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List of Subjects in 21 CFR Part 530

Administrative practice and procedure, Advertising, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, 21 CFR part 530 is amended as follows:

PART 530—EXTRALABEL DRUG USE IN ANIMALS

■ 1. The authority citation for 21 CFR part 530 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

■ 2. In § 530.41, add and reserve paragraph (c) and add paragraph (d) to read as follows:

§ 530.41 Drugs prohibited for extralabel use in animals.

* * * * *

(c) [Reserved]

(d) The following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in chickens, turkeys, and ducks:

(1) Adamantanes.

(2) Neuraminidase inhibitors.

Dated: March 14, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–2689 Filed 3–20–06; 11:00 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2006N–0100]

Medical Devices; Immunology and Microbiology Devices; Classification of Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying Reagents for detection of specific novel influenza A viruses into class II (special controls). Special controls that will apply to the device are the guidance document entitled, ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses'' and limitations of distribution of these reagents. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, the Food and Drug Administration Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002. 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 publishing a notice of availability of a guidance document that is a special control for this device.

DATES: This rule becomes effective April 21, 2006. The classification was effective February 3, 2006.

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

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of 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 previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (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 (513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a notice on January 26, 2006, classifying the Centers for Disease Control and Prevention (CDC)'s Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set in class III, because it was not substantially equivalent to a class I or class II 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 January 26, 2006, CDC submitted a petition requesting classification of the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set 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 CDC's Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set 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, ''Reagents for detection of specific novel influenza A viruses.'' The Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set is intended for the in vitro qualitative detection of Influenza A/H5 (Asian lineage) virus RNA either directly in patient respiratory specimens or in viral cultures for the presumptive laboratory identification of Influenza A/H5 (Asian lineage) virus. Testing with the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set should be used in conjunction with other laboratory testing and clinical observations for the following indications: (1) Providing epidemiological information for the surveillance of human infection with Influenza A/H5 (Asian lineage) virus; (2) identifying patients who may be infected with Influenza A/H5 (Asian lineage) virus based on clinical and epidemiological risk factors.

FDA has identified the risks to health associated with this type of device as improper patient management and public health response, laboratory-acquired infection, and potential influenza A virus reassortment. Failure of testing with reagents for detection of specific novel influenza A viruses to correctly identify a specific novel influenza A virus, or failure to properly interpret test results obtained with these reagents, could lead to incorrect patient management decisions and inappropriate public health responses. Also, the use of reagents for detection of specific novel influenza A viruses without appropriate biosafety equipment and containment could result in laboratory-acquired infection and viral reassortment.

The class II special controls guidance document provides information on how to meet premarket (510(k)) submission requirements for the device, including recommendations on validation of performance characteristics and labeling. It also addresses postmarket measures to assure the continued safety and effectiveness of the device by identifying changes in performance that may result from mutation in the virus that the device is intended to detect or changes in the prevalence of human infection. FDA believes that following the class II special controls guidance document and the additional special control specified in the classification regulation generally addresses the risks to health identified in the previous paragraph. Therefore, on February 3, 2006, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 866.3332.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for reagents for detection of specific novel influenza A viruses will need to address the issues covered in the special controls guidance, which contains recommendations for the contents of premarket notification submissions including performance testing, labeling, and postmarket data collection and analysis; and will have to limit distribution of these reagents to laboratories with: (1) Experienced personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and (2) appropriate biosafety equipment and containment. However, regarding the issues covered in the special controls guidance, 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 notification is necessary because FDA review of performance characteristics, test methodology, and labeling to satisfy requirements of 21 CFR 807.87(e), 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 containing information on the reagents for detection of specific novel influenza A viruses before marketing the device.

II. Environmental Impact

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. Analysis of Impacts

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 $115 million, using the most current (2003) 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. Federalism

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. 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 (PRA) is not required. FDA concludes that the special controls guidance document contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled, ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses''; the notice contains an analysis of the paperwork burden for the guidance.

VI. Reference

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 CDC, dated January 26, 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 866.3332 is added to subpart D to read as follows:

§ 866.3332 Reagents for detection of specific novel influenza A viruses.

(a) *Identification.* Reagents for detection of specific novel influenza A viruses are devices that are intended for use in a nucleic acid amplification test to directly detect specific virus RNA in human respiratory specimens or viral cultures. Detection of specific virus RNA aids in the diagnosis of influenza caused by specific novel influenza A viruses in patients with clinical risk of infection with these viruses, and also aids in the presumptive laboratory identification of specific novel influenza A viruses to provide epidemiological information on influenza. These reagents include primers, probes, and specific influenza A virus controls.

(b) *Classification.* Class II (special controls). The special controls are:

(1) FDA's guidance document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses.'' See § 866.1(e) for information on obtaining this document.

(2) The distribution of these devices is limited to laboratories with experienced personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and appropriate biosafety equipment and containment.

Dated: March 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–2742 Filed 3–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13–06–011]

RIN 1625–AA00

Safety Zone: Camp Rilea Offshore Small Arms Firing Range; Warrenton, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone offshore of Camp Rilea, Warrenton, Oregon. Small arms training and fire will be conducted within this zone, and a safety zone is needed to ensure the safety of persons and vessels operating in this area during the specified periods. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated representative.

DATES: This rule is effective from 5 a.m. to 8 p.m. from March 10, 2006 through March 20, 2006. This rule is enforced during daylight hours from March 10, 2006 through March 20, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD13–06–011 and are available for inspection or copying at Coast Guard Sector Portland, 6767 North Basin Avenue, Portland, OR