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:

* * * * *

(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*-amino-benzoate 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.

[FR Doc. 2014–00721 Filed 1–15–14; 8:45 am]

BILLING CODE 4160–01–P

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.

Dated: January 9, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–00722 Filed 1–15–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R07–OAR–2013–0483; FRL–9905–9905–21–Region 7]

Approval and Promulgation of Implementation Plans and Title V Operating Permit Program; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to the State Implementation Plan (SIP) for the state of Iowa. These revisions amend the Iowa air quality rules to eliminate state-only emissions testing procedures and adopt Federal methods; to reduce notification time for portable plant relocations, and allow electronic submittals of notifications; to update air quality definitions to be consistent with federal definitions, and to place into rule the specific procedures for conducting emissions testing.

EPA is also approving revisions to the Iowa Title V Operating Permits Program to revise the definition of ''EPA Reference Method,'' and to adopt by reference the revised Title V Periodic Monitoring Guidance.

DATES: This direct final rule will be effective March 17, 2014, without further notice, unless EPA receives adverse comment by February 18, 2014, If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2013–0483, by one of the following methods:

1. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. *Email: Algoe-eakin.amy@epa.gov.*

3. *Mail or Hand Delivery:* Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2013–0483. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov* or email information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. The Regional Office's official hours of business are Monday through Friday, 8:00 to 4:30 excluding legal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7942, or by email at *Algoe-eakin.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. What is being addressed in this document?

The Iowa Department of Natural Resources (IDNR) is requesting EPA action on including revisions to the Iowa State Implementation Plan (SIP) and the Iowa Title V Program. IDNR has requested the SIP be amended to include revisions made to Chapter 20 ''Scope of Title- Definitions- Forms-Rules of Practice,'' Chapter 22, ''Controlling Pollution,'' and Chapter 25 ''Measurement of Emissions'' in the Iowa Administrative Code. The purpose of the rules is to provide consistency between the state and Federal regulations.

II. Have the requirements for approval of a SIP and Title V revision been met?

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V and the Title V Operating program.

III. What action is EPA taking?

EPA is taking direct final action to approve SIP revisions to amend the Iowa air quality rules, to eliminate state-only emissions testing procedures and adopt Federal methods; to reduce notification time for portable plant relocations, and allow electronic submittals of notifications; to update air quality definitions to be consistent with federal definitions, and to place into rule the specific procedures for conducting emissions testing.

EPA is also taking direct final action to approve the Iowa Title V Operating Permits Program to revise the definition of ''EPA Reference Method,'' and to adopt by reference the revised Title V Periodic Monitoring Guidance. EPA received the request from the State to adopt revisions to the local air agency rules into the SIP on November 26, 2012. The revisions were adopted by the Iowa Environmental Protection Commission on August 21, 2012, and became effective on October 24, 2012.

EPA is taking direct final action to approve the following: (1) Amending the definitions to rule 567–20.2(455B) include revisions to the definitions of ''EPA reference method'', particulate