DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

Animal Drugs, Feeds, and Related Products; Trichlorfon, etc.; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions that reflect approval of 11 new animal drug applications (NADAs) listed below. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADAs.

DATES: This rule is effective May 21, 2001.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5593.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the NADAs listed below because the products are no longer manufactured or marketed:

Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166–6812.	NADA 48–915 Purina® Bot Control (trichlorfon)	520.2520a (017800)
Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334.	NADA 97–567 Tylan® 10 Premix (tylosin phosphate).	558.625(b)(17) (021780)
.....	NADA 97–615 Swine Med-A-Mix TS 8000 Premix, Tylan® 5, 10, 20, 40 Sulfa-G (tylosin phosphate and sulfamethazine).	558.630(b)(4) and (b)(10) (021780)
Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318–1093.	NADA 110–440 Hygromix Hygrowormer Hyanthelmix (hygromycin B).	558.274(a)(2), (a)(3), (a)(4), (c)(1)(i), and (c)(1)(ii) (016968)
Steris Laboratories Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705.	NADA 45–578 Lidocaine Hydrochloride With Epinephrine Injection 2%.	522.1258 (000402)
.....	NADA 44–585 Oxytocin Injection	522.1680 (000402)
.....	NADA 45–737 Sodium Pentobarbital Injection	522.1704(b) (000402)
.....	NADA 45–848 Phenylbutazone Injection	522.1720 (000402)
.....	NADA 110–349 Dexamethasone Injection	522.540(c)(2) (000402)
.....	NADA 110–350 Dexamethasone Injection	522.540(b)(2)(ii) (000402)
.....	NADA 117–973 Prednisolone Sodium Succinate for Injection.	522.1884(c) (000402)

Following the withdrawal of approval of these NADAs, Golden Sun Feeds, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove entries for the sponsor.

Steris Laboratories currently has another approved application for dexamethasone injection (NADA 104–606). Therefore, the regulation is not amended to reflect the withdrawal of approval of NADA 110–349 (dexamethasone injection).

Steris Laboratories NADA 44–585 oxytocin injection is not codified under 21 CFR 522.1680 oxytocin injection. Also, Steris Laboratories NADA 45–848 phenylbutazone injection is not codified under 21 CFR 522.1720 phenylbutazone injection. Therefore, amendments of the cited regulations are not required.

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

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

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry ''Golden Sun Feeds, Inc.'', and in the table in paragraph (c)(2) by removing the entry ''021780''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.2520a [Removed]

4. Section 520.2520a *Trichlorfon oral* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1258 [Removed]

6. Section 522.1258 *Lidocaine injection with epinephrine* is removed.

§ 522.1704 [Amended]

7. Section 522.1704 *Sodium pentobarbital injection* is amended by removing and reserving paragraph (b).

§ 522.1884 [Amended]

8. Section 522.1884 *Prednisolone sodium succinate injection* is amended by removing the second sentence of

paragraph (c) and by removing paragraph (d)(2)(iv).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.274 [Amended]

10. Section 558.274 *Hygromycin B* is amended as follows:

a. In paragraph (a)(2) by removing ''016968 and'';

b. By removing and reserving paragraph (a)(3);

c. In paragraph (a)(4) by removing ''016968,'';

d. In the table in paragraph (c)(1) in the fifth column of the first entry in items (i) and (ii) by removing ''016968,''.

§ 558.625 [Amended]

11. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(17).

§ 558.630 [Amended]

12. Section 558.630 *Tylosin and sulfamethazine* is amended by removing and reserving paragraph (b)(4), and in paragraph (b)(10) by removing ''021780,''.

Dated: May 2, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–11621 Filed 5–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Narasin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health which provides for establishing a tolerance for residues of narasin in edible tissues of chickens.

DATES: This regulation is effective May 9, 2001.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 118–980 that provides for the use of Monteban® (36, 45, 54, 72, or 90 grams per pound narasin activity), a Type A medicated article. The supplement provides for establishing a tolerance for residues of narasin in the abdominal fat of chickens. The supplement is approved as of April 11, 2001, and 21 CFR 556.428 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA is taking the opportunity to codify the acceptable daily intake for total residues of narasin which was previously established.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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.

2. Section 556.428 is revised to read as follows:

§ 556.428 Narasin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of narasin is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Chickens* (*abdominal fat*). The tolerance for parent narasin (the marker residue) is 480 parts per billion.

(2) [Reserved]

Dated: May 1, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 01–11584 Filed 5–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF 452]

RIN 1512–AA07

River Junction Viticultural Area (98R–192P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule, Treasury Decision.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is establishing a viticultural area located in southern San Joaquin County, California, to be known as ''River Junction.'' This viticultural area is the result of a petition filed by Mr. Ronald W. McManis. ATF believes that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising allow wineries to designate the specific areas where the grapes used to make the wine were grown and enable consumers to better identify the wines they purchase.

EFFECTIVE DATE: July 9, 2001.

FOR FURTHER INFORMATION CONTACT: Tim DeVanney, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226; Telephone (202) 927–8196.

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF–53 (43 FR 37672, 54624) revising regulations in 27 CFR part 4. These regulations allow the establishment of definite American viticultural areas (AVAs). The regulations also allow the name of an