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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–089–3]

Add Denmark to the List of Regions Free of Exotic Newcastle Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to add Denmark to the list of regions considered free of exotic Newcastle disease. This final rule follows an interim rule that removed Denmark from that list due to an outbreak of exotic Newcastle disease in that region. A recent risk analysis indicated that Denmark now meets our requirements for recognition as a region free of exotic Newcastle disease. This rule relieves certain restrictions on the importation of carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, and other birds from Denmark into the United States.

DATES: Effective Date: July 6, 2006.

FOR FURTHER INFORMATION CONTACT: Dr. Chip Wells, Senior Staff Veterinarian, Regionalization Evaluation Services—Import, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of specified animals and animal products into the United States in order to prevent the introduction of various animal diseases. The regulations in § 94.6 govern, among other things, the importation of carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from regions where exotic Newcastle disease (END) is considered to exist. END is considered to exist in all regions not listed in § 94.6(a)(2).

In an interim rule effective July 16, 2002, and published in the **Federal Register** on September 20, 2002 (67 FR 59136–59137, Docket No. 02–089–1), we amended the regulations by removing Denmark from the list of regions considered to be free of END. The interim rule was necessary because END had been confirmed in Denmark. The effect of the interim rule was to restrict the importation of carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, and other birds into the United States from Denmark.

Although we removed Denmark from the list of regions considered free of END, we recognized that Denmark immediately responded to the outbreak of END by imposing restrictions on the movement of poultry and poultry products within its borders and initiating measures to eradicate the disease. We stated that we intended to reassess the situation in the region at a future date, and that as part of that reassessment process, we would consider all comments received regarding the interim rule. We received no comments on the interim rule.

Additionally, we stated that our future assessment would enable us to determine whether it would be necessary to continue to restrict the importation of poultry and poultry products from Denmark, whether we could restore Denmark to the list of regions in which END is not known to exist, or whether we could restore portions of Denmark as free of END.

On May 5, 2005, we published in the **Federal Register** (70 FR 23809–23810, Docket No. 02–089–2) a notice announcing the availability of a risk analysis we had prepared concerning the END status of Denmark and the related disease risks associated with importing carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, and other birds from Denmark into the United States.

We solicited public comments concerning the evaluation for 60 days ending July 5, 2005. We received two comments in that time; one from the European Commission (EC) and the other from a group of private individuals. Both commenters raised concerns regarding APHIS procedures for recognizing the disease status of other countries. These concerns are discussed below.

Issue: Both the EC and the private citizens expressed concern about the procedures used by APHIS in first removing and then reinstating Denmark from the list of END free regions. The private citizens expressed concern that there was a 2-month difference between the detection of the outbreak and the publication of the interim rule in 2002. The EC stated that the United States has been unacceptably slow in returning Denmark to the list of END free regions, as the EC considered Denmark to be END free as of March 1, 2003. Furthermore, the EC stated that the present APHIS rulemaking process is not in compliance with the OIE Terrestrial Animal Health Code Article 2.7.13.2 or with agreements between the United States and the EC regarding regionalization of the European Union (EU).

Response: We are required to adhere to certain procedures in establishing or amending regulations, including actions regarding the animal health status of a region. Our policy in situations in which a region experiences a disease outbreak is to issue an immediate administrative ban on imports from an affected region and then follow with the rulemaking process required by the Administrative Procedure Act; the interim rule may be given an effective date earlier than the date of the rule's signature or publication to affirm our authority for issuing previous administrative orders. In this case, a port alert instructing APHIS port offices to refuse any shipment of poultry or poultry products from Denmark that did not meet the requirements for poultry or poultry products from regions affected with END was issued on July 31, 2002. This action applied retroactively to shipments received on or after July 16, 2002, the day suspicion of the outbreak was initially reported. The interim rule removing Denmark from the list of END-free regions was also made effective retroactively to July 16, 2002.

We received the request to return Denmark to the list of END-free regions

in April 2004. Once the request was received, we responded by initiating the risk analysis. Some aspects of the information submitted required clarification, and during the review period (after receipt of the original submission) Denmark made a significant change to its END control policy with the implementation of a mandatory vaccination policy. We considered it necessary to acquire additional information to evaluate the effect of this change. We exchanged correspondence on several occasions with the EC and received the requested information on November 26, 2004. On May 5, 2005, we published the notice of availability cited above and invited public review and comment of the risk analysis cited above until July 5, 2005. While we were considering the public comments received, Denmark experienced a single new END outbreak, which was reported on October 21, 2005. We have considered the impact of this situation on the previously published risk analysis, and this final rule reflects that consideration.

Issue: The group of private citizens stated that the focus on live poultry in the risk analysis was misplaced, and the focus should have been on the risk of introducing END through poultry products.

Response: As we explained in the exposure assessment portion of the risk analysis, it was necessary for us to focus on exposure pathways involving live poultry because historically END introductions into the United States have been associated with the importation of live birds. Live birds were, therefore, considered a higher risk pathway than the importation of poultry products. Since the risk from live birds was low, the risk from poultry products should also be low.

Issue: The group of private citizens asked for clarification of the process APHIS uses in adding and removing countries on the list in § 94.6(a)(2) of the regulations. They also asked for more information on the procedures that APHIS uses to rank risk.

Response: The regulatory process we use to recognize the animal health status of a region or to reestablish a region's disease-free status after an outbreak is detailed in 9 CFR part 92. General information on determining animal disease status and risk assessment can be found online at the Veterinary Services Regionalization Evaluation Services Staff Web site, *http://www.aphis.usda.gov/vs/ncie/reg-request.html*. The informational document ''Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking,'' which describes the process APHIS follows when conducting foreign animal disease status evaluation, regionalization, risk analysis, and related rulemaking, is available to the public through that Web site by clicking on the document title at the bottom of the page.

Issue: The private citizens stated that APHIS should have made a site visit to Denmark to evaluate the END status of the region.

Response: We disagree. As we explained in the risk analysis, prior to the outbreaks in 2002, the United States had a long history of trade of poultry and poultry products with Denmark. Denmark, as a country and as a Member State of the EU, has previously been evaluated for END and other animal diseases. We have maintained contact with Danish veterinary authorities who keep us advised of animal disease conditions in their country. Furthermore, the EU system for animal disease control for classical swine fever has been extensively evaluated by APHIS and provides additional confidence in the EU veterinary infrastructure. The document referenced above, ''Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking,'' describes circumstances when a site visit may not be deemed necessary for an evaluation. Accordingly, we concluded that a document review was sufficient for the needs of the risk analysis.

As noted previously, while we were reviewing these comments and preparing its response, Denmark experienced a new outbreak of END in a single flock. We monitored the situation and evaluated the information provided by Danish veterinary authorities and have concluded that the outbreak was limited to a single flock, which was depopulated, and that the outbreak has successfully been contained and eradicated. Denmark has lifted all protective measures as of December 4, 2005. We consider this isolated outbreak to be consistent with the conclusions stated in the previously released risk analysis.

Therefore, for the reasons given in this document and based on our risk analysis, we are amending § 94.6 in this final rule to add Denmark to the list of regions considered free of END.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

We are amending the regulations by adding Denmark to the list of regions considered free of END. We are taking this action because Denmark has met our requirements for recognition as a region free of END. This action relieves restrictions on the importation of carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from Denmark which are no longer warranted.

Denmark produced 412 million pounds (equivalent to about 1.2 percent of U.S. production) and exported 250 million pounds (equivalent to about 0.7 percent of U.S. production) of poultry meat in 2005. The United States is the world's largest producer and exporter of poultry meat. In 2005, U.S. poultry meat production totaled 35.3 billion pounds, of which 84.3 percent was broiler meat, 12.4 percent was turkey meat, and 3.3 percent was other chicken meat. During the same period, the United States exported 6 billion pounds of poultry meat valued at $2.5 billion.

In theory, if poultry available for consumption in U.S. markets increases, poultry prices would decrease, U.S. consumers of poultry would benefit, and U.S. producers would be harmed. U.S. freight forwarding, trucking, and transport firms that transport poultry from U.S. ports could benefit from increased economic activity. However these impacts are expected to be negligible because the amounts of poultry products produced in Denmark are a small fraction of U.S. production. Denmark has a well established world-wide market and is unlikely to divert its exports from these markets to the more distant U.S. market.

The Small Business Administration (SBA) has established guidelines for determining which types of firms are to be considered small under the Regulatory Flexibility Act. This rule would mainly affect poultry farms (North American Industry Classification System [NAICS] code 112320). According to the 2002 Census of Agriculture, there are 83,381 poultry farms that produce broilers and other meat type chickens. These facilities are considered to be small if their annual receipts are not more than $750,000. Over 93 percent of these operations are considered to be small. Any effects of the rule for U.S. producers will be negligible. Other entities that could theoretically be affected include U.S. trucking firms (NAICS code 4842302), U.S. freight forwarders (NAICS code 4885101), and deep sea freight transport companies (NAICS code 483111). The SBA classifies trucking firms as small if their annual receipts are less than $21.5

million; freight forwarding firms are small if their annual receipts are less than $6 million, and deep sea freight transport firms are small if they have not more than 500 workers. According to the 2002 Economic Census, there were 9,177 trucking firms, 5,840 freight forwarders, and 383 deep sea freight transport companies. Over 99 percent of trucking firms, 90 percent freight forwarders, and 70 percent of deep sea freight transport firms are considered to be small. Although the majority of these establishments are small entities, the effect of this rule will be negligible.

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 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no 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 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 94.6 [Amended]

■ 2. In § 94.6, paragraph (a)(2) is amended by adding the word ''Denmark,'' before the word ''Fiji.''

Done in Washington, DC, this 29th day of June 2006.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E6–10555 Filed 7–5–06; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Altana Inc. The ANADA provides for veterinary prescription use of gentamicin sulfate, betamethasone valerate, clotrimazole ointment for the treatment of canine otitis externa.

DATES: This rule is effective July 6, 2006.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Altana Inc., 60 Baylis Rd., Melville, NY 11747, filed ANADA 200–283 that provides for veterinary prescription use of VETRO–MAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP, ointment) for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin. Altana Inc.'s VETRO–MAX Otic Ointment is approved as a generic copy of Schering-Plough Animal Health Corp.'s OTOMAX Ointment approved under NADA 140–896. The ANADA is approved as of June 1, 2006, and the regulations are amended in 21 CFR 524.1044g to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

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 524

Animal drugs.

■ 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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. In § 524.1044g, add paragraph (b)(4) to read as follows:

§ 524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

* * * * *

(b) * * *

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

* * * * *

Dated: June 22, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–10496 Filed 7–5–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Corporate Distributions and Adjustments

CFR Correction

In Title 26 of the Code of Federal Regulations, part 1 (§§ 1.301 to 1.400),