1125; email to *James.Brow@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

This action affirms the interim rule concerning Executive Orders 12866, 12988, and 13563; the Regulatory Flexibility Act (5 U.S.C. 601–612; the Paperwork Reduction Act (44 U.S.C. Chapter 35); and the E-Gov Act (44 U.S.C. 101). Further, for this action, the Office of Management and Budget has determined that this action is not significant under Executive Order 12866 and therefore has not been reviewed by OMB.

Background Information

The Soybean Promotion, Research, and Consumer Information Act (Act) (7 U.S.C. 6301–6311) provides for the establishment of a coordinated program of promotion and research designed to strengthen the soybean industry's position in the marketplace, and to maintain and expand domestic and foreign markets and uses for soybeans and soybean products. The program is financed by an assessment of 0.5 of 1 percent of the net market price of soybeans sold by producers. The final rule establishing a Soybean Promotion, Research, and Consumer Information program was published in the July 9, 1991, issue of the **Federal Register** (56 FR 31043), and assessments began on September 1, 1991.

The Act specifies that the Secretary shall, five years after the conduct of the initial referendum and every five years thereafter, provide soybean producers an opportunity to request a referendum on the Soybean Promotion, Research, and Consumer Information Order (Order). Additionally, the Act specifies that these subsequent polls require that at least 10 percent (not in excess of one-fifth in any one State) of all producers must request a referendum in order to trigger the conduct of a referendum. If a referendum is requested, it will be held within one year of that determination.

The next Request for Referendum will be conducted May 2019, at FSA county offices.

Changes to the Regulations

In the interim rule, AMS amended § 1220.616 to remove the specific number of soybean producers from the regulatory language. Data provided by FSA has been used to amend the number of soybean producers prior to any Request for Referendum. The data have been sorted in such a manner as to include all producers who were engaged in the production of soybeans in at least one of the two years prior to the Request for Referendum, excluding counting a producer more than once if that producer engaged in production during both years. Using the last two crop-year acreage reports for which complete data is available ensures that all eligible producers are counted, as some producers use soybeans in rotation with other crops and do not plant soybeans every year. This methodology is consistent with that used in previous requests for referendum and will continue to be used by USDA to update the number of eligible soybean producers.

For the 2014 Request for Referendum previously conducted and subsequent requests for referendum, the data provided by FSA allows the Secretary to update this number.

In addition to the changes relating to the number of eligible soybean producers, AMS amended §§ 1220.619, 1220.622 and 1220.628 with more flexible language.

Comments

On March 4, 2014, USDA published in the **Federal Register** (79 FR 12037) an interim rule with a request for comments to be received by April 3, 2014. USDA received no comments.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Reporting and recordkeeping requirements, Soybeans and soybean products.

For the reasons set forth in the preamble, 7 CFR Part 1220 is amended as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

■ Accordingly, the interim rule that amended 7 CFR Part 1220, which was published on March 4, 2014 at 79 FR 12037, is adopted as a final rule without change.

Dated: September 4, 2014.

Rex A. Barnes,

Associate Administrator.

[FR Doc. 2014–21512 Filed 9–9–14; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket No. APHIS–2014–0058]

Bovine Tuberculosis Status of Michigan; Advance Counties From Modified Accredited Advanced to Accredited-Free

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the bovine tuberculosis regulations to advance the status of Antrim, Charlevoix, Cheboygan, Crawford, Emmet, Otsego, and Presque Isle Counties in Michigan from modified accredited advanced to accredited-free. We have determined that these counties meet the criteria for accredited-free status. This action relieves certain restrictions on the interstate movement of cattle and bison from these areas of Michigan.

DATES: This interim rule is effective on September 10, 2014. We will consider all comments that we receive on or before November 10, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0058.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0058, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0058* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. C. William Hench, Senior Staff Veterinarian, Surveillance, Preparedness and Response Services, Cattle Health Center, VS, APHIS, 2150 Centre Avenue, Building B, MSC 3–E–20, Fort Collins, CO 80526–8117; (970) 494–7378.

SUPPLEMENTARY INFORMATION:

Background

Bovine tuberculosis is a contagious and infectious granulomatous disease caused by the bacterium *Mycobacterium bovis.* Although commonly defined as a chronic debilitating disease, bovine tuberculosis can occasionally assume an acute, rapidly progressive course. While any body tissue can be affected, lesions are most frequently observed in the lymph nodes, lungs, intestines, liver, spleen, pleura, and peritoneum. Although cattle are considered to be the true hosts of *M. bovis,* the disease has been reported in several other species of livestock, most notably bison and captive cervids. There have also been instances of infection in other domestic and nondomestic animals, as well as in humans. Through the National Cooperative State/Federal Bovine Tuberculosis Eradication Program, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) works cooperatively with the Nation's livestock industry and State animal health agencies to eradicate bovine tuberculosis from domestic livestock in the United States and prevent its recurrence.

Federal regulations implementing this program are contained in 9 CFR part 77, ''Tuberculosis'' (referred to below as the regulations) and in the ''Uniform Methods and Rules—Bovine Tuberculosis Eradication'' (UMR) which is incorporated by reference within the regulations.

The status of a State or zone is based on its prevalence of tuberculosis in cattle and bison, the effectiveness of the State's tuberculosis eradication program, and the degree of the State's compliance with standards for cattle and bison contained in the UMR. The regulations provide that a State may request partitioning into specific geographic regions or zones with different status designations (commonly referred to as split-State status) if bovine tuberculosis is detected in a portion of a State and the State demonstrates that it meets certain criteria with regard to zone classification.

We have received from the State of Michigan a request to reclassify the modified accredited advanced zone in the State's Lower Peninsula as accredited free. Based on the findings of a review of the tuberculosis eradication program in Michigan, APHIS has determined that the zone meets the criteria for advancement of status contained in the regulations.

State animal health officials in Michigan have demonstrated that the State enforces and complies with the provisions of the UMR. The State of Michigan has demonstrated that the modified accredited advanced zone has zero percent prevalence of cattle and bison herds affected with tuberculosis and has had no findings of tuberculosis in any cattle or bison in the zone since the last affected herd in the zone was depopulated in April 2011. Therefore, Michigan has demonstrated that the zone within the State's Lower Peninsula previously classified as modified accredited advanced meets the criteria for accredited-free status as set forth in the definition of accredited-free State or zone in § 77.5 of the regulations.

Based on our evaluation of Michigan's request, we are classifying the zone consisting of Antrim, Charlevoix, Cheboygan, Crawford, Emmet, Otsego, and Presque Isle Counties as accredited free.

Immediate Action

Immediate action is warranted to relieve restrictions on the interstate movement of cattle and bison from Antrim, Charlevoix, Cheboygan, Crawford, Emmet, Otsego, and Presque Isle Counties in Michigan. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This interim rule is subject to Executive Order 12866. However, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. The full analysis may be viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov) or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Michigan has submitted a request for split-State bovine tuberculosis status that will advance seven counties on the Lower Peninsula of Michigan (Antrim, Charlevoix, Cheboygan, Crawford, Emmet, Otsego, and Presque Isle) from modified accredited advanced to accredited-free status. This status advancement will eliminate pre-movement testing requirements for producers in the seven counties, saving them time and money. Based on national statistics and Small Business Administration size standards, most if not all of the cattle and dairy operations affected are likely to be small entities.

The number of herds in the 7 counties that require surveillance testing will be reduced from about 390 to fewer than 120. Tuberculosis testing, including veterinary fees, costs about $10 to $15 per head. Based on an estimated 33 head per herd, total annual cost savings are expected to range between $90,000 and $135,000 yearly in the 7 counties.

The average value of cattle and calves in Michigan is about $1,100 per head. Thus, the savings by forgoing tuberculosis testing represent about 1.3 percent of the average value of the animals. This action will not significantly change program operations and will have no significant effects on other Federal agencies, State government, or local governments.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule has no retroactive effect and does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

Accordingly, we are amending 9 CFR part 77 as follows:

PART 77—TUBERCULOSIS

■ 1. The authority citation for part 77 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 77.7 [Amended]

■ 2. In § 77.7, paragraph (b)(1) is amended by removing the words ''zones that comprise'' and adding the words ''zone that comprises'' in their place and by removing the words ''§ 77.9(b)(1) and''.

■ 3. In § 77.9, paragraph (b) is revised to read as follows:

§ 77.9 Modified accredited advanced States or zones.

* * * * *

(b) The following are modified accredited advanced zones: None.

* * * * *

Done in Washington, DC, this 4th day of September 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–21583 Filed 9–9–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2014–N–1166]

Medical Devices; Immunology and Microbiology Devices; Classification of Dengue Virus Nucleic Acid Amplification Test Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying dengue virus nucleic acid amplification test reagents into class II (special controls). The Agency is classifying the device into class II (special controls) because special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 10, 2014. The classification was applicable May 24, 2012.

FOR FURTHER INFORMATION CONTACT: Beena Puri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5553, Silver Spring, MD 20993–0002, 301–796–6202.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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), 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012, 126 Statute 1054), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will 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 this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on February 24, 2012, classifying the CDC DENV–1–4 Real-Time RT–PCR Assay into 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 March 12, 2012, the Centers for Disease Control and Prevention submitted a request for de novo classification of the CDC DENV–1–4 Real-Time RT–PCR Assay under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request for de novo classification in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices 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 request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name dengue virus nucleic acid amplification test reagents, and it is identified as devices that consist of primers, probes, enzymes, and controls for the amplification and detection of dengue virus serotypes 1, 2, 3, or 4 from viral ribonucleic acid (RNA) in human serum and plasma from individuals who have signs and symptoms consistent with dengue (mild or severe). The identification of dengue virus serotypes 1, 2, 3, or 4 in human serum and plasma (sodium citrate) collected from human