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, 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. In § 510.600, in the table in paragraph (c)(1), remove the entry for ''ADM Animal Health & Nutrition Division''; and in the table in paragraph (c)(2), remove the entry for ''017519''.

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.

■ 4. In § 520.445b, revise the section heading, and paragraphs (b) and (d)(4)(iii)(C) to read as follows:

§ 520.445b Chlortetracycline powder.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 048164 for use as in paragraph (d) of this section.

(2) No. 053501 for use as in paragraph (d)(4) of this section.

(3) No. 000010 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (iv) of this section.

(4) Nos. 021930 and 059130 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), (d)(4)(ii), and (d)(4)(iii) of this section.

* * * * *

(d) * * *

(4) * * *

(iii) * * *

(C) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days. For Nos. 000010 and 021930, do not slaughter animals for food within 5 days of treatment; for No. 053501, do not slaughter animals for food within 24 hours of treatment.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.95 [Amended]

■ 6. In paragraph (a)(4) of § 558.95, remove ''016968, 017519, and 017790'' and in its place add ''Nos. 016968, 017790, and 021930''.

§ 558.128 [Amended]

■ 7. In § 558.128, in paragraph (b)(2), remove ''017519'' and in its place add ''021930''; and in the tables in paragraphs (e)(1) through (e)(4), in the ''Sponsor'' column remove ''017519'' wherever it occurs and in its place add ''021930''.

§ 558.274 [Amended]

■ 8. In § 558.274, in paragraph (a)(7), remove ''017519'' and in its place add ''021930''; and in the table in paragraphs (c)(1)(i) and (c)(1)(ii), in the ''Sponsor'' column remove ''017519'' and in numerical sequence add ''021930''.

§ 558.485 [Amended]

■ 9. In paragraph (b)(3) of § 558.485, remove ''017519'' and in numerical sequence add ''021930''.

§ 558.625 [Amended]

■ 10. In paragraph (b)(10) of § 558.625, remove ''017519'' and in its place add ''021930''.

§ 558.630 [Amended]

■ 11. In § 558.630, remove and reserve paragraphs (b)(3) and (b)(8); and in paragraph (b)(10) remove ''017519''.

Dated: December 29, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–118 Filed 1–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2006N–0517]

Medical Devices; Immunology and Microbiology Devices; Classification of Quality Control Material for Cystic Fibrosis Nucleic Acid Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying quality control material for cystic fibrosis nucleic acid assays into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This final rule is effective February 9, 2007. The classification was effective October 12, 2006.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496, ext. 117.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an

order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on August 7, 2006, classifying the Maine Molecular Quality Controls, Inc., INTROL™ CF Panel I Control as class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On August 10, 2006, Maine Molecular Quality Controls, Inc., submitted a petition requesting classification of the INTROL™ CF Panel I Control under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Maine Molecular Quality Controls, Inc., INTROL™ CF Panel I Control can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''quality control material for cystic fibrosis nucleic acid assays.'' It is identified as a device intended to help monitor reliability of a test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing. This type of device includes recombinant, synthetic, and cell line based DNA controls.

Quality control (QC) material is intended to help monitor reliability of a test system. Therefore, failure of the QC material for cystic fibrosis nucleic acid assays to perform as indicated may lead to error in assessment of test results, and reporting of inaccurate results. This could potentially lead to patient mismanagement. For example, if the controls fail even though the test system was accurate, this may lead to unnecessary retesting, and delay in reporting results. In cases of patient samples that are difficult to obtain, this may cause additional risk to the patient. Conversely, if a QC material does not accurately reflect when the test system has failed, this may lead to false assurance of test operability, and reporting of inaccurate patient results.

FDA believes the class II special controls guidance document will aid in mitigating potential risks by providing recommendations on validation of performance characteristics, and labeling specifications appropriate for the use of controls in genetic in vitro diagnostic assays. The guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that following the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph. Therefore, on October 12, 2006, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 866.5910.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a quality control material for genetic testing will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket review of the system's key performance characteristics, test methodology, labeling, and other requirements as outlined in 21 CFR 807.87, will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the quality control material for cystic fibrosis nucleic acid assays they intend to market.

II. What Is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) 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.

III. What Is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National

Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

The guidance for this final rule references previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB Control No 0910–0231; the collections of information in 21 CFR part 809 have been approved under OMB Control No. 0910–0485.

VI. What References are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Maine Molecular Quality Controls, Inc., dated August 10, 2006.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.5910 is added to subpart F to read as follows:

§ 866.5910 Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.

(a) *Identification.* Quality control material for cystic fibrosis nucleic acid assays. A quality control material for cystic fibrosis nucleic acid assays is a device intended to help monitor reliability of a test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing. This type of device includes recombinant, synthetic, and cell line-based DNA controls.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.'' See § 866.1(e) for the availability of this guidance document.

Dated: December 21, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health

[FR Doc. E7–119 Filed 1–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD11–06–048]

RIN 1625–AA09

Drawbridge Operation Regulations; Sacramento River, at Paintersville, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Paintersville Drawbridge across the Sacramento River, mile 33.4, at Paintersville, CA. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period. The deviation is necessary for the bridge owner, the California Department of Transportation (Caltrans), to refurbish and replace aging operating machinery.

DATES: This deviation is effective from 7 a.m. on February 28, 2007 to 5 p.m. on March 8, 2007.

ADDRESSES: Materials referred to in this document are available for inspection or copying at Commander (dpw), Eleventh Coast Guard District, Building 50–2, Coast Guard Island, Alameda, CA 94501–5100, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516.

SUPPLEMENTARY INFORMATION: Caltrans requested a temporary change to the operation of the Paintersville Drawbridge, mile 33.4, over the Sacramento River, at Paintersville, CA. The Paintersville Drawbridge's navigation span provides a vertical clearance of 24 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal from 9 a.m. to 5 p.m., November 1 through April 30, and at all other times if at least 4 hours notice is given as required by 33 CFR 117.189. Navigation on the waterway is recreational, search and rescue, and commercial traffic hauling materials for levee repair. Caltrans requested to secure the drawspan in the closed to navigation position from 7 a.m. on February 28, 2007 to 5 p.m. on March 8, 2007. During this time the drawspan motors will be refurbished and the control house replaced to ensure the continuing operation of the drawspan. This temporary deviation has been coordinated with waterway users. Caltrans has reduced the period of time the bridge will be closed to navigation to reduce the impact to levee repair in the area. Vessels that can transit the bridge while in the closed-to-navigation position may continue to do so at any time.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 29, 2006.

R.C. Lorigan,

Captain, U.S. Coast Guard, Acting Commander, Eleventh Coast Guard District.

[FR Doc. E7–151 Filed 1–9–07; 8:45 am]

BILLING CODE 4910–15–P