

§ 530.30

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 prohibi-

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tion 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 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) Iprnidazole;
- (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.

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

[62 FR 27947, May 22, 1997, as amended at 67 FR 5471, Feb. 6, 2002]

EFFECTIVE DATE NOTES: 1. At 68 FR 9530, Feb. 28, 2003, § 530.41 was amended by adding paragraph (a)(12), effective May 29, 2003. For the convenience of the user, the added text is set forth as follows:

§ 530.41 Drugs prohibited for extralabel use in animals.

- (a) * * *
- (12) Phenylbutazone.

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2. At 68 FR 14134, Mar. 24, 2003, § 530.41 was corrected on page 9530, in the first column, in paragraph (a)(12), “Phenylbutazone.” was corrected to read “Phenylbutazone in female dairy cattle 20 months of age or older.”, effective May 29, 2003.

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

Subpart A—General Provisions

Sec.
556.1 General considerations; tolerances for residues of new animal drugs in food.

Subpart B—Specific Tolerances for Residues of New Animal Drugs

- 556.20 2-Acetyl-amino-5-nitrothiazole.
- 556.30 Aklomide.
- 556.34 Albendazole.
- 556.38 Amoxicillin.
- 556.40 Ampicillin.

- 556.50 Amprolium.
- 556.52 Apramycin.
- 556.60 Arsenic.
- 556.70 Bacitracin.
- 556.90 Buquinolate.
- 556.100 Carbadox.
- 556.110 Carbomycin.
- 556.113 Ceftiofur.
- 556.115 Cephapirin.
- 556.120 Chlorhexidine.
- 556.140 Chlorobutanol.
- 556.150 Chlortetracycline.
- 556.160 Clopidol.
- 556.163 Clorsulon.
- 556.165 Cloxacillin.
- 556.167 Colistimethate.
- 556.169 Danofloxacin.
- 556.170 Decoquinolate.
- 556.180 Dichlorvos.
- 556.185 Diclazuril.
- 556.200 Dihydrostreptomycin.
- 556.220 3,5-Dinitrobenzamide.
- 556.225 Doramectin.
- 556.227 Eprinomectin.
- 556.228 Enrofloxacin.
- 556.230 Erythromycin.
- 556.240 Estradiol and related esters.
- 556.260 Ethopabate.
- 556.270 Ethylenediamine.
- 556.273 Famphur.
- 556.275 Fenbendazole.
- 556.277 Fenprostalene.
- 556.283 Florfenicol.
- 556.286 Flunixin meglumine.
- 556.290 Furazolidone.
- 556.300 Gentamicin sulfate.
- 556.304 Gonadotropin.
- 556.308 Halofuginone hydrobromide.
- 556.310 Haloxon.
- 556.320 Hydrocortisone.
- 556.330 Hygromycin B.
- 556.344 Ivermectin.
- 556.347 Lasalocid.
- 556.350 Levamisole hydrochloride.
- 556.360 Lincomycin.
- 556.375 Maduramicin ammonium.
- 556.380 Melengestrol acetate.
- 556.390 Methylparaben.
- 556.400 Methylprednisolone.
- 556.410 Metoserpate hydrochloride.
- 556.420 Monensin.
- 556.425 Morantel tartrate.
- 556.426 Moxidectin.
- 556.428 Narasin.
- 556.430 Neomycin.
- 556.440 Nequinolate.
- 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.
- 556.520 Prednisolone.