tilimicosin concentration in muscle alone does not predict residue safety for the other edible tissues.

### C. Other Proposed Changes to Part 556

This proposal includes other changes to the current part 556 regulations. First, FDA proposes to delete salt designations from the tolerance listings in subpart B. For example, maduramicin ammonium, morantel tartrate, and sulfabromomethazine sodium will be listed as maduramicin, morantel, and sulfabromomethazine, respectively. FDA proposes this change for several reasons. The residues derived from salt formulations and hydrated forms of a given drug are the same. In addition, the approved regulatory methods ordinarily measure the free drug, a metabolite, or some combination of residues, not the salts. FDA also believes such a simplification of tolerance listings will improve their readability. However, when FDA lists the ADI for a compound, the specific compound that was administered in the pivotal toxicological feeding study will be indicated, as toxicological outcome could be affected by salt formulation.

Second, FDA proposes to cross-reference drug tolerances in part 556 to the approved or conditionally approved conditions of use listed in 21 CFR parts 516, 520, 522, 524, 526, 529, and 558. These listings specify the drug, salt, dosage form, and indications for use (amount, animal species/production class, and limitations) of approved or conditionally approved animal drug products. In conjunction with adding these cross-references, FDA proposes to remove references to production classes from tolerance listings in subpart B. In a few past instances, FDA codified tolerances specifying the production class (*e.g.*, beef or dairy cattle) of food-producing species. This was done in an effort to be consistent with the listed approved conditions of use, but for only a few animal drugs listed in part 556.

FDA also proposes to delete safe concentrations from the tolerance listings in part 556. Although tolerances have been codified using the total residue, target tissue, and marker residue concepts for about 25 years, the particular types of information codified have varied. For some drugs, FDA listed only tolerances. For other drugs, FDA listed safe concentrations as well as tolerances, leading some readers to misinterpret the safe concentrations as tolerances. Because a tolerance can be a small fraction of the safe concentration, such a misunderstanding could lead to referencing an incorrect residue safety standard for a specific drug. FDA

tentatively concludes that removing safe concentrations from the codified listings will reduce the potential for this confusion. The Agency invites comment on this removal.

Further, FDA proposes to remove the word “negligible” from tolerance citations, because the word is outdated. A tolerance is the maximum concentration of a new animal drug residue that can legally remain in an edible tissue of a treated animal and raise no concern for human food safety. In other words, by definition, a tolerance essentially represents the negligible level of residue. Therefore, FDA no longer uses the word “negligible” to characterize residues.

Finally, FDA is proposing to delete the word “uncooked” from the individual listings in subpart B. Because the general considerations and the proposed definition of tolerance clarifies that all tolerances refer to the concentrations of the marker residue, or other residues indicated for monitoring, permitted in uncooked edible tissues, including the word “uncooked” in individual listings is no longer necessary.

FDA seeks comment on the proposed changes to part 556. In particular, the Agency is interested to know if the reorganization and standardization of content enhances the clarity and utility of part 556 and if the definitions of terms are clear and understandable. FDA does not, however, seek comment on the numerical drug residue tolerance values listed in subpart B as these values were determined by FDA in conjunction with the approval or conditional approval of each new animal drug application and, as such, are not the subject of public comment. An exception would be the notation of a technical error where the numerical value cited in the published document does not conform to an approved application or application for conditional approval.

### III. Environmental Impact

The Agency has 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.

### IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by the Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would not impose compliance costs on the current or future sponsors of any approved and conditionally approved new animal drugs, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

### V. Federalism

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

### VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collections of information. Therefore,

clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

### VII. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal be effective 60 days after the date of its publication in the **Federal Register**.

### VIII. Comments

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

### 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, 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, it is proposed that 21 CFR chapter I, subchapter E, be amended as follows:

### PART 500—GENERAL

1. The authority citation for 21 CFR 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 21 CFR part 520 continues to read as follows:

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

4. In § 520.1840, revise paragraph (c) to read as follows:

**§ 520.1840 Poloxalene.**

\* \* \* \* \*

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

\* \* \* \* \*

5. 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**

6. The authority citation for 21 CFR part 522 continues to read as follows:

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

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

**§ 522.770 Doramectin.**

\* \* \* \* \*

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

\* \* \* \* \*

8. In § 522.2640, revise paragraph (d) to read as follows:

**§ 522.2640 Tylosin.**

\* \* \* \* \*

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

\* \* \* \* \*

**PART 524—OPHTHALMIC AND  
TOPICAL DOSAGE FORM NEW  
ANIMAL DRUGS**

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

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

10. In § 524.920, revise paragraph (c)(4) to read as follows:

**§ 524.920 Fenthion.**

\* \* \* \* \*

(c) \* \* \*

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

\* \* \* \* \*

**PART 529—CERTAIN OTHER DOSAGE  
FORM NEW ANIMAL DRUGS**

11. The authority citation for 21 CFR part 529 continues to read as follows:

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

12. In § 529.1003, add paragraph (d) to read as follows:

**§ 529.1003 Flurogestone acetate-  
impregnated vaginal sponge.**

\* \* \* \* \*

(d) *Related tolerances.* See § 556.290 of this chapter.

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

13. The authority citation for 21 CFR part 556 is revised to read as follows:

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

14. Revise part 556 to read as follows:

**Subpart A—General Provisions**

Sec.

- 556.1 Scope.
- 556.3 Definitions.
- 556.5 General considerations.

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

Sec.

- 556.34 Albendazole.
- 556.36 Altrenogest.
- 556.38 Amoxicillin.
- 556.40 Ampicillin.
- 556.50 Amprolium.
- 556.52 Apramycin.
- 556.60 Arsenic.
- 556.68 Azaperone.
- 556.70 Bacitracin.
- 556.75 Bambermycins.
- 556.100 Carbadox.
- 556.110 Carbomycin.
- 556.113 Ceftiofur.
- 556.115 Cephapirin.
- 556.120 Chlorhexidine.
- 556.150 Chlortetracycline.
- 556.160 Clopidol.
- 556.163 Clorsulon.
- 556.165 Cloxacillin.
- 556.167 Colistimethate.
- 556.168 Coumaphos.
- 556.169 Danofloxacin.
- 556.170 Decoquinat.
- 556.180 Dichlorvos.
- 556.185 Diclazuril.
- 556.200 Dihydrostreptomycin.
- 556.222 Doramectin.
- 556.224 Efrotomycin.
- 556.226 Enrofloxacin.
- 556.227 Eprinomectin.
- 556.230 Erythromycin.
- 556.240 Estradiol and related esters.
- 556.260 Ethopabate.
- 556.273 Famphur.
- 556.275 Fenbendazole.
- 556.277 Fenprostalene.
- 556.280 Fenthion.
- 556.283 Florfenicol.
- 556.286 Flunixin.
- 556.290 Flurogestone.
- 556.292 Gamithromycin.
- 556.300 Gentamicin.
- 556.304 Gonadotropin.
- 556.308 Halofuginone.
- 556.310 Haloxon.

- 556.330 Hygromycin B.
- 556.344 Ivermectin.
- 556.346 Laidlomycin.
- 556.347 Lasalocid.
- 556.350 Levamisole.
- 556.360 Lincomycin.
- 556.375 Maduramicin.
- 556.380 Melengestrol.
- 556.410 Metoserpate.
- 556.420 Monensin.
- 556.425 Morantel.
- 556.426 Moxidectin.
- 556.428 Narasin.
- 556.430 Neomycin.
- 556.440 Nequinat.
- 556.445 Nicarbazin.
- 556.460 Novobiocin.
- 556.470 Nystatin.
- 556.480 Oleandomycin.
- 556.490 Ormetoprim.
- 556.495 Oxfendazole.
- 556.500 Oxytetracycline.
- 556.510 Penicillin.
- 556.513 Piperazine.
- 556.515 Pirlimycin.
- 556.517 Poloxalene.
- 556.540 Progesterone.
- 556.560 Pyrantel.
- 556.570 Ractopamine.
- 556.580 Robenidine.
- 556.592 Salinomycin.
- 556.597 Semduramicin.
- 556.600 Spectinomycin.
- 556.610 Streptomycin.
- 556.620 Sulfabromomethazine.
- 556.625 Sulfachloropyrazine.
- 556.630 Sulfachloropyridazine.
- 556.640 Sulfadimethoxine.
- 556.650 Sulfaethoxyypyridazine.
- 556.660 Sulfamerazine.
- 556.670 Sulfamethazine.
- 556.685 Sulfaquinoxaline.
- 556.690 Sulfathiazole.
- 556.700 Sulfomyxin.
- 556.710 Testosterone.
- 556.720 Tetracycline.
- 556.730 Thiabendazole.
- 556.733 Tildipirosin.
- 556.735 Tilmicosin.
- 556.738 Tiamulin.
- 556.739 Trenbolone.
- 556.741 Tripelennamine.
- 556.745 Tulathromycin.
- 556.746 Tylosin.
- 556.748 Tylvalosin.
- 556.750 Virginiamycin.
- 556.760 Zeranol.
- 556.765 Zilpaterol.
- 556.770 Zoalene.

**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 amount of total residue that can safely be consumed per day over a human's lifetime without adverse health effect. The ADI is calculated by dividing the no-observed-effect-level (NOEL) (from the most appropriate toxicological study) by a safety factor. The safety factor reflects, among other things, the extrapolation of long-term effects from shorter-term exposures, extrapolation of animal data to humans, and variability in sensitivity among human populations.

*Acceptable single-dose intake (ASDI)* means the amount of total residue that may safely be consumed in a single meal. The ASDI may be used to derive the tolerance for residue of the drug at the injection site where the drug is administered according to the label.

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

*Marker residue* means the residue selected for assay by the regulatory method whose concentration in the target tissue is in a known relationship to the concentration of the total residue in the target tissue. A finding that the concentration of marker residue is at or below the tolerance in the target tissue from a tested animal indicates that all edible tissues (excluding milk and eggs unless otherwise specified) from that animal are safe.

*mg/kg* means milligrams per kilogram.

*No-Observed-Effect Level (NOEL)* means the highest dose level of a drug tested that produces no observable effects.

*Not required*, in reference to tolerances in this part, 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

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)).

*Regulatory method* means the aggregate of all experimental procedures for measuring and confirming the presence of the marker residue in the target tissue of the target animal.

*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. (A finding, using the approved regulatory method, that the concentration of the marker residue or other residue indicated for monitoring is present in the target tissue at a concentration at or below the tolerance, indicates that all edible tissues (excluding milk and eggs unless otherwise specified) from the tested animal are safe. All tolerances refer to the concentrations of a marker residue, or other residue indicated for monitoring, permitted in uncooked tissues.)

*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 no detectable residues are allowed when using a method of detection prescribed or approved by FDA. Any residue detectable using the prescribed or approved method renders the tissue 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 use and conditionally approved use conditions, including the species and production classes of the animals, are cited under paragraph (c) *Related*

*conditions of use* for each tolerance listing of 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 develop a regulatory method to measure drug residues in edible tissues of approved target species at concentrations around the tolerance as provided in § 514.1(b)(7) of this chapter. Because FDA determines the tolerance for the marker residue using data collected with the approved regulatory method, the tolerance is directly tied to that method. Approved regulatory methods are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

### 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 § 520.45 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 tolerance for altrenogest (the marker residue) is:

(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 tolerances for amoxicillin are:  
 (1) *Cattle—Edible tissues*: 0.01 ppm.  
 (2) [Reserved]  
 (c) *Related conditions of use*. See §§ 520.88, 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, and 522.90 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) *Tolerance*. 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 Arsenic.

- (a) [Reserved]  
 (b) *Tolerances*. The tolerances for total residue of combined arsenic (calculated as As) are:  
 (1) *Chickens and turkeys—(i) Muscle and eggs*: 0.5 ppm.  
 (ii) *Other edible tissues*: 2 ppm.  
 (2) *Swine—(i) Liver and kidney*: 2 ppm.  
 (ii) *Muscle and fat*: 0.5 ppm.  
 (c) *Related conditions of use*. See §§ 520.2087, 520.2088, 520.2089, 558.62, 558.120, 558.369, and 558.530 of this chapter.

#### § 556.68 Azaperone.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residues of azaperone is 0.63 µg/kg of body weight per day.  
 (b) *Tolerances*. The tolerances for azaperone are:  
 (1) *Swine—(i) 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 §§ 520.154, 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) *Tolerance*. 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 tolerances for carbomycin are:  
 (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 acceptable single-dose intake—(1) Acceptable daily intake (ADI)*. The ADI for total residue of ceftiofur is 30 µg/kg of body weight per day.  
 (2) *Acceptable single-dose intake (ASDI)*. The ASDI total residue for ceftiofur is 0.830 mg/kg of body weight. The ASDI is the amount of total residue

of ceftiofur that may safely be consumed in a single meal.

(b) *Tolerances*. The tolerances for desfurioylceftiofur (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 §§ 522.313 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.

#### § 556.120 Chlorhexidine.

- (a) [Reserved]  
 (b) *Tolerances*. The tolerances for chlorhexidine are:  
 (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 §§ 520.445, 558.128, 558.145, and 558.155 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 tolerances for cloxacillin are:  
 (1) *Cattle—Edible tissues*: 0.01 ppm.  
 (2) [Reserved]  
 (c) *Related conditions of use.* See § 526.464 of this chapter.

#### § 556.167 Colistimethate.

- (a) [Reserved]  
 (b) *Tolerances.* The tolerances for colistimethate are:  
 (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 Decoquinat.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of decoquinat is 75 µg/kg of body weight per day.  
 (b) *Tolerances.* The tolerances for decoquinat 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 § 558.195 of this chapter.

#### § 556.180 Dichlorvos.

- (a) [Reserved]  
 (b) *Tolerances.* The tolerances for dichlorvos are:  
 (1) *Swine—Edible tissues*: 0.1 ppm.  
 (2) [Reserved]  
 (c) *Related conditions of use.* See § 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 §§ 520.2158b, 520.2158c, 522.650, and 526.1696b 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 tolerances for efrotomycin are:  
 (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 desethylen 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<sub>1a</sub> (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) *Tolerances.* 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 tolerances for famphur including its oxygen analog are:  
 (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) *Goats*—(i) *Liver (target tissue)*: 0.8 ppm fenbendazole (marker residue).  
 (ii) *Muscle*: 0.4 ppm fenbendazole.  
 (3) *Swine*—(i) *Liver (target tissue)*: 6 ppm fenbendazole (marker residue).  
 (ii) *Muscle*: 2 ppm fenbendazole.  
 (4) *Turkeys*—(i) *Liver (target tissue)*: 6 ppm fenbendazole sulfone (marker residue).  
 (ii) *Muscle*: 2 ppm fenbendazole sulfone.  
 (c) *Related conditions of use.* See §§ 520.905 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) *Tolerance.* The tolerances for fenthion are:

(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 and 522.970 of this chapter.

#### § 556.290 Fluogestone.

(a) [Reserved]  
 (b) *Tolerances.* The tolerances for fluogestone are:  
 (1) *Sheep—Edible tissues (excluding milk)*: Not required.  
 (2) [Reserved]  
 (c) *Related conditions of use.* See § 529.1003 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 §§ 522.1044, 524.1044e, and 529.1044b 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, 522.1078, 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 tolerances for haloxon are:  
 (1) *Cattle—Edible tissues (excluding milk)*: 0.1 ppm.  
 (2) [Reserved]  
 (c) *Related conditions of use.* See § 520.1120 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<sub>1a</sub> (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) *Tolerance*. 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 §§ 520.1242, 522.1244, 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 §§ 520.1263b, 520.1263c, 522.1260, and 558.325 of this chapter.

#### § 556.375 Maduramicin.

(a) [Reserved]

(b) *Tolerance*. 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) *Tolerance*. 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 tolerances for metoserpate are:

(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 §§ 520.1450 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) *Tolerance*. 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 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, and 558.364 of this chapter.

#### § 556.440 Nequinatate.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use.* See § 558.365 of this chapter.

**§ 556.445 Nicarbazin.**

(a) [Reserved]  
(b) *Tolerances.* The tolerances for nicarbazin are:

- (1) *Chickens*—(i) *Muscle*: 4 ppm.
- (ii) *Liver*: 4 ppm.
- (2) [Reserved]

(c) *Related conditions of use.* See § 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, 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.

**§ 556.480 Oleandomycin.**

(a) [Reserved]  
(b) *Tolerances.* The tolerances for oleandomycin are:

- (1) *Chickens and turkeys*—*Edible tissues (excluding eggs)*: 0.15 ppm.
- (2) *Swine*—*Edible tissues*: 0.15 ppm.

(c) *Related conditions of use.* See § 558.435 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) *Tolerance.* 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 §§ 520.1660, 522.1660, 522.1662, 524.1662b, 529.1660, and 558.450 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 §§ 520.1696, 522.1696, 526.1696, and 558.460 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 tolerances for poloxalene are:

(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) *Tolerances.* 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 Robenidone.**

(a) [Reserved]

(b) *Tolerances.* The tolerances for robenidone 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 tolerances for sulfachloropyrazine are:

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

(2) [Reserved]

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

**§ 556.630 Sulfachloropyridazine.**

(a) [Reserved]

(b) *Tolerances*. The tolerances for sulfachloropyridazine 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 §§ 520.2220, 522.2220, and 558.575 of this chapter.

**§ 556.650 Sulfaethoxyypyridazine.**

(a) [Reserved]

(b) *Tolerances*. The tolerances for sulfaethoxyypyridazine 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 §§ 520.2240 and 522.2240 of this chapter.

**§ 556.660 Sulfamerazine.**

(a) [Reserved]

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

(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 §§ 520.2260, 520.2261, 522.2260, 558.145, 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 §§ 520.2325 and 558.586 of this chapter.

**§ 556.690 Sulfathiazole.**

(a) [Reserved]

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

(1) *Swine—Edible tissues*: 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use*. See § 558.155 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) *Tolerances*. 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 558.615 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 tolerances for tildipirosin (the marker residue) are:  
 (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 §§ 522.2471 and 558.618 of this chapter.

#### § 556.738 Tiamulin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of tiamulin is 25 µg/kg of body weight per day.  
 (b) *Tolerance*. 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 558.600 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 tolerances for trenbolone are:  
 (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 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 tolerances for zilpaterol freebase (marker residue) are:  
 (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

15. The authority citation for 21 CFR part 558 continues to read as follows:

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

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

#### § 558.95 Bambermycins.

\* \* \* \* \*

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

\* \* \* \* \*

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

#### § 558.185 Coumaphos.

\* \* \* \* \*

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

\* \* \* \* \*

18. In § 558.235, add paragraph (c) to read as follows:

#### § 558.235 Efrotomycin.

\* \* \* \* \*

(c) *Related tolerances*. See § 556.224 of this chapter.

19. In § 558.464, add paragraph (c) to read as follows:

#### § 558.464 Poloxalene.

\* \* \* \* \*

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

20. In § 558.465, add paragraph (c) to read as follows:

**§ 558.465 Poloxalene free-choice liquid Type C feed.**

\* \* \* \* \*

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

21. In § 558.625, revise paragraph (e) to read as follows:

**§ 558.625 Tylosin.**

\* \* \* \* \*

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

\* \* \* \* \*

22. In § 558.630, revise paragraph (d) to read as follows:

**§ 558.630 Tylosin and sulfamethazine.**

\* \* \* \* \*

(d) *Related tolerances.* See §§ 556.670 and 556.746 of this chapter.

\* \* \* \* \*

Dated: November 26, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-29322 Filed 12-4-12; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1 and 31

[REG-130074-11]

RIN 1545-BK54

#### Rules Relating to Additional Medicare Tax

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains proposed regulations relating to Additional Hospital Insurance Tax on income above threshold amounts (“Additional Medicare Tax”), as added by the Affordable Care Act. Specifically, these proposed regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax. This document also contains proposed regulations relating to the requirement to file a return reporting Additional Medicare Tax, the employer process for making adjustments of underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund for an overpayment of

Additional Medicare Tax. This document also provides notice of a public hearing on these proposed rules.

**DATES:** Written or electronic comments must be received by March 5, 2013. Requests to speak (with outlines of topics to be discussed) at the public hearing scheduled for April 4, 2013, must be received by March 5, 2013.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-130074-11), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-130074-11), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG-130074-11). The public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:**

Concerning the proposed regulations, Andrew K. Holubeck or Ligeia M. Donis at (202) 622-6040; concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, please contact Oluwafunmilayo (Funmi) Taylor at [Oluwafunmilayo.P.Taylor@irscounsel.treas.gov](mailto:Oluwafunmilayo.P.Taylor@irscounsel.treas.gov) or (202) 622-7180 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Paperwork Reduction Act**

The collection of information contained in these proposed regulations was previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-2097. Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by February 4, 2013. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in §§ 31.6011(a)-1, 31.6011(a)-2, 31.6205-1, 31.6402(a)-2, 31.6413(a)-1, and 31.6413(a)-2. This information is required by the IRS to verify compliance with return requirements under section 6011, employment tax adjustments under sections 6205 and 6413, and claims for refund of overpayments under section 6402. This information will be used to determine whether the amount of tax has been reported and calculated correctly. The likely respondents are employers and individuals.

*Estimated total annual reporting and/or recordkeeping burden:* 1,900,000 hours.

*Estimated average annual burden per respondent:* 1 hour.

*Estimated number of respondents:* 1,900,000.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

**Background**

These proposed regulations are issued in connection with the Additional Hospital Insurance Tax on income above threshold amounts (“Additional Medicare Tax”), as added by section 9015 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 (124 Stat. 119 (2010)), and as amended by section 10906 of the PPACA and section 1402(b) of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively, the “Affordable Care Act”). The proposed regulations include amendments to § 1.1401-1 of the Income Tax Regulations, and §§ 31.3101-2, 31.3102-1, 31.3102-4, 31.3202-1, 31.6011(a)-1, 31.6011(a)-2, 31.6205-1, 31.6402(a)-2, 31.6413(a)-1, and 31.6413(a)-2 of the Employment Tax Regulations. The proposed regulations provide guidance for