

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

**PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE:**

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155.

**§ 14.100 [Amended]**

■ 2. Section 14.100 is amended by removing paragraph (f) and redesignating paragraph (g) as paragraph (f).

Dated: November 14, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013–27854 Filed 11–21–13; 8:45 am]

**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 123**

[Docket No. FDA–2013–D–0269]

**Guidance for Industry on Purchasing Reef Fish Species Associated With the Hazard of Ciguatera Fish Poisoning; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning.” The document provides guidance to primary seafood processors who purchase reef fish on how to minimize the risk of ciguatera fish poisoning (CFP) from fish that they distribute. The guidance intends to help protect the public health by reducing the risk of CFP.

**DATES:** Submit either electronic or written comments on FDA guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to Division of Seafood Safety/Office of Food Safety,

Center for Food Safety and Applied Nutrition, (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Karen Swajian, Division of Seafood Safety, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2300.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

We are announcing the availability of a guidance for industry entitled “Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning.” This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of March 26, 2013 (78 FR 18273), FDA made available a draft guidance entitled “Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning” and gave interested parties an opportunity to submit comments by May 28, 2013, for us to consider before beginning work on the final version of the guidance. We received three comments on the draft guidance, but the comments did not prompt us to revise the guidance. Therefore, we are issuing the guidance with minor changes (revising dates mentioned in the guidance to reflect the most current information). The guidance announced in this notice finalizes the draft guidance dated March 2013.

**II. Comments**

Interested persons may submit either electronic comments regarding the guidance to <http://www.regulations.gov> or written comments to the Division of

Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

**III. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 15, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–27913 Filed 11–21–13; 8:45 am]

**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

[Docket No. FDA–2013–N–0002]

**Withdrawal of Approval of New Animal Drug Applications; Carbarsone; Roxarsone**

**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 approval of three new animal drug applications (NADAs) for roxarsone or carbarsone Type A medicated articles at the sponsor’s request because the products are no longer manufactured or marketed.

**DATES:** This rule is effective December 2, 2013.

**FOR FURTHER INFORMATION CONTACT:** John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, [john.bartkowiak@fda.hhs.gov](mailto:john.bartkowiak@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007, has requested that FDA withdraw approval of the following three NADAs because the products, used to manufacture Type B and Type C medicated feeds, are no longer manufactured or marketed: NADA 007–891 for 3–NITRO (roxarsone) Type A

medicated articles, NADA 092–953 for Roxarsone Type A Medicated Articles, and NADA 010–285 for CARB–O–SEP (carbarsonne) Type A medicated article.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 007–891, 010–285, and 092–953, and all supplements and amendments thereto, is withdrawn, effective December 2, 2013. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

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 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 part 558 is amended as follows:

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

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

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

**§ 558.120 [Amended]**

- 2. In § 558.120, remove and reserve paragraphs (a)(1) and (d)(1)(i).
- 3. In § 558.530, remove and reserve paragraphs (a) and (b); and revise the tables in paragraphs (d)(1) through (3) to read as follows:

**§ 558.530 Roxarsone.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) [Reserved] ..... (ii) 22.7 to 45.4 .....	Chlortetracycline 10 to 50.	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 22.7 to 45.4 .....	Chlortetracycline 100 to 200.	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 22.7 to 45.4 .....	Chlortetracycline 200 to 400.	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 22.7 to 45.4 .....	Chlortetracycline 500.	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline.	Feed continuously for 5 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(2) \* \* \*

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) [Reserved] ..... (ii) 22.7 to 45.4 .....	Chlortetracycline 10 to 50.	Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(iii) 22.7 to 45.4 .....	Chlortetracycline 200.	Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 22.7 to 45.4 .....	Chlortetracycline 400.	1. Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of hexamitiasis caused by <i>Hexamita meleagrides</i> susceptible to chlortetracycline. 2. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 22.7 to 45.4 .....	Chlortetracycline, 25 mg/lb body weight daily.	Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(3) \* \* \*

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) [Reserved] .....	Chlortetracycline 400 (to administer 10 mg/lb body weight).	Growing and finishing swine: For increased rate of weight gain and improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	Feed for not more than 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.	054771
(ii) 22.7 to 34.1 .....				
(iii) [Reserved] .....	Chlortetracycline 10 to 50.	Growing and finishing swine: For increased rate of weight gain and improved feed efficiency; and for treatment of swine dysentery.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	054771
(iv) 181.5 .....				
(v) 181.5 .....	Chlortetracycline 400 (to administer 10 mg/lb body weight).	Growing and finishing swine: For the treatment of swine dysentery; and for treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to chlortetracycline.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	054771

\* \* \* \* \*

Dated: November 18, 2013.

**Bernadette Dunham,***Director, Center for Veterinary Medicine.*

[FR Doc. 2013-27917 Filed 11-21-13; 8:45 am]

BILLING CODE 4160-01-P

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 117**

[Docket No. USCG-2013-0936]

**Drawbridge Operation Regulation; Upper Mississippi River, Rock Island, IL****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Rock Island Railroad and Highway Drawbridge across the Upper Mississippi River, mile 482.9, at Rock Island, Illinois. The deviation is necessary to allow the bridge owner time to perform preventive maintenance and critical repairs that are essential to the continued safe operation of the drawbridge. The work is scheduled in the winter, when the impact on navigation is minimal, instead of scheduling the work at other times in the year, when river traffic is prevalent. This deviation allows the bridge to be maintained in the closed-to-navigation position for 77 days.

**DATES:** This deviation is effective from 7:30 a.m., December 18, 2013 to 7:30 a.m. March 4, 2014.

**ADDRESSES:** The docket for this deviation, USCG-2013-0936, is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone (314) 269-2378, email [Eric.Washburn@uscg.mil](mailto:Eric.Washburn@uscg.mil). If you have questions on

viewing the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone (202)366-9826.

**SUPPLEMENTARY INFORMATION:** The U.S. Army Rock Island Arsenal requested a temporary deviation for the Rock Island Railroad and Highway Drawbridge, mile 482.9, at Rock Island, Illinois across the Upper Mississippi River. It has a vertical clearance of 23.8 feet above normal pool in the closed position. The Rock Island Railroad and Highway Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart.

The deviation period is from 7:30 a.m., December 18, 2013 to 7:30 a.m., March 4, 2014 when the draw span will remain in the closed-to-navigation position. During this time the bridge owner will replace critical control components that are essential to the continued safe operation of the drawbridge. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass this section of the Upper Mississippi River. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

Winter conditions on the Upper Mississippi River coupled with the closure of Army Corps of Engineer's Lock No. 18 (Mile 410.5 UMR) and Lock No. 22 (Mile 301.2 UMR) till 11 a.m., March 4, 2014 will preclude any significant navigation demands for the drawspan opening.

There are no alternate routes for vessels transiting this section of the Upper Mississippi River.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 5, 2013.

**Eric A. Washburn,***Bridge Administrator, Western Rivers.*

[FR Doc. 2013-28039 Filed 11-21-13; 8:45 am]

BILLING CODE 9110-04-P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[EPA-R07-OAR-2013-0585; FRL-9903-14-Region 7]

**Approval and Promulgation of Implementation Plans; State of Missouri; Restriction of Emission of Sulfur Compounds and Emissions Banking and Trading****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.

**SUMMARY:** EPA is approving two revisions to the State Implementation Plan (SIP) for Missouri that were submitted on September 5, 2012. The revision to the Missouri rule "Restriction of Emission of Sulfur Compounds" removes redundant sulfur dioxide standards and outdated compliance dates. Due to these revisions, several within-rule references are amended. Revisions to the Missouri rule "Emissions Banking and Trading" removes all definitions, as they are now included in the general definitions rule. The reference to the state's Ambient Air Quality Standards rule that is included in the definition of National Ambient Air Quality Standards is also removed. The revisions to Missouri's rules do not have an adverse affect on air quality. EPA's approval of this SIP revision is being done in accordance with the requirements of the Clean Air Act (CAA).

**DATES:** This direct final rule will be effective January 21, 2014, without further notice, unless EPA receives adverse comment by December 23, 2013. 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-2013-0585, by one of the following methods:

1. [www.regulations.gov](http://www.regulations.gov). Follow the on-line instructions for submitting comments.
2. Email: [bhesania.amy@epa.gov](mailto:bhesania.amy@epa.gov).
3. Mail or Hand Delivery: Amy Bhesania, 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-2013-0585. EPA's policy is that all comments received will be included in the public docket without change and may be