

“codex” and are written or painted on animal skins (cattle, sheep/goat, camel) known as parchment.

I. Painting

1. *Wall paintings*—On various kinds of plaster and which generally portray religious images and scenes of Biblical events. Surrounding paintings may contain animal, floral, or geometric designs, including borders and bands.

2. *Panel Paintings (Icons)*—Smaller versions of the scenes on wall paintings, and may be partially covered with gold or silver, sometimes encrusted with semi-precious or precious stones and are usually painted on a wooden panel, often for inclusion in a wooden screen (iconostasis). May also be painted on ceramic.

J. *Mosaics*—Wall mosaics generally portray religious images and scenes of Biblical events.

Surrounding panels may contain animal, floral, or geometric designs. They are made from stone and glass cut into small bits (tesserae) and laid into a plaster matrix.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

Because this rule involves a foreign affairs function of the United States, it is not subject to Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR Part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *
Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;
* * * * *

■ 2. In § 12.104g, paragraph (a), the table is amended by adding the Republic of Bulgaria to the list in appropriate alphabetical order as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
Bulgaria	Archaeological material representing Bulgaria's cultural heritage from Neolithic period (7500 B.C.) through approximately 1750 A. D. and ecclesiastical ethnological material representing Bulgaria's Middle Ages (681 A. D.) through approximately 1750 A. D.	CBP Dec. 14-01
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Thomas S. Winkowski,
Acting Commissioner, U.S. Customs and
Border Protection.

Approved: January 8, 2014.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.
[FR Doc. 2014-00615 Filed 1-15-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Argent Laboratories; Formalin; Tricaine Methanesulfonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of two new animal drug applications (NADAs) held by Argent Laboratories. Withdrawal of approval of these NADAs was at the sponsor's request because the products

are no longer manufactured or marketed.

DATES: This final rule is effective January 27, 2014.

FOR FURTHER INFORMATION CONTACT:

David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843 david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052 has requested that FDA withdraw approval of the following two NADAs because the products are no longer manufactured or marketed: NADA 042-427 for FINQUEL (tricaine methanesulfonate) and NADA 140-831 for PARACIDE-F (formalin).

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 042-427 and 140-831, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the

animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Argent Laboratories will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for this firm.

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 Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 529 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. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Argent Laboratories”; and in the table in paragraph (c)(2), remove the entry for “051212”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

- 4. In § 529.1030:
 - a. Revise paragraph (b);
 - b. Remove paragraphs (d)(1)(i) and (d)(1)(ii), and redesignate paragraphs (d)(1)(iii), (d)(1)(iv), and (d)(1)(v) as paragraphs (d)(1)(i), (d)(1)(ii), and (d)(1)(iii);
 - c. Remove paragraphs (d)(2)(i) and (d)(2)(ii), and redesignate paragraphs (d)(2)(iii), (d)(2)(iv), and (d)(2)(v) as paragraphs (d)(2)(i), (d)(2)(ii), and (d)(2)(iii); and
 - d. Revise the introductory text in newly designated paragraph (d)(2)(ii), and revise paragraph (d)(2)(iii).

The revisions read as follows:

§ 529.1030 Formalin.

* * * * *

(b) **Sponsors.** See Nos. 049968, 050378, and 067188 in § 510.600(c) of this chapter.

* * * * *

(d) * * *

(2) * * *

(ii) For control of external parasites on finfish:

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(iii) For control of fungi of the family Saprolegniaceae on finfish eggs: Eggs of all finfish except Acipenseriformes, 1,000 to 2,000 µL/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 µL/L (ppm) for 15 minutes.

* * * * *

- 5. Revise § 529.2503 to read as follows:

§ 529.2503 Tricaine methanesulfonate.

(a) **Specifications.** Ethyl-m-aminobenzoate methanesulfonate.

(b) **Sponsor.** See No. 050378 in § 510.600(c) of this chapter.

(c) **Conditions of use.** It is used as follows:

(1) **Amount**—(i) For fish the drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) For amphibians and other aquatic coldblooded 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.** It is used 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 should exceed 10 °C. (50 °F). In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use.

Dated: January 10, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Argent Laboratories; Formalin; Tricaine Methanesulfonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) held by Argent Laboratories. Withdrawal of approval of these NADAs was at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective January 27, 2014.

FOR FURTHER INFORMATION CONTACT:

David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843, david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052 has requested that FDA withdraw approval of the following two NADAs because the products are no longer manufactured or marketed: NADA 042-427 for FINQUEL (tricaine methanesulfonate) and NADA 140-831 for PARACIDE-F (formalin).

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 042-427 and 140-831, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.