

to the objections and is denying the requests for a hearing. In addition, FWW's request for a stay of the effectiveness of the August 18, 2006, regulation until a hearing is held is moot because FDA is denying the hearing request. FDA is confirming August 18, 2006, as the effective date of the regulation.

## VI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. "Evaluating the Safety of Food Chemicals," National Research Council, National Academy of Sciences, Washington DC, p. 55.

2. Jacobs, T., A. Darji, N. Frahm, et al., "Listeriolysin O: Cholesterol Inhibits Cytolysis But Not Binding to Cellular Membranes," *Molecular Microbiology*, 28:1081-1089, 1998.

3. U.S. Department of Agriculture Nutritive Value of Foods, Home and Garden Bulletin Number 72, USDA, Agricultural Research Service.

4. Guyton, A.C., J.E. Hall, *Textbook of Medical Physiology* (9th ed.) Philadelphia: W.B. Saunders Co., p. 817, 1996.

Dated: March 17, 2011.

**Leslie Kux,**

Acting Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 556

[Docket No. FDA-2011-N-0003]

#### Tolerances for Residues of New Animal Drugs in Food; 2-Acetylamino-5-Nitrothiazole; Buquinolate; Chlorobutanol; Estradiol and Related Esters; Ethylenediamine; Florfenicol; Flunixin; Furazolidone; Hydrocortisone; Methylparaben; Methylprednisolone; Prednisolone; Prednisone; Progesterone; Propylparaben; and Salicylic Acid

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correcting amendments.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the revocation of tolerances for residues of

various substances in food because approval has been withdrawn for the underlying food additive petitions (FAPs) or new animal drug applications (NADAs). This action is being taken to improve the accuracy of the regulations.

**DATES:** This rule is effective March 23, 2011.

#### FOR FURTHER INFORMATION CONTACT:

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**SUPPLEMENTARY INFORMATION:** Section 512(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(i)) (21 CFR 514.105(a)) directs FDA to establish tolerances by regulation, as necessary, when a new animal drug is approved for use in food-producing animals. However, section 512(i) of the FD&C Act (21 CFR 514.115(e)) also obligates FDA to revoke such tolerance regulations upon the withdrawal of approval of the related NADA.

FDA has noticed that the animal drug regulations contain tolerances for residues of substances in food that were established by approval of FAPs for animal drug products prior to the Animal Drug Amendments of 1968 or by NADA for which an underlying application for use in a food-producing species is not currently approved. Following codification of the tolerance, the underlying FAP may have been withdrawn, or an NADA for the same drug product was not filed or was withdrawn, either voluntarily or for cause. When regulations for these products were removed or omitted from various redesignation rules, the appropriate conforming amendments to remove the revoked tolerances from part 556 (21 CFR part 556) were not made. The following chemical substances and new animal drugs have codified tolerances for which FDA finds no applications with corresponding approved conditions of use in food-producing animals:

1. *2-Acetylamino-5-nitrothiazole* (§ 556.20). In 1979, FDA acknowledged the voluntary withdrawal of approval of NADA 9-424 for use of 2-acetylamino-5-nitrothiazole for use in turkey feed and revoked 21 CFR 558.25 (44 FR 40888, July 13, 1979), but did not amend part 556 to remove the associated tolerances.

2. *Chlorobutanol* (§ 556.140). In 1963, FDA established a tolerance for chlorobutanol in milk of dairy animals at § 121.1131 (21 CFR 121.1131) incidental to the approval of an FAP for a combination drug, antibiotic/steroid intramammary infusion (28 FR 4948,

May 17, 1963). Section 121.1131 was redesignated as 21 CFR 135g.31 (35 FR 15372 at 15376, October 2, 1970) and as § 556.140 (40 FR 13802 at 13947, March 27, 1975).

3. *Estradiol and progesterone in edible tissues of lambs* (§§ 556.240 and 556.540). In 1973, FDA acknowledged the voluntary withdrawal of approval of a subcutaneous implant for use in lambs containing estradiol benzoate and progesterone under NADA 9-442 (38 FR 7481, March 22, 1973). Subsequently, FDA removed the approved conditions of use in 21 CFR 522.1940 (44 FR 6707 at 6708, February 2, 1979), but did not amend part 556 to remove the associated tolerances in uncooked edible tissues of lambs.

4. *Ethylenediamine* (§ 556.270). In 1965, FDA established a tolerance for ethylenediamine in milk of dairy animals at § 121.1184 (21 CFR 121.1184) incidental to the approval of an FAP for a combination drug, antibiotic intramammary infusion (30 FR 11952 at 11954, September 18, 1965). Section 121.1184 was redesignated as 21 CFR 135g.48 (35 FR 15372 at 15378) and as § 556.270 (40 FR 13802 at 13950).

5. *Furazolidone* (§ 556.290). In 1963, FDA established a tolerance for furazolidone in uncooked edible tissues of swine at § 121.2582 (21 CFR 121.2582) incidental to the approval of an FAP for use in medicated swine feed (28 FR 12664 at 12665, November 28, 1963). Section 121.2582 was redesignated as 21 CFR 121.1145 (30 FR 15845 at 15917, December 23, 1965), as 21 CFR 135g.36 (35 FR 15372 at 15376), and as § 556.290 (40 FR 13802 at 13950). In 1971, FDA proposed to withdraw approval of NADAs for use of furazolidone in food-producing animals on grounds that the drug, when administered to laboratory animals, was shown to produce tumors (36 FR 5927, March 31, 1971) and in 1991 withdrew approval after a full evidentiary hearing (56 FR 41902, August 23, 1991). Currently, there is no approved application for use of furazolidone in a food-producing species. A 1996 order codified a prohibition of extralabel use of furazolidone in food-producing animals (61 FR 57732 at 57743, November 7, 1996 as amended 67 FR 5470 at 5471, February 6, 2002). See 21 CFR 530.41(a)(7).

6. *Hydrocortisone* (§ 556.320). In 1970, FDA established a tolerance for hydrocortisone in milk of dairy animals at § 135g.3 (21 CFR 135g.3) incidental to the approval of an FAP for a combination drug, antibiotic/steroid intramammary infusion (35 FR 12332 at 12333, August 1, 1970). Section 135g.3

was redesignated as § 556.320 (40 FR 13802 at 13950).

7. *Methylparaben* (§ 556.390). In 1964, FDA established a tolerance for methylparaben in milk of dairy animals at § 121.1158 (21 CFR 121.1158) incidental to the approval of an FAP for a combination drug, antibiotic intramammary infusion (29 FR 14624, October 27, 1964). Section 121.1158 was redesignated as 21 CFR 135g.41 (35 FR 15372 at 15376) and as § 556.390 (40 FR 13802 at 13956).

8. *Methylprednisolone* (§ 556.400). In 1970, FDA established a tolerance for methylprednisolone in milk of dairy animals at § 135g.67 (21 CFR 135g.67) incidental to the approval of an FAP for a combination drug, antibiotic/steroid intramammary infusion (35 FR 12332 at 12333). Section 135g.67 was redesignated as § 556.400 (40 FR 13802 at 13956).

9. *Prednisolone* (§ 556.520). In 1964, FDA established a tolerance for prednisolone in milk of dairy animals at § 121.1147 (21 CFR 121.1147) incidental to the approval of an FAP for a combination drug, antibiotic intramammary infusion (29 FR 3393, March 14, 1964). Section 121.1147 was redesignated as 21 CFR 135g.37 (35 FR 15372 at 15376) and as § 556.520 (40 FR 13802 at 13956).

10. *Prednisone* (§ 556.530). In 1964, FDA established a tolerance for prednisone in milk of dairy animals at § 121.1157 (21 CFR 121.1157) incidental to the approval of an FAP for a combination drug, antibiotic intramammary infusion (29 FR 14624). Section 121.1157 was redesignated as 21 CFR 135g.40 (35 FR 15372 at 15376) and as § 556.530 (40 FR 13802 at 13956).

11. *Propylparaben* (§ 556.550). In 1964, FDA established a tolerance for propylparaben in milk of dairy animals at § 121.1159 incidental to the approval of an FAP for a combination drug, antibiotic intramammary infusion (29 FR 14624). Section 121.1159 was redesignated as 21 CFR 135g.42 (35 FR 15372 at 15376) and as § 556.550 (40 FR 13802 at 13956).

12. *Salicylic acid* (§ 556.590). In 2005, FDA acknowledged the voluntary withdrawal of approval of salicylic acid for use in cattle under NADA 010-481 and revoked 21 CFR 529.2090 (70 FR 50181, August 26, 2005), but did not remove the associated tolerance.

At this time, FDA is revoking the tolerances for 2-acetyl-amino-5-nitrothiazole, buquinolate, chlorobutanol, estradiol in lamb, ethylenediamine, furazolidone, hydrocortisone, methylparaben, methylprednisolone, prednisolone, prednisone, progesterone in lamb,

propylparaben, and salicylic acid. Accordingly, §§ 556.20, 556.140, 556.270, 556.290, 556.320, 556.390, 556.400, 556.520, 556.530, 556.550, and 556.590 are being removed, and §§ 556.240 and 556.540 are being amended to reflect the revoked tolerances.

Also, FDA is amending the animal drug regulations in §§ 556.283 and 556.286 to cross reference an approved combination drug injectable solution containing florfenicol and flunixin (75 FR 1274, January 11, 2010). FDA is further amending § 556.286 to reflect the marker residue in milk for residues of flunixin meglumine. This action is being taken to comply with section 512(i) of the FD&C Act and to improve the accuracy of the regulations.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

#### List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 556 is amended as follows:

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

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

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

§ 556.20 [Removed]

■ 2. Remove § 556.20.

§ 556.140 [Removed]

■ 3. Remove § 556.140.

§ 556.240 [Amended]

■ 4. In § 556.240, remove and reserve paragraph (b).

§ 556.270 [Removed]

■ 5. Remove § 556.270.

■ 6. Revise § 556.283 to read as follows:

§ 556.283 **Florfenicol.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of florfenicol is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for florfenicol amine (the marker residue) is 3.7 parts per million (ppm).

(ii) *Muscle*. The tolerance for florfenicol amine (the marker residue) is 0.3 ppm.

(2) *Swine*—(i) *Liver (the target tissue)*. The tolerance for parent florfenicol (the marker residue) is 2.5 ppm.

(ii) *Muscle*. The tolerance for parent florfenicol (the marker residue) is 0.2 ppm.

(3) *Catfish*. The tolerance for florfenicol amine (the marker residue) in muscle (the target tissue) is 1 ppm.

(4) *Salmonids*. The tolerance for florfenicol amine (the marker residue) in muscle/skin (the target tissues) is 1 ppm.

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

■ 7. In § 556.286, revise paragraphs (b)(1)(iii) and (c) to read as follows:

§ 556.286 **Flunixin.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

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

\* \* \* \* \*

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

§ 556.290 [Removed]

■ 8. Remove § 556.290.

§ 556.320 [Removed]

■ 9. Remove § 556.320.

§ 556.390 [Removed]

■ 10. Remove § 556.390.

§ 556.400 [Removed]

■ 11. Remove § 556.400.

§ 556.520 [Removed]

■ 12. Remove § 556.520.

§ 556.530 [Removed]

■ 13. Remove § 556.530.

§ 556.540 [Amended]

■ 14. In § 556.540, remove and reserve paragraph (b).

§ 556.550 [Removed]

■ 15. Remove § 556.550.

§ 556.590 [Removed]

■ 16. Remove § 556.590.

Dated: March 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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