For the reasons discussed above, I certify that this AD:

(1) Is not a “significant regulatory action” under Executive Order 12866;

(2) Is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–23–09 Eurocopter France:


(a) Applicability


(b) Unsafe Condition

This AD defines the unsafe condition as loss of the self-locking feature of the sliding door lower ball-joint nut. This condition could result in detachment of the lower ball-joint bolt from the sliding door and subsequent loss of the sliding door from the helicopter in flight.

(c) Effective Date

This AD becomes effective December 27, 2013.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 165 hours time-in-service, remove each nut, part number (P/N) ASNS52320BHB060N, and each washer, P/N 23111A100E, from the left-hand and right-hand sliding door lower ball-joint bolts and replace them with an airworthy nut and washer.

(2) Do not install a nut, P/N ASNS52320BHB060N, or washer, P/N 23111A100E, on any sliding door lower ball-joint bolt.

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone 817–222–5110; email Robert.grant@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Eurocopter Alert Service Bulletin (ASB) No. ASB350–52.00.34 for Model AS350B, B1, B2, B3, BA, BB and D and L1 helicopters and ASB No. ASB355–52.00.26 for Model AS355E, F, F1, F2, N, and NP helicopters, both Revision 0 and both dated July 9, 2012, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at http://www.eurocopter.com/tecpub. You may refer to the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.


(i) Subject


Issued in Fort Worth, Texas, on November 5, 2013.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–27636 Filed 11–21–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2013–N–1380]

Advisory Committee; Veterinary Medicine Advisory Committee; Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Veterinary Medicine Advisory Committee. This document removes the Veterinary Advisory Committee from the Agency’s list of standing advisory committees.

DATES: This rule is effective November 22, 2013.

FOR FURTHER INFORMATION CONTACT: Michael Ortworh, Advisory Committee Oversight and Management Staff, Food and Drugs Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring MD 20993–0002, FAX: 301–847–8640, or email at Michael.Ortworh@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Veterinary Medicine Committee was established on April 24, 1984 (49 FR 20809; May 17, 1984). The purpose of the Committee was to review and evaluate available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal diseases and increased animal production. The Committee is no longer needed and was terminated on September 24, 2013.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40 (d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Veterinary Medicine Advisory Committee from the list of FDA’s standing advisory committees in 21 CFR 14.100.

Therefore, the Agency is amending 21 CFR 14.100(f) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.
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:

§ 14.100 [Amended]

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


§ 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


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:

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.

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...