

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Amendment of February 4, 2004, Order To Embargo Birds and Bird Products Imported From Pakistan

SUMMARY: On February 4, 2004, the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services issued an order to ban immediately the import of all birds (Class: *Aves*) from specified countries, subject to limited exemptions for returning pet birds of U.S. origin and certain processed bird-derived products. HHS/CDC took this step because birds from these countries potentially can infect humans with avian influenza (influenza A/ [H5N1]). The February 4, 2004, order complemented a similar action taken at the same time by the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA).

On March 10, 2004, HHS/CDC lifted the embargo of birds and bird products from the Hong Kong Special Administrative Region (HKSAR) because of the documented public-health and animal health measures taken by Hong Kong officials to prevent spread of the outbreak within the HKSAR, and the absence of highly pathogenic avian influenza H5N1 cases in Hong Kong's domestic and wild bird populations. USDA/APHIS took a similar action. On September 28, 2004, HHS/CDC extended the embargo on birds and bird products to include Malaysia because of the documented cases of highly pathogenic avian influenza A H5N1 in poultry in Malaysia. On July 20, 2005, USDA/APHIS adopted as a final rule the interim rule that became effective on February 4, 2004, which amended its regulations to prohibit or restrict the importation of birds, poultry, and unprocessed birds and poultry products from regions that have reported the presence of highly pathogenic avian influenza H5N1 in poultry. (See 70 FR 41608 [July 20, 2005].) As the United Nations Food and Agriculture Organization and the World Organization for Animal Health (OIE) have confirmed additional cases of highly pathogenic avian influenza (H5N1), USDA/APHIS has added additional countries to its ban. Because of the documentation of highly pathogenic avian influenza H5N1 in poultry, HHS/CDC added the following countries to its embargo: Kazakhstan,

Romania, Russia, Turkey, and Ukraine on December 29, 2005; Nigeria on February 8, 2006; India on February 22, 2006; Egypt on February 27, 2006; Niger on March 2, 2006; Albania, Azerbaijan, Cameroon, and Burma (Myanmar) on March 15, 2006; Israel on March 20, 2006; Afghanistan on March 21, 2006; Jordan on March 29, 2006; and Burkina Faso on April 10, 2006.

On April 4, 2006, OIE reported confirmation of highly pathogenic avian influenza H5N1 in poultry in Pakistan. At this time, HHS/CDC is adding Pakistan to its current embargo. This action is effective on April 10, 2006, and will remain in effect until further notice.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 2006, OIE reported confirmation of highly pathogenic avian influenza H5 type in commercial poultry in Charsada and Abbottabad, Northwest Frontier, Pakistan. H5N1 typing was confirmed by OIE on April 4, 2006.

Introduction of birds infected with highly pathogenic avian influenza H5N1 into the United States could lead to outbreaks of disease among birds and among the human population, a significant public health threat. Banning the importation of all avian species from affected countries is an effective means of limiting this threat. HHS/CDC is therefore taking this action to reduce the likelihood of introduction or spread of influenza A H5N1 into the United States.

Immediate Action

Therefore, pursuant to 42 CFR 71.32(b), HHS/CDC is amending the February 4, 2004, order to add Pakistan to the list of countries subject to the order's embargo of birds and products derived from birds. All other portions of the February 4, 2004, order, as further amended on March 10, 2004; September 28, 2004; December 29, 2005; February 8, 2006; February 22, 2006; February 27, 2006; March 2, 2006; March 15, 2006; March 20, 2006; March 21, 2006; March 29, 2006; and April 10, 2006, shall remain in effect until further notice.

Dated: April 13, 2006.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. E6-5839 Filed 4-18-06; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Amendment of February 4, 2004, Order To Embargo Birds and Bird Products Imported From Burkina Faso

SUMMARY: On February 4, 2004, the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services issued an order to ban immediately the import of all birds (Class: *Aves*) from specified countries, subject to limited exemptions for returning pet birds of U.S. origin and certain processed bird-derived products. HHS/CDC took this step because birds from these countries potentially can infect humans with avian influenza (influenza A/ [H5N1]). The February 4, 2004, order complemented a similar action taken at the same time by the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA).

On March 10, 2004, HHS/CDC lifted the embargo of birds and bird products from the Hong Kong Special Administrative Region (HKSAR) because of the documented public-health and animal health measures taken by Hong Kong officials to prevent spread of the outbreak within the HKSAR, and the absence of highly pathogenic avian influenza H5N1 cases in Hong Kong's domestic and wild bird populations. USDA/APHIS took a similar action. On September 28, 2004, HHS/CDC extended the embargo on birds and bird products to include Malaysia because of the documented cases of highly pathogenic avian influenza A H5N1 in poultry in Malaysia. On July 20, 2005, USDA/APHIS adopted as a final rule the interim rule that became effective on February 4, 2004, which amended its regulations to prohibit or restrict the importation of birds, poultry, and unprocessed birds and poultry products from regions that have reported the presence of highly pathogenic avian influenza H5N1 in poultry. (See 70 FR 41608 [July 20, 2005].) As the United Nations Food and Agriculture Organization and the World Organization for Animal Health (OIE) have confirmed additional cases of highly pathogenic avian influenza (H5N1), USDA/APHIS has added additional countries to its ban. Because of the documentation of highly pathogenic avian influenza H5N1 in poultry, HHS/CDC added the following countries to its embargo: Kazakhstan,

Romania, Russia, Turkey, and Ukraine on December 29, 2005; Nigeria on February 8, 2006; India on February 22, 2006; Egypt on February 27, 2006; Niger on March 2, 2006; Albania, Azerbaijan, Cameroon, and Burma (Myanmar) on March 15, 2006; Israel on March 20, 2006; Afghanistan on March 21, 2006; and Jordan on March 29, 2006.

On April 3, 2006, OIE reported confirmation of highly pathogenic avian influenza H5N1 in guinea fowl in Burkina Faso. USDA added Burkina Faso to their ban on April 5, 2006. At this time, HHS/CDC is adding Burkina Faso to its current embargo. This action is effective on April 10, 2006, and will remain in effect until further notice.

SUPPLEMENTARY INFORMATION:

Background

An outbreak of avian influenza subtype H5N1 in guinea fowl has been reported at Gampéla, Kadiogo province, Burkina Faso.

Introduction of birds infected with highly pathogenic avian influenza H5N1 into the United States could lead to outbreaks of disease among birds and among the human population, a significant public health threat. Banning the importation of all avian species from affected countries is an effective means of limiting this threat. HHS/CDC is therefore taking this action to reduce the likelihood of introduction or spread of influenza A H5N1 into the United States.

Immediate Action

Therefore, pursuant to 42 CFR 71.32(b), HHS/CDC is amending the February 4, 2004, order to add Burkina Faso to the list of countries subject to the order's embargo of birds and products derived from birds. All other portions of the February 4, 2004, order, as further amended on March 10, 2004; September 28, 2004; December 29, 2005; February 8, 2006; February 22, 2006; February 27, 2006; March 2, 2006; March 15, 2006; March 20, 2006; March 21, 2006; and March 29, 2006, shall remain in effect until further notice.

Dated: April 13, 2006.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. E6-5841 Filed 4-18-06; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 2, 2006, from 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make a recommendation on the reclassification of the noninvasive bone growth stimulator indicated for the treatment of established nonunion fractures acquired secondary to trauma and as an adjunct to the treatment of lumbar spinal fusion surgery for one or two levels.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panel> (click on "Upcoming CDRH Advisory Panel/Committee Meetings").

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 19, 2006. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Time allotted for each presentation may be limited. Those

desiring to make formal oral presentations should notify the contact person before May 19, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks at 240-276-0450, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 12, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6-5783 Filed 4-18-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 2005D-0195

Guidance for Industry and FDA Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9." This guidance document is intended to assist facilities and their personnel in meeting the Mammography Quality Standards Act (MQSA) final regulations.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "The Mammography Quality Standards Act Final Regulations: