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appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) *Amphibians and other aquatic cold-blooded animals.* The drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(2) *Indications for use.* For the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) *Limitations.* Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature exceeding 10 °C (50 °F). In other fish and in coldblooded animals, the drug should be limited to hatchery or laboratory use.

[79 FR 10974, Feb. 27, 2014]

§ 529.2620 **Triptorelin.**

(a) *Specifications.* Each milliliter of gel contains 100 micrograms (mcg) triptorelin as triptorelin acetate.

(b) *Sponsor.* See No. 051072 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* Administer 200 mcg intravaginally approximately 96 hours after weaning.

(2) *Indications for use.* For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.

(3) *Limitations.* Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals. Should not be used in sows with obvious reproductive tract abnormalities.

[77 FR 64717, Oct. 23, 2012, as amended at 90 FR 6801, Jan. 21, 2025]

PART 530—EXTRALABEL DRUG USE IN ANIMALS

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AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

SOURCE: 61 FR 57743, Nov. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 530.1 **Scope.**

This part applies to the extralabel use in an animal of any approved new animal drug or approved new human drug by or on the lawful order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship.

§ 530.2 Purpose.

The purpose of this part is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat. This section implements the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103-396).

§ 530.3 Definitions.

(a) *Extralabel use* means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

(b) *FDA* means the U.S. Food and Drug Administration.

(c) The phrase *a reasonable probability that a drug's use may present a risk to the public health* means that FDA has reason to believe that use of a drug may be likely to cause a potential adverse event.

(d) The phrase *use of a drug may present a risk to the public health* means that FDA has information that indicates that use of a drug may cause an adverse event.

(e) The phrase *use of a drug presents a risk to the public health* means that FDA has evidence that demonstrates that the use of a drug has caused or likely will cause an adverse event.

(f) A *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.

(g) A *safe level* is a conservative estimate of a drug residue level in edible animal tissue derived from food safety data or other scientific information. Concentrations of residues in tissue

below the safe level will not raise human food safety concerns. A safe level is not a safe concentration or a tolerance and does not indicate that an approval exists for the drug in that species or category of animal from which the food is derived.

(h) *Veterinarian* means a person licensed by a State or Territory to practice veterinary medicine.

(i) A *valid veterinarian-client-patient relationship* is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

§ 530.4 Advertising and promotion.

Nothing in this part shall be construed as permitting the advertising or promotion of extralabel uses in animals of approved new animal drugs or approved human drugs.

§ 530.5 Veterinary records.

(a) As a condition of extralabel use permitted under this part, to permit FDA to ascertain any extralabel use or intended extralabel use of drugs that the agency has determined may present a risk to the public health, veterinarians shall maintain the following records of extralabel uses. Such records shall be legible, documented in an accurate and timely manner, and be readily accessible to permit prompt retrieval of information. Such records shall be adequate to substantiate the identification of the animals and shall

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be maintained either as individual records or, in food animal practices, on a group, herd, flock, or per-client basis. Records shall be adequate to provide the following information:

(1) The established name of the drug and its active ingredient, or if formulated from more than one ingredient, the established name of each ingredient;

(2) The condition treated;

(3) The species of the treated animal(s);

(4) The dosage administered;

(5) The duration of treatment;

(6) The numbers of animals treated; and

(7) The specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or any food which might be derived from any food animals treated.

(b) A veterinarian shall keep all required records for 2 years or as otherwise required by Federal or State law, whichever is greater.

(c) Any person who is in charge, control, or custody of such records shall, upon request of a person designated by FDA, permit such person designated by FDA to, at all reasonable times, have access to, permit copying, and verify such records.

Subpart B—Rules and Provisions for Extralabel Uses of Drugs in Animals

§ 530.10 Provision permitting extralabel use of animal drugs.

An approved new animal drug or human drug intended to be used for an extralabel purpose in an animal is not unsafe under section 512 of the act and is exempt from the labeling requirements of section 502(f) of the act if such use is:

(a) By or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship; and

(b) In compliance with this part.

§ 530.11 Limitations.

In addition to uses which do not comply with the provision set forth in § 530.10, the following specific extralabel uses are not permitted and result in the drug being deemed unsafe

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within the meaning of section 512 of the act:

(a) Extralabel use in an animal of an approved new animal drug or human drug by a lay person (except when under the supervision of a licensed veterinarian);

(b) Extralabel use of an approved new animal drug or human drug in or on an animal feed;

(c) Extralabel use resulting in any residue which may present a risk to the public health; and

(d) Extralabel use resulting in any residue above an established safe level, safe concentration or tolerance.

§ 530.12 Labeling.

Any human or animal drug prescribed and dispensed for extralabel use by a veterinarian or dispensed by a pharmacist on the order of a veterinarian shall bear or be accompanied by labeling information adequate to assure the safe and proper use of the product. Such information shall include the following:

(a) The name and address of the prescribing veterinarian. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian;

(b) The established name of the drug or, if formulated from more than one active ingredient, the established name of each ingredient;

(c) Any directions for use specified by the veterinarian, including the class/species or identification of the animal or herd, flock, pen, lot, or other group of animals being treated, in which the drug is intended to be used; the dosage, frequency, and route of administration; and the duration of therapy;

(d) Any cautionary statements; and

(e) The veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal or animals.

§ 530.13 Extralabel use from compounding of approved new animal and approved human drugs.

(a) This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.

(b) Extralabel use from compounding of approved new animal or human drugs is permitted if:

(1) All relevant portions of this part have been complied with;

(2) There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;

(3) The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;

(4) Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;

(5) The scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and

(6) All relevant State laws relating to the compounding of drugs for use in animals are followed.

(c) Guidance on the subject of compounding may be found in guidance documents issued by FDA.

Subpart C—Specific Provisions Relating to Extralabel Use of Animal and Human Drugs in Food-Producing Animals

§ 530.20 Conditions for permitted extralabel animal and human drug use in food-producing animals.

(a) The following conditions must be met for a permitted extralabel use in food-producing animals of approved new animal and human drugs:

(1) There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.

(2) Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;

(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;

(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and

(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

(b) The following additional conditions must be met for a permitted extralabel use of in food-producing animals an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:

(1) Such use must be accomplished in accordance with an appropriate medical rationale; and

(2) If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.

(c) Extralabel use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the particular use.

§ 530.21 Prohibitions for food-producing animals.

(a) FDA may prohibit the extralabel use of an approved new animal or

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human drug or class of drugs in food-producing animals if FDA determines that:

(1) An acceptable analytical method needs to be established and such method has not been established or cannot be established; or

(2) The extralabel use of the drug or class of drugs presents a risk to the public health.

(b) A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.

§ 530.22 Safe levels and analytical methods for food-producing animals.

(a) FDA may establish a safe level for extralabel use of an approved human drug or an approved new animal drug when the agency finds that there is a reasonable probability that an extralabel use may present a risk to the public health. FDA may:

(1) Establish a finite safe level based on residue and metabolism information from available sources;

(2) Establish a safe level based on the lowest level that can be measured by a practical analytical method; or

(3) Establish a safe level based on other appropriate scientific, technical, or regulatory criteria.

(b) FDA may require the development of an acceptable analytical method for the quantification of residues above any safe level established under this part. If FDA requires the development of such an acceptable analytical method, the agency will publish notice of that requirement in the FEDERAL REGISTER.

(c) The extralabel use of an animal drug or human drug that results in residues exceeding a safe level established under this part is an unsafe use of such drug.

(d) If the agency establishes a safe level for a particular species or category of animals and a tolerance or safe concentration is later established through an approval for that particular species or category of animals, for that species or category of animals, the safe level is superseded by the tolerance or

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safe concentration for that species or category of animals.

§ 530.23 Procedure for setting and announcing safe levels.

(a) FDA may issue an order establishing a safe level for a residue of an extralabel use of an approved human drug or an approved animal drug. The agency will publish in the FEDERAL REGISTER a notice of the order. The notice will include:

(1) A statement setting forth the agency's finding that there is a reasonable probability that extralabel use in animals of the human drug or animal drug may present a risk to the public health;

(2) A statement of the basis for that finding; and

(3) A request for public comments.

(b) A current listing of those drugs for which a safe level for extralabel drug use in food-producing animals has been established, the specific safe levels, and the availability, if any, of a specific analytical method or methods for drug residue detection will be codified in § 530.40.

§ 530.24 Procedure for announcing analytical methods for drug residue quantification.

(a) FDA may issue an order announcing a specific analytical method or methods for the quantification of extralabel use drug residues above the safe levels established under § 530.22 for extralabel use of an approved human drug or an approved animal drug. The agency will publish in the FEDERAL REGISTER a notice of the order, including the name of the specific analytical method or methods and the drug or drugs for which the method is applicable.

(b) Copies of analytical methods for the quantification of extralabel use drug residues above the safe levels established under § 530.22 will be available upon request from the Communications and Education Branch (HFV-12), Division of Program Communication and Administrative Management, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855. When an analytical method for the detection of extralabel use drug residues above the safe levels established under § 530.22 is

developed, and that method is acceptable to the agency, FDA will incorporate that method by reference.

§ 530.25 Orders prohibiting extralabel uses for drugs in food-producing animals.

(a) FDA may issue an order prohibiting extralabel use of an approved new animal or human drug in food-producing animals if the agency finds, after providing an opportunity for public comment, that:

(1) An acceptable analytical method required under § 530.22 has not been developed, submitted, and found to be acceptable by FDA or that such method cannot be established; or

(2) The extralabel use in animals presents a risk to the public health.

(b) After making a determination that the analytical method required under § 530.22 has not been developed and submitted, or that such method cannot be established, or that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, FDA will publish in the FEDERAL REGISTER, with a 90-day delayed effective date, an order of prohibition for an extralabel use of a drug in food-producing animals. Such order shall state that an acceptable analytical method required under § 530.22 has not been developed, submitted, and found to be acceptable by FDA; that such method cannot be established; or that the extralabel use in animals presents a risk to the public health; and shall:

(1) Specify the nature and extent of the order of prohibition and the reasons for the prohibition;

(2) Request public comments; and

(3) Provide a period of not less than 60 days for comments.

(c) The order of prohibition will become effective 90 days after date of publication of the order unless FDA publishes a notice in the FEDERAL REGISTER prior to that date, that revokes the order of prohibition, modifies it, or extends the period of public comment.

(d) The agency may publish an order of prohibition with a shorter comment period and/or delayed effective date than specified in paragraph (b) of this section in exceptional circumstances (e.g., where there is immediate risk to

the public health), provided that the order of prohibition states that the comment period and/or effective date have been abbreviated because there are exceptional circumstances, and the order of prohibition sets forth the agency's rationale for taking such action.

(e) If FDA publishes a notice in the FEDERAL REGISTER modifying an order of prohibition, the agency will specify in the modified order of prohibition the nature and extent of the modified prohibition, the reasons for it, and the agency's response to any comments on the original order of prohibition.

(f) A current listing of drugs prohibited for extralabel use in animals will be codified in § 530.41.

(g) After the submission of appropriate information (i.e., adequate data, an acceptable method, approval of a new animal drug application for the prohibited extralabel use, or information demonstrating that the prohibition was based on incorrect data), FDA may, by publication of an appropriate notice in the FEDERAL REGISTER, remove a drug from the list of human and animal drugs prohibited for extralabel use in animals, or may modify a prohibition.

(h) FDA may prohibit extralabel use of a drug in food-producing animals without establishing a safe level.

Subpart D—Extralabel Use of Human and Animal Drugs in Animals Not Intended for Human Consumption

§ 530.30 Extralabel drug use in nonfood animals.

(a) Because extralabel use of animal and human drugs in nonfood-producing animals does not ordinarily pose a threat to the public health, extralabel use of animal and human drugs is permitted in nonfood-producing animal practice except when the public health is threatened. In addition, the provisions of § 530.20(a)(1) will apply to the use of an approved animal drug.

(b) If FDA determines that an extralabel drug use in animals not intended for human consumption presents a risk to the public health, the agency may publish in the FEDERAL REGISTER a notice prohibiting such use

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following the procedures in § 530.25. The prohibited extralabel drug use will be codified in § 530.41.

Subpart E—Safe Levels for Extralabel Use of Drugs in Animals and Drugs Prohibited From Extralabel Use in Animals

§ 530.40 Safe levels and availability of analytical methods.

(a) In accordance with § 530.22, the following safe levels for extralabel use of an approved animal drug or human drug have been established: [Reserved]

(b) In accordance with § 530.22, the following analytical methods have been accepted by FDA: [Reserved]

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

- (1) Chloramphenicol;
- (2) Clenbuterol;
- (3) Diethylstilbestrol (DES);
- (4) Dimetridazole;
- (5) Ipronidazole;
- (6) Other nitroimidazoles;
- (7) Furazolidone.
- (8) Nitrofurazone.

(9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxyypyridazine);

- (10) Fluoroquinolones; and
- (11) Glycopeptides.

(12) Phenylbutazone in female dairy cattle 20 months of age or older.

(13) Cephalosporins (not including cephalirin) in cattle, swine, chickens, or turkeys:

- (i) For disease prevention purposes;
- (ii) At unapproved doses, frequencies, durations, or routes of administration; or

(iii) If the drug is not approved for that species and production class.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals: [Reserved]

(c) [Reserved]

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(d) The following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in chickens, turkeys, and ducks:

- (1) Adamantanes.
- (2) Neuraminidase inhibitors.

[62 FR 27947, May 22, 1997, as amended at 67 FR 5471, Feb. 6, 2002; 68 FR 9530, Feb. 28, 2003; 68 FR 14134, Mar. 24, 2003; 71 FR 14377, Mar. 22, 2006; 77 FR 745, Jan. 6, 2012]

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

Subpart A—General Provisions

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

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- 556.40 Ampicillin.
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- 556.110 Carbomycin.
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- 556.115 Cephapirin.
- 556.118 Chloramine-T.
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- 556.160 Clopidol.
- 556.163 Clorsulon.
- 556.165 Cloxacillin.
- 556.167 Colistimethate.
- 556.168 Coumaphos.
- 556.169 Danofloxacin.
- 556.170 Decoquinatone.
- 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.
 556.292 Gamithromycin.
 556.300 Gentamicin.
 556.304 Gonadotropin.
 556.308 Halofuginone.
 556.310 Haloxon.
 556.316 Hetacillin.
 556.330 Hygromycin B.
 556.344 Ivermectin.
 556.345 Ketoprofen.
 556.346 Laidlomycin.
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 556.350 Levamisole.
 556.360 Lincomycin.
 556.370 Lubabegron.
 556.375 Maduramicin.
 556.380 Melengestrol.
 556.410 Metoserpate.
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 556.570 Ractopamine.
 556.580 Robenidine.
 556.592 Salinomycin.
 556.597 Semduramicin.
 556.600 Spectinomycin.
 556.610 Streptomycin.
 556.625 Sulfachloropyrazine.
 556.630 Sulfachloropyridazine.
 556.640 Sulfadimethoxine.
 556.650 Sulfathoxypridazine.
 556.660 Sulfamerazine.
 556.670 Sulfamethazine.
 556.685 Sulfaquinoxaline.
 556.700 Sulfomyxin.
 556.710 Testosterone.
 556.720 Tetracycline.
 556.732 Tiamulin.
 556.733 Tildipirosin.
 556.735 Tilmicosin.
 556.739 Trenbolone.
 556.741 Tripeleennamine.
 556.745 Tulathromycin.
 556.746 Tylosin.
 556.748 Tylvalosin.
 556.750 Virginiamycin.
 556.760 Zeranol.
 556.765 Zilpaterol.
 556.770 Zoalene.

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

SOURCE: 84 FR 32993, July 11, 2019, unless otherwise noted.

Subpart A—General Provisions

§ 556.1 Scope.

(a) The Federal Food, Drug, and Cosmetic Act requires an applicant seeking approval or conditional approval of a new animal drug to submit a proposed tolerance as part of its new animal drug application when such a tolerance is needed to assure that the proposed use of the new animal drug will be safe (see sections 512(b)(1)(H) and 571(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act). FDA assigns tolerances for animal drugs used in food-producing animals as part of the application approval process. Tolerances for approved and conditionally approved new animal drugs are codified in subpart B of this part.

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

§ 556.3 Definitions.

As used in this part:

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

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

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

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

mg/kg means milligrams per kilogram.

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

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

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

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

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

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

Residue means any compound present in edible tissues that results from the use of a drug, and includes the drug, its metabolites, and any other substance formed in or on food because of the drug's use.

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

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

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

µg/kg means microgram per kilogram.

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

§ 556.5 General considerations.

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

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erance section in subpart B of this part.

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

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

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

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

§ 556.34 Albendazole.

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

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

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

(ii) Muscle: 0.05 ppm.

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

(ii) Muscle: 0.05 ppm.

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

(ii) [Reserved]

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

§ 556.36 Altrenogest.

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

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

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

(ii) Muscle: 1 ppb.

(2) [Reserved]

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

§ 556.38 Amoxicillin.

(a) [Reserved]

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

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

(2) [Reserved]

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

[84 FR 32993, July 11, 2019, as amended at 86 FR 13188, Mar. 8, 2021]

§ 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 §§ 520.90c, 522.90a, and 522.90b of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18120, Apr. 1, 2020]

§ 556.50 Amprolium.

(a) [Reserved]

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

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

(ii) Fat: 2.0 ppm.

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

(ii) Muscle: 0.5 ppm.

(iii) Eggs:

(A) Egg yolks: 8 ppm.

(B) Whole eggs: 4 ppm.

(3) *Pheasants*. (i) Liver: 1 ppm.

(ii) Muscle: 0.5 ppm.

(c) *Related conditions of use*. See §§ 520.100, 558.55, and 558.58 of this chapter.

§ 556.52 Apramycin.

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

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

(1) *Swine*. Kidney (target tissue): 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use*. See §§ 520.110 and 558.59 of this chapter.

§ 556.60 Avilamycin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of avilamycin is 1.1 mg/kg of body weight per day.

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

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

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

(c) *Related conditions of use*. See § 558.68 of this chapter.

§ 556.68 Azaperone.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of azaperone is 0.63 µg/kg of body weight per day.

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

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

(2) [Reserved]

(c) *Related conditions of use*. See § 522.150 of this chapter.

§ 556.70 Bacitracin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of bacitracin is 0.05 mg/kg of body weight per day.

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

(1) *Cattle*. Edible tissues: 0.5 ppm.

(2) *Chickens, turkeys, pheasants, quail*. Edible tissues: 0.5 ppm.

(3) *Swine*. Edible tissues: 0.5 ppm.

(c) *Related conditions of use*. See §§ 520.154a, 520.154c, 558.76, and 558.78 of this chapter.

§ 556.75 Bambermycins.

(a) [Reserved]

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

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

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

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

(c) *Related conditions of use*. See § 558.95 of this chapter.

§ 556.100 Carbadox.

(a) [Reserved]

(b) *Tolerances*. The tolerance for quinoxaline-2-carboxylic acid (marker residue) is:

(1) *Swine*. Liver (target tissue): 30 ppb.

(2) [Reserved]

(c) *Related conditions of use*. See § 558.115 of this chapter.

§ 556.110 Carbomycin.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use*. See § 520.1664 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 88 FR 55567, Aug. 16, 2023]

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake and acute reference dose*—(1) *Acceptable daily intake (ADI)*. The ADI for total residue of ceftiofur is 30 µg/kg of body weight per day.

(2) *Acute reference dose (ARfD)*. The ARfD for total residue of ceftiofur is 0.830 mg/kg of body weight.

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

(1) *Cattle*. (i) Kidney (target tissue): 0.4 ppm.

(ii) Liver: 2 ppm.

(iii) Muscle: 1 ppm.

(iv) Milk: 0.1 ppm.

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

(3) *Goats*. (i) Kidney (target tissue): 8 ppm.

(ii) Liver: 2 ppm.

(iii) Muscle: 1 ppm.

(iv) Milk: 0.1 ppm.

(4) *Sheep*. Edible tissues (excluding milk): Not required.

(5) *Swine*. (i) Kidney (target tissue): 0.25 ppm.

(ii) Liver: 3 ppm.

(iii) Muscle: 2 ppm.

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(c) *Related conditions of use*. See §§ 522.313a, 522.313b, 522.313c, and 526.313 of this chapter.

§ 556.115 Cephapirin.

(a) [Reserved]

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

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

(ii) Milk: 0.02 ppm.

(2) [Reserved]

(c) *Related conditions of use*. See §§ 526.363 and 526.365 of this chapter.

§ 556.118 Chloramine-T.

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

(b) *Tolerances*. The tolerance for *para*-toluenesulfonamide (marker residue) is:

(1) *Fish*. Muscle/skin (target tissue): 0.9 ppm.

(2) [Reserved]

(c) *Related conditions of use*. See § 529.382 of this chapter.

§ 556.120 Chlorhexidine.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use*. See § 529.400 of this chapter.

§ 556.150 Chlortetracycline.

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

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

(1) *Cattle*. (i) Liver: 6 ppm.

(ii) Kidney and fat: 12 ppm.

(iii) Muscle: 2 ppm.

(2) *Chickens, turkeys, and ducks*. (i) Liver: 6 ppm.

(ii) Kidney and fat: 12 ppm.

(iii) Muscle: 2 ppm.

(iv) Eggs: 0.4 ppm for chlortetracycline only.

(3) *Sheep*. (i) Liver: 6 ppm.

(ii) Kidney and fat: 12 ppm.

(iii) Muscle: 2 ppm.

(4) *Swine*. (i) Liver: 6 ppm.

(ii) Kidney and fat: 12 ppm.
 (iii) Muscle: 2 ppm.
 (c) *Related conditions of use.* See §§ 520.441, 520.443, 520.445, 558.128, and 558.140 of this chapter.

§ 556.160 Clopidol.

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

§ 556.163 Clorsulon.

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

§ 556.165 Cloxacillin.

(a) [Reserved]
 (b) *Tolerances.* The tolerance for cloxacillin is:
 (1) *Cattle.* Edible tissues: 0.01 ppm.
 (2) [Reserved]
 (c) *Related conditions of use.* See §§ 526.464 and 526.465 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020; 86 FR 13188, Mar. 8, 2021]

§ 556.167 Colistimethate.

(a) [Reserved]
 (b) *Tolerances.* The tolerance for colistimethate is:
 (1) *Chickens.* Edible tissues (excluding eggs): Not required.
 (2) [Reserved]
 (c) *Related conditions of use.* See § 522.468 of this chapter.

§ 556.168 Coumaphos.

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

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

(ii) Eggs: 0.1 ppm.
 (2) [Reserved]
 (c) *Related conditions of use.* See § 558.185 of this chapter.

[86 FR 14821, Mar. 19, 2021]

§ 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 Decoquinatate.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of decoquinatate is 75 µg/kg of body weight per day.
 (b) *Tolerances.* The tolerances for decoquinatate are:
 (1) *Cattle.* (i) Muscle: 1 ppm.
 (ii) Other edible tissues (excluding milk): 2 ppm.
 (2) *Chickens.* (i) Muscle: 1 ppm.
 (ii) Other edible tissues (excluding eggs): 2 ppm.
 (3) *Goats.* (i) Muscle: 1 ppm.
 (ii) Other edible tissues (excluding milk): 2 ppm.
 (c) *Related conditions of use.* See §§ 520.534 and 558.195 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 13188, Mar. 8, 2021]

§ 556.180 Dichlorvos.

(a) [Reserved]
 (b) *Tolerances.* The tolerance for dichlorvos is:
 (1) *Swine.* Edible tissues: 0.1 ppm.
 (2) [Reserved]
 (c) *Related conditions of use.* See §§ 520.596 and 558.198 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 13188, Mar. 8, 2021]

§ 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:

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- (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 § 558.205 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 13188, Mar. 8, 2021]

§ 556.200 Dihydrostreptomycin.

- (a) [Reserved]
(b) *Tolerances.* The tolerances for dihydrostreptomycin are:
(1) *Cattle.* (i) Kidney: 2.0 ppm.
(ii) Other edible tissues (excluding milk): 0.5 ppm.
(iii) Milk: 0.125 ppm.
(2) *Swine.* (i) Kidney: 2.0 ppm.
(ii) Other edible tissues: 0.5 ppm.
(c) *Related conditions of use.* See §§ 522.650, 526.1696b, and 526.1696c of this chapter.

§ 556.222 Doramectin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of doramectin is 0.75 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for doramectin (marker residue) are:
(1) *Cattle.* (i) Liver (target tissue): 300 ppb.
(ii) Muscle: 30 ppb.
(2) *Swine.* Liver (target tissue): 160 ppb.
(c) *Related conditions of use.* See §§ 522.770, 522.772, and 524.770 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 88 FR 16549, Mar. 20, 2023]

§ 556.224 Efrotomycin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of efrotomycin is 10 µg/kg of body weight per day.
(b) *Tolerances.* The tolerance for efrotomycin is:
(1) *Swine.* Edible tissues: Not required.
(2) [Reserved]
(c) *Related conditions of use.* See § 558.235 of this chapter.

§ 556.226 Enrofloxacin.

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

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

- (1) *Cattle.* Liver (target tissue): 0.1 ppm desethylene ciprofloxacin (marker residue).
(2) *Swine.* Liver (target tissue): 0.5 ppm enrofloxacin (marker residue).
(c) *Related conditions of use.* See §§ 516.812 and 522.812 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 13188, Mar. 8, 2021]

§ 556.227 Eprinomectin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of eprinomectin is 10 µg/kg of body weight per day.
(b) *Tolerances.* The tolerances for eprinomectin B_{1a} (marker residue) are:
(1) *Cattle.* (i) Liver (target tissue): 1.5 ppm.
(ii) Muscle: 100 ppb.
(iii) Milk: 12 ppb.
(2) [Reserved]
(c) *Related conditions of use.* See §§ 522.814 and 524.814 of this chapter.

§ 556.230 Erythromycin.

- (a) [Reserved]
(b) *Tolerances.* The tolerances for erythromycin are:
(1) *Cattle.* (i) Edible tissues (excluding milk): 0.1 ppm.
(ii) Milk: Zero.
(2) *Chickens and turkeys.* (i) Edible tissues (excluding eggs): 0.125 ppm.
(ii) Eggs: 0.025 ppm.
(c) *Related conditions of use.* See §§ 520.823, 522.820, 526.820, and 558.248 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.240 Estradiol and related esters.

- (a) [Reserved]
(b) *Residues.* Residues of estradiol are not permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated animals:
(1) *Cattle.* (i) Muscle: 0.2 ppb.
(ii) Liver: 0.6 ppb.
(iii) Kidney: 1.2 ppb.
(iv) Fat: 1.2 ppb.
(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.840, 522.850, 522.1940, 522.2343, 522.2477, and 522.2478 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 87 FR 17947, Mar. 29, 2022]

§ 556.260 Ethopabate.

(a) [Reserved]

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

- (1) *Chickens.* (i) Liver: 1.5 ppm.
- (ii) Kidney: 1.5 ppm.
- (iii) Muscle: 0.5 ppm.

(2) [Reserved]

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

§ 556.273 Famphur.

(a) [Reserved]

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

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

(2) [Reserved]

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

§ 556.275 Fenbendazole.

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

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

(1) *Cattle.* (i) Liver (target tissue): 0.8 ppm fenbendazole (marker residue).

(ii) Milk: 0.22 ppm fenbendazole sulfone (marker residue).

(2) *Chickens.* (i) Liver (target tissue): 5.2 ppm fenbendazole sulfone (marker residue).

(ii) Eggs: 1.8 ppm fenbendazole sulfone (marker residue).

(3) *Goats.* (i) Liver (target tissue): 0.8 ppm fenbendazole (marker residue).

(ii) [Reserved]

(4) *Swine.* (i) Liver (target tissue): 3.2 ppm fenbendazole (marker residue).

(ii) [Reserved]

(5) *Turkeys.* (i) Liver (target tissue): 6 ppm fenbendazole sulfone (marker residue).

(ii) [Reserved]

(6) *Quail.* (i) Liver (target tissue): 6 ppm fenbendazole sulfone (marker residue).

(ii) [Reserved]

(c) *Related conditions of use.* See §§ 520.905a, 520.905b, 520.905c, 520.905d, and 558.258 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 57998, Oct. 20, 2021; 86 FR 61686, Nov. 8, 2021; 89 FR 85428, Oct. 28, 2024]

§ 556.277 Fenprostalene.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of fenprostalene is 0.08 µg/kg of body weight per day.

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

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

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

(c) *Related conditions of use.* See § 522.914 of this chapter.

§ 556.280 Fenthion.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use.* See § 524.920 of this chapter.

§ 556.283 Florfenicol.

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

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

(1) *Cattle.* (i) Liver (target tissue): 3.7 ppm.

(ii) Muscle: 0.3 ppm.

(2) *Swine.* (i) Liver (target tissue): 2.5 ppm.

(ii) Muscle: 0.2 ppm.

(3) *Catfish.* Muscle (target tissue): 1 ppm.

(4) *Freshwater-reared warmwater finfish (other than catfish) and salmonids.* Muscle/skin (target tissue): 1 ppm.

(c) *Related conditions of use.* See §§ 520.955, 522.955, 522.956, and 558.261 of this chapter.

§ 556.286 Flunixin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of flunixin is 0.72 µg/kg of body weight per day.

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

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(1) *Cattle*. (i) Liver (target tissue): 125 ppb flunixin free acid (marker residue).

(ii) Muscle: 25 ppb flunixin free acid.

(iii) Milk: 2 ppb 5-hydroxy flunixin (marker residue).

(2) *Swine*. (i) Liver (target tissue): 30 ppb flunixin free acid (marker residue).

(ii) Muscle: 25 ppb flunixin free acid.

(c) *Related conditions of use*. See §§ 522.956, 522.970, 522.1664, and 524.970 of this chapter.

§ 556.292 Gamithromycin.

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

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

(1) *Cattle*. (i) Liver (target tissue): 500 ppb.

(ii) Muscle: 150 ppb.

(2) [Reserved]

(c) *Related conditions of use*. See § 522.1014 of this chapter.

§ 556.300 Gentamicin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of gentamicin is 60 µg/kg of body weight per day.

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

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

(2) *Swine*. (i) Liver: 0.3 ppm.

(ii) Kidney (target tissue): 0.4 ppm gentamicin (marker residue).

(iii) Fat: 0.4 ppm.

(iv) Muscle: 0.1 ppm.

(c) *Related conditions of use*. See §§ 520.1044a, 520.1044b, 520.1044c, 522.1044, 524.1044e, and 529.1044b of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 13188, Mar. 8, 2021]

§ 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.

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(c) *Related conditions of use*. See §§ 522.1079 and 522.1081 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.308 Halofuginone.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of halofuginone hydrobromide is 0.7 µg/kg of body weight per day.

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

(1) *Chickens*. Liver (target tissue): 0.16 ppm.

(2) *Turkeys*. Liver (target tissue): 0.13 ppm.

(c) *Related conditions of use*. See § 558.265 of this chapter.

§ 556.310 Haloxon.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use*. See §§ 520.1120a and 520.1120b of this chapter.

§ 556.316 Hetacillin.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use*. See § 526.1130 of this chapter.

[84 FR 53311, Oct. 7, 2019]

§ 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 5 µg/kg of body weight per day.

(b) *Tolerances*. The tolerances for 22,23-dihydroavermectin B_{1a} (marker residue) are:

(1) *American bison*. Liver (target tissue): 15 ppb.

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- (2) *Cattle*. (i) Liver (target tissue): 1.6 ppm.
- (ii) Muscle: 650 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.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.345 Ketoprofen.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residue of ketoprofen is 5 µg/kg of body weight per day.
- (b) *Tolerances*. The tolerances for ketoprofen (marker residue) are:
 - (1) *Cattle*. (i) Kidney (target tissue): 0.36 ppm.
 - (ii) [Reserved]
 - (c) *Related conditions of use*. See §§ 522.1225 and 522.2632 of this chapter.

[86 FR 61686, Nov. 8, 2021]

§ 556.346 Laidlomycin.

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

§ 556.347 Lasalocid.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residue of lasalocid is 10 µg/kg of body weight per day.
- (b) *Tolerances*. The tolerances for lasalocid (marker residue) are:
 - (1) *Cattle*. Liver (target tissue): 0.7 ppm.
 - (2) *Chickens*. (i) Skin with adhering fat (target tissue): 1.2 ppm.
 - (ii) Liver: 0.4 ppm.
 - (3) *Rabbits*. Liver (target tissue): 0.7 ppm.
 - (4) *Sheep*. Liver (target tissue): 1.0 ppm.

- (5) *Turkeys*. (i) Liver (target tissue): 0.4 ppm.
- (ii) Skin with adhering fat: 0.4 ppm.
- (c) *Related conditions of use*. See § 558.311 of this chapter.

§ 556.350 Levamisole.

- (a) [Reserved]
- (b) *Tolerances*. The tolerances for levamisole are:
 - (1) *Cattle*. Edible tissues (excluding milk): 0.1 ppm.
 - (2) *Sheep*. Edible tissues (excluding milk): 0.1 ppm.
 - (3) *Swine*. Edible tissues: 0.1 ppm.
 - (c) *Related conditions of use*. See §§ 520.1242a, 520.1242b, 520.1242d, 520.1242e, 520.1242f, 520.1242g, 522.1242, and 524.1240 of this chapter.

§ 556.360 Lincomycin.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residue of lincomycin is 25 µg/kg of body weight per day.
- (b) *Tolerances*. The tolerances for lincomycin are:
 - (1) *Chickens*. Edible tissues (excluding eggs): Not required.
 - (2) *Swine*. (i) Liver: 0.6 ppm.
 - (ii) Muscle: 0.1 ppm.
 - (3) *Honey*. 750 ppb.
 - (c) *Related conditions of use*. See §§ 520.1263b, 522.1260, and 558.325 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

EDITORIAL NOTE: At 86 FR 13188, Mar. 8, 2021, in § 556.360, paragraph (c) was amended; however, the amendment could not be incorporated due to inaccurate amendatory instruction.

§ 556.370 Lubabegron.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residues of lubabegron is 3 micrograms per kilogram of body weight per day.
- (b) *Tolerances*. The tolerances for lubabegron (marker residue) are:
 - (1) *Cattle*. (i) Liver (target tissue): 10 ppb.
 - (ii) Muscle: 3 ppb.
 - (iii) Kidney: 20 ppb.
 - (2) [Reserved]
 - (c) *Related conditions of use*. See § 558.330 of this chapter.

[84 FR 12494, Apr. 2, 2019, as amended at 87 FR 17947, Mar. 29, 2022]

§ 556.375

§ 556.375 Maduramicin.

- (a) [Reserved]
- (b) *Tolerances.* The tolerance for maduramicin (marker residue) is:
 - (1) *Chickens.* Fat (target tissue): 0.38 ppm.
 - (2) [Reserved]
- (c) *Related conditions of use.* See § 558.340 of this chapter.

§ 556.380 Melengestrol.

- (a) [Reserved]
- (b) *Tolerances.* The tolerance for melengestrol is:
 - (1) *Cattle.* Fat: 25 ppb.
 - (2) [Reserved]
- (c) *Related conditions of use.* See § 558.342 of this chapter.

§ 556.410 Metoserpate.

- (a) [Reserved]
- (b) *Tolerances.* The tolerance for metoserpate is:
 - (1) *Chickens.* Edible tissues (excluding eggs): 0.02 ppm.
 - (2) [Reserved]
- (c) *Related conditions of use.* See § 520.1422 of this chapter.

§ 556.420 Monensin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of monensin is 12.5 µg/kg of body weight per day.
- (b) *Tolerances.* The tolerances for monensin are:
 - (1) *Cattle.* (i) Liver: 0.10 ppm.
(ii) Muscle, kidney, and fat: 0.05 ppm.
(iii) Milk: Not required.
 - (2) *Chickens and turkeys.* Edible tissues (excluding eggs): Not required.
 - (3) *Goats.* Edible tissues (excluding milk): 0.05 ppm.
 - (4) *Quail.* Edible tissues (excluding eggs): Not required.
- (c) *Related conditions of use.* See § 558.355 of this chapter.

§ 556.425 Morantel.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of morantel tartrate is 10 µg/kg of body weight per day.
- (b) *Tolerances.* The tolerances for N-methyl-1,3-propanediamine (marker residue) are:
 - (1) *Cattle.* (i) Liver (target tissue): 0.7 ppm.
(ii) Milk: Not required.

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- (2) *Goats.* (i) Liver (target tissue): 0.7 ppm.
(ii) Milk: Not required.
- (c) *Related conditions of use.* See §§ 520.1450a, 520.1450b, 520.1450c, and 558.360 of this chapter.

§ 556.426 Moxidectin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of moxidectin is 4 µg/kg of body weight per day.
- (b) *Tolerances.* The tolerances for moxidectin (marker residue) are:
 - (1) *Cattle.* (i) Fat (target tissue): 900 ppb.
(ii) Liver: 200 ppb.
(iii) Muscle: 50 ppb.
(iv) Milk: 40 ppb.
 - (2) *Sheep.* (i) Fat (target tissue): 900 ppb.
(ii) Liver: 200 ppb.
(iii) Muscle: 50 ppb.
- (c) *Related conditions of use.* See §§ 520.1454, 522.1450, and 524.1450 of this chapter.

§ 556.428 Narasin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of narasin is 5 µg/kg of body weight per day.
- (b) *Tolerances.* The tolerance for narasin (marker residue) is:
 - (1) *Chickens.* Abdominal fat (target tissue): 480 ppb.
 - (2) [Reserved]
- (c) *Related conditions of use.* See §§ 558.363 and 558.364 of this chapter.

§ 556.430 Neomycin.

- (a) *Acceptable daily intake (ADI).* The ADI for total residue of neomycin is 6 µg/kg of body weight per day.
- (b) *Tolerances.* The tolerances for neomycin are:
 - (1) *Cattle.* (i) Kidney (target tissue): 7.2 ppm.
(ii) Liver: 3.6 ppm.
(iii) Muscle: 1.2 ppm.
(iv) Fat: 7.2 ppm.
(v) Milk: 0.15 ppm.
 - (2) *Sheep and goats.* (i) Kidney (target tissue): 7.2 ppm.
(ii) Liver: 3.6 ppm.
(iii) Muscle: 1.2 ppm.
(iv) Fat: 7.2 ppm.
(v) Milk: 0.15 ppm.
 - (3) *Swine.* (i) Kidney (target tissue): 7.2 ppm.
(ii) Liver: 3.6 ppm.

- (iii) Muscle: 1.2 ppm.
- (iv) Fat: 7.2 ppm.
- (4) *Turkeys*. (i) Skin with adhering fat: 7.2 ppm.
- (ii) Liver: 3.6 ppm.
- (iii) Muscle: 1.2 ppm.
- (c) *Related conditions of use*. See §§ 520.1484, 524.1600b, 558.365, and 558.455 of this chapter.

§ 556.445 Nicarbazin.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residues of nicarbazin (4,4'-dinitrocarbanilide and 2-hydroxy-4,6-dimethylpyrimidine) is 200 µg/kg of body weight per day.
- (b) *Tolerances*. The tolerance for 4,4'-dinitrocarbanilide (marker residue) is:
 - (1) *Chickens*. Liver (target tissue): 52 ppm.
 - (2) [Reserved]
 - (c) *Related conditions of use*. See §§ 558.364 and 558.366 of this chapter.

§ 556.460 Novobiocin.

- (a) [Reserved]
- (b) *Tolerances*. The tolerances for novobiocin are:
 - (1) *Cattle*. (i) Edible tissues (excluding milk): 1 ppm.
 - (ii) Milk: 0.1 ppm.
 - (2) *Chickens, turkeys, and ducks*. Edible tissues (excluding eggs): 1 ppm.
 - (c) *Related conditions of use*. See §§ 526.1590, 526.1696d, and 558.415 of this chapter.

§ 556.470 Nystatin.

- (a) [Reserved]
- (b) *Tolerances*. The tolerances for nystatin are:
 - (1) *Cattle*. Edible tissues (excluding milk): Zero.
 - (2) *Chickens and turkeys*. Edible tissues: Zero.
 - (c) *Related conditions of use*. See §§ 524.1600b and 558.430 of this chapter.

§ 556.490 Ormetoprim.

- (a) [Reserved]
- (b) *Tolerances*. The tolerances for ormetoprim are:
 - (1) *Chickens, turkeys, ducks, and chukar partridges*. Edible tissues (excluding eggs): 0.1 ppm.
 - (2) *Salmonids and catfish*. Edible tissues: 0.1 ppm.
 - (c) *Related conditions of use*. See § 558.575 of this chapter.

§ 556.495 Oxfendazole.

- (a) *Acceptable daily intake (ADI)*. The ADI for total residue of oxfendazole is 7 µg/kg of body weight per day.
- (b) *Tolerances*. The tolerance for fenbendazole (marker residue) is:
 - (1) *Cattle*. Liver (target tissue): 0.8 ppm.
 - (2) [Reserved]
 - (c) *Related conditions of use*. See §§ 520.1629 and 520.1630 of this chapter.

§ 556.500 Oxytetracycline.

- (a) *Acceptable daily intake (ADI)*. The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 µg/kg of body weight per day.
- (b) *Tolerances*. The tolerances for the sum of tetracycline residues are:
 - (1) *Cattle*. (i) Muscle: 2 ppm.
 - (ii) Liver: 6 ppm.
 - (iii) Fat and kidney: 12 ppm.
 - (iv) Milk: 0.3 ppm.
 - (2) *Chickens and turkeys*. (i) Muscle: 2 ppm.
 - (ii) Liver: 6 ppm.
 - (iii) Fat and kidney: 12 ppm.
 - (3) *Finfish*. Muscle (with adhering skin when edible): 2 ppm.
 - (4) *Lobster*. Muscle: 2 ppm.
 - (5) *Swine and sheep*. (i) Muscle: 2 ppm.
 - (ii) Liver: 6 ppm.
 - (iii) Fat and kidney: 12 ppm.
 - (6) *Honey*. 750 ppb.
 - (c) *Related conditions of use*. See §§ 520.1660c, 520.1660d, 520.1664, 522.1660a, 522.1660b, 522.1662, 522.1664, 529.1660, 558.450, and 558.455 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020; 88 FR 16549, Mar. 20, 2023, 88 FR 55567, Aug. 16, 2023]

§ 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.

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(c) *Related conditions of use.* See §§ 520.1696a, 522.1696a, 522.1696b, 526.1696, 526.1697, and 526.1698 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020; 86 FR 13188, Mar. 8, 2021]

§ 556.515 Pirlimycin.

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

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

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

(ii) Muscle: 0.3 ppm.

(iii) Milk: 0.4 ppm.

(2) [Reserved]

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

§ 556.517 Poloxalene.

(a) [Reserved]

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

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

(2) [Reserved]

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

[84 FR 32993, July 11, 2019, as amended at 86 FR 14821, Mar. 19, 2021]

§ 556.530 Pradofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of pradofloxacin is 2 µg/kg of body weight per day.

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

(1) *Cattle.* Kidney (target tissue): 30 ppb.

(2) *Swine.* Kidney (target tissue): 1 ppm.

(c) *Related conditions of use.* See § 522.1860 of this chapter.

[89 FR 85428, Oct. 28, 2024]

§ 556.540 Progesterone.

(a) [Reserved]

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

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

(ii) Liver: 15 ppb.

(iii) Kidney: 30 ppb.

(iv) Fat: 30 ppb.

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(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.

§ 556.625 Sulfachloropyrazine.

(a) [Reserved]

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

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

(2) [Reserved]

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

§ 556.630 Sulfachlorpyridazine.

(a) [Reserved]

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

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

(2) [Reserved]

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

§ 556.640 Sulfadimethoxine.

(a) [Reserved]

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

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

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

(ii) Milk: 0.01 ppm.

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

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

§ 556.650 Sulfaethoxyppyridazine.

(a) [Reserved]

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

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

(ii) Milk: Zero.

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

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

§ 556.660 Sulfamerazine.

(a) [Reserved]

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

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

(2) [Reserved]

(c) *Related conditions of use*. See §§ 520.2218 and 558.582 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 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 §§ 520.445, 520.2218, 520.2260a, 520.2260b,

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520.2260c, 520.2261a, 520.2261b, 522.2260, 558.140, and 558.630 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020; 86 FR 13188, Mar. 8, 2021]

§ 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 §§ 520.2218, 520.2325a, 520.2325b, and 558.586 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.700 Sulfomyxin.

(a) [Reserved]

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

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

(2) [Reserved]

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

§ 556.710 Testosterone.

(a) [Reserved]

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

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

(ii) Kidney: 1.9 ppb.

(iii) Liver: 1.3 ppb.

(iv) Muscle: 0.64 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 522.2343 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 87 FR 10970, Feb. 28, 2022]

§ 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.

§ 556.732 Tiamulin.

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

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

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

(2) [Reserved]

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

§ 556.733 Tildipirosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of tildipirosin is 50 µg/kg of body weight per day.

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

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

(ii) [Reserved]

(2) [Reserved]

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

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.735 Tilmicosin.

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

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

(1) *Cattle.* (i) Liver (target tissue): 1.2 ppm.

(ii) Muscle: 0.1 ppm.

(2) *Sheep.* (i) Liver (target tissue): 1.2 ppm.

(ii) Muscle: 0.1 ppm.

(3) *Swine.* (i) Liver (target tissue): 7.5 ppm.

(ii) Muscle: 0.1 ppm.

(c) *Related conditions of use.* See §§ 520.2471, 522.2471, and 558.618 of this chapter.

§ 556.739 Trenbolone.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of trenbolone is 0.4 µg/kg of body weight per day.

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

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

(2) [Reserved]

(c) *Related conditions of use*. See §§ 522.2476, 522.2477, and 522.2478 of this chapter.

§ 556.741 Tripeleminamine.

(a) [Reserved]

(b) *Tolerances*. The tolerances for tripeleminamine 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 and 522.2632 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 86 FR 61686, Nov. 8, 2021]

§ 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.

(4) *Honey*. 500 ppb.

(c) *Related conditions of use*. See §§ 520.2640, 522.2640, 558.625, and 558.630 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.748 Tylvalosin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of tylvalosin is 47.7 µg/kg of body weight per day.

(b) *Tolerances*. A tolerance for tylvalosin in edible tissues of swine is not required.

(c) *Related conditions of use*. See §§ 520.2645 and 558.633 of this chapter.

§ 556.750 Virginiamycin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of virginiamycin is 250 µg/kg of body weight per day.

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

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

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

(3) *Swine*. (i) Kidney, skin, and fat: 0.4 ppm.

(ii) Liver: 0.3 ppm.

(iii) Muscle: 0.1 ppm.

(c) *Related conditions of use*. See § 558.635 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.760 Zeranol.

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

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

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

(2) *Sheep*. Edible tissues (excluding milk): 20 ppb.

(c) *Related conditions of use*. See § 522.2680 of this chapter.

§ 556.765 Zilpaterol.

(a) *Acceptable daily intake (ADI)*. The ADI for total residue of zilpaterol is 0.083 µg/kg of body weight per day.

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

(1) *Cattle*. (i) Liver (target tissue): 12 ppb.

(ii) Muscle: 10 ppb.

(2) [Reserved]

(c) *Related conditions of use*. See § 558.665 of this chapter.

[84 FR 32993, July 11, 2019, as amended at 85 FR 18121, Apr. 1, 2020]

§ 556.770

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§ 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.

- 558.360 Morantel.
- 558.363 Narasin.
- 558.364 Narasin and nicarbazin.
- 558.365 Neomycin sulfate.
- 558.366 Nicarbazin.
- 558.415 Novobiocin.
- 558.430 Nystatin.
- 558.450 Oxytetracycline.
- 558.455 Oxytetracycline and neomycin.
- 558.464 Poloxalene.
- 558.470 Polyoxyethylene.
- 558.485 Pyrantel.
- 558.500 Ractopamine.
- 558.515 Robenidine.
- 558.550 Salinomycin.
- 558.555 Semduramicin.
- 558.575 Sulfadimethoxine and ormetoprim.
- 558.582 Sulfamerazine.
- 558.586 Sulfaquinoxaline.
- 558.612 Tiamulin.
- 558.618 Tilmicosin.
- 558.625 Tylosin.
- 558.630 Tylosin and sulfamethazine.
- 558.633 Tylvalosin.
- 558.635 Virginiamycin.
- 558.665 Zilpaterol.
- 558.680 Zoalene.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Subpart A—General Provisions

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Subpart B—Specific New Animal Drugs For Use in Animal Feeds

- 558.55 Amprolium.
- 558.58 Amprolium and ethopabate.
- 558.59 Apramycin.
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- 558.128 Chlortetracycline.
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- 558.175 Clopidol.
- 558.185 Coumaphos.
- 558.195 Decoquinolate.
- 558.198 Dichlorvos.
- 558.205 Diclazuril.
- 558.235 Efrotomycin.
- 558.248 Erythromycin.
- 558.254 Famphur.
- 558.258 Fenbendazole.
- 558.261 Florfenicol.
- 558.265 Halofuginone hydrobromide.
- 558.274 Hygromycin B.
- 558.295 Iodinated casein.
- 558.300 Ivermectin.
- 558.305 Laidlomycin.
- 558.311 Lasalocid.
- 558.325 Lincomycin.
- 558.330 Lubabegron.
- 558.340 Maduramicin.
- 558.342 Melengestrol.
- 558.348 Mibolerone.
- 558.355 Monensin.

AUTHORITY: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each major species for which they are approved or are approved for use only in minor species.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one major species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of carcinogenic