1767.71 Periods of retention.
1767.72–1767.85 [Reserved]

Subpart D—Preservation of Records

§ 1767.66 Purpose.

This subpart establishes policies and procedures for the effective preservation and efficient maintenance of financial records of Electric borrowers.

§ 1767.67 General.

(a) Rural Development endorses the guidelines as described by the Federal Energy Regulatory Commission's (FERC) ''Regulations to Govern the Preservation of Records of Public Utilities and Licensees.'' The FERC guidelines can be found in 18 CFR part 125.

(b) The regulations prescribed in this part apply to all books of account, contracts, records, memoranda, documents, papers, and correspondence prepared by or on behalf of the borrower as well as those which come into its possession in connection with the acquisition of property by purchase, consolidation, merger, etc.

(c) The regulations prescribed in this part shall not be construed as excusing compliance with any other lawful requirements for the preservation of records.

§ 1767.68 Designation of a supervisory official.

Each borrower shall designate one or more officials to supervise the preservation of its records.

§ 1767.69 Index of records.

(a) Each borrower shall maintain a master index of records. The master index shall identify the records retained, the related retention period, and the locations where the records are maintained. The master index shall be subject to review by Rural Development and Rural Development shall reserve the right to add records, or lengthen retention periods upon finding that retention periods may be insufficient for its purposes.

(b) At each office where records are kept or stored the borrower shall arrange, file, and index the records currently at that site so that they may be readily identified and made available to representatives of Rural Development.

§ 1767.70 Record storage media.

The media used to capture and store the data will play an important part of each Rural Development borrower. Each borrower has the flexibility to select its own storage media. The following are required:

(a) The storage media shall have a life expectancy at least equal to the applicable retention period provided for in the master index of records, unless there is a quality transfer from one media to another with no loss of data. Each transfer of data from one media to another shall be verified for accuracy and documented.

(b) Each borrower shall implement internal control procedures that assure the reliability of, and ready access to, data stored on machine-readable media. The borrower's internal control procedures shall be documented by a responsible supervisory official.

(c) Records shall be indexed and retained in such a manner that they are easily accessible.

(d) The borrower shall have the hardware and software available to locate, identify, and reproduce the records in readable form without loss of clarity.

(e) At the expiration of the retention period, the borrower may use any appropriate method to destroy records.

(f) When any records are lost or destroyed before the expiration of the retention period set forth in the master index, a certified statement shall be added to the master index listing, as far as may be determined, the records lost or destroyed and describing the circumstances of the premature loss or destruction.

§ 1767.71 Periods of retention.

(a) Records of Rural Development borrowers of a kind not listed in the FERC regulations should be governed by those applicable to the closest similar records. Financial requirement and expenditure statements, which are not specifically covered by FERC regulations, are recommended to be kept for one year after the ''as of date'' of Rural Development's loan fund and accounting review.

(b) Consumer accounts' records should be kept for those years for which patronage capital has not been allocated.

(c) Records supporting construction financed by Rural Development shall be retained until audited and approved by Rural Development.

(d) Records related to plant in service must be retained until the facilities are permanently removed from utility service, all removal and restoration activities are completed, and all costs are retired from the accounting records unless accounting adjustments resulting from reclassification and original costs studies have been approved by Rural Development or other regulatory body having jurisdiction.

(e) Life and mortality study data for depreciation purposes must be retained for 25 years or for 10 years after plant is retired, whichever is longer.

§ 1767.72–1767.85 [Reserved]

Dated: April 7, 2008.

James M. Andrew,

Administrator, Rural Utilities Service.

[FR Doc. E8–11264 Filed 5–23–08; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

[Docket No. APHIS–2006–0036]

RIN 0579–AC42

Exotic Newcastle Disease; Quarantine Restrictions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are making several changes to the exotic Newcastle disease domestic quarantine regulations, including adding an option for the movement of pet birds; adding restrictions on the interstate movement of live ratites out of quarantined areas; harmonizing our domestic and import regulations regarding the movement of dressed carcasses of dead birds and dead poultry; providing for the use of alternative procedures for treating manure and litter and for composting; and adding an additional surveillance period after the conditions for removing quarantine are met before quarantine is removed. We concluded that these changes are necessary based on our experiences during the eradication programs for the 2002–2003 outbreaks of exotic Newcastle disease in California, Arizona, Nevada, and Texas. In the event of an exotic Newcastle disease outbreak, these changes will help to ensure that exotic Newcastle disease does not spread from quarantined areas and that exotic Newcastle disease is eradicated within quarantined areas.

DATES: *Effective Date:* June 26, 2008.

FOR FURTHER INFORMATION CONTACT: Dr. Glen Garris, Director, National Veterinary Stockpile, National Center for Animal Health Emergency Management, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231; (301) 734–8073.

SUPPLEMENTARY INFORMATION:

Background

Exotic Newcastle disease (END) is a contagious and fatal viral disease affecting the respiratory, nervous, and

digestive systems of birds and poultry. END is so virulent that many birds and poultry die without showing any clinical signs. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. END can infect and cause death even in vaccinated poultry.

The regulations in ''Subpart A—Exotic Newcastle Disease (END)'' (9 CFR 82.1 through 82.16, referred to below as the regulations) were established to prevent the spread of END in the United States in the event of an outbreak. These regulations specify the conditions under which certain articles, including live birds and live poultry, dead birds and dead poultry, manure and litter, eggs other than hatching eggs, hatching eggs, and vehicles and conveyances, may be moved out of areas listed in § 82.3 as quarantined for END.

On March 27, 2006, we published in the **Federal Register** (71 FR 15047–15059, Docket No. APHIS–2006–0036) a proposal [1] to amend the regulations by adding an option for the movement of pet birds; adding restrictions on the interstate movement of live ratites out of quarantined areas; harmonizing the domestic and foreign regulations regarding the movement of dressed carcasses of dead birds and dead poultry, including one change to the importation regulations; providing for the use of alternative procedures for treating manure and litter and for composting; and adding an additional surveillance period after the conditions for removing quarantine are met before quarantine is removed.

The changes we proposed were based on experience we gained during our most recent eradication effort for END. Between November 21, 2002, and September 16, 2003, areas of the States of California, Arizona, Nevada, New Mexico, and Texas were quarantined due to the presence of END. In order to make better decisions on how to eradicate END from those areas, we completed several risk assessments and epidemiological investigations in the context of our activities under the regulations. The experience we gained during those outbreaks in enforcing the regulations and conducting the risk assessments and epidemiological investigations informed the proposed rule. (The risk assessments are available from the person listed under **FOR FURTHER INFORMATION CONTACT**.)

We solicited comments concerning our proposal for 60 days ending May 26, 2006. We received seven comments by that date. They were from producers and private citizens. They are discussed below by topic.

Other Live Birds, Including Ratites

The regulations in § 82.5(b) provide that birds other than pet birds and poultry not known to be infected with or exposed to END are allowed to be moved interstate from an area quarantined for END only if the following conditions are met:

- They are accompanied by a permit;
- They are covered in such a way as to prevent feathers and other debris from blowing or falling off the means of conveyance;
- They are moved in a means of conveyance either under official seal or are accompanied by a Federal representative;
- They are not unloaded until their arrival at their destination listed on the permit, except for emergencies; and
- The permit is presented upon arrival at the destination and copies of the permit are submitted so that a copy is received by the State animal health official and the veterinarian in charge for the State of destination within 72 hours of arrival.

Birds other than poultry are required to be moved to a site approved by the Administrator. Poultry are required to be moved to a recognized slaughtering establishment and must be slaughtered within 24 hours of arrival at such an establishment; the required permit must be presented to a State or Federal representative upon arrival at such an establishment.

We proposed to amend the regulations to place the same requirements on ratites moved interstate from a quarantined area as we do on poultry. The term ''ratites'' encompasses cassowaries, emus, kiwis, ostriches, and rheas. Surveillance of these birds for infection with END is more difficult than surveillance of poultry. Detection of virus shedding in live ratites is unpredictable. Examiners may not always be able to detect END infection by examination or testing of swabs for virus, which are the standard procedures for testing other birds whose movement is regulated under § 82.5(b). Tissue samples can provide additional certainty in diagnosing END; however, while the death loss rates in production flocks of poultry mean that tissue samples are normally available for testing, the death loss rates in flocks of ratites are much lower, meaning that tissue samples of ratites may be unavailable. The relative lack of dead ratites for surveillance purposes also means that tests on tissues of dead ratites are less reliable than tests on tissues of dead poultry. For these reasons, no consensus exists on optimal surveillance techniques for END in live ratites. This means that any determination that ratites to be moved interstate from a quarantined area are not known to be infected with END is, at best, uncertain.

In addition, it is often difficult to determine whether ratites have been exposed to END; they are mostly maintained in outdoor pens or in backyard flocks, which are often less biologically secure than the facilities in which commercial flocks of poultry are maintained. Ratites that have been kept in these conditions within a quarantined area may, therefore, be more likely to have been exposed to END than other birds kept under more biologically secure conditions. Finally, ratites typically live in highly concentrated populations, meaning that END could be spread quickly by an infected or exposed ratite moved interstate from a quarantined area.

Slaughtering and disposing of live poultry moved interstate from a quarantined area, as required by § 82.5(b), ensures that END virus is not spread from any poultry that, despite not being known to be infected with or exposed to END, may pose a risk of spreading the END virus during interstate movement. We proposed to require that ratites be moved to slaughter under the same conditions as live poultry to ensure that the END virus would not be spread through the movement of ratites from quarantined areas.

We received three comments on this proposed change. All three of the commenters opposed the change, stating instead that ratites should be treated similarly to other birds and allowed to move from the quarantined area without moving directly to slaughter. Instead, the commenters favored testing and holding the ratites under quarantine until they were proved not to be infected with END. Two of the commenters stated that there are tests that can identify END in ratites, making such a policy feasible.

We agree that there are methods that can be used to test ratites for END. As discussed in the proposed rule, however, surveillance of these birds for infection with END is more difficult than surveillance of poultry. Detection of virus shedding in live ratites is unpredictable. Examiners may not always be able to detect END infection by examination or testing of swabs for virus, which are the standard procedures for testing other birds whose movement is regulated by § 82.5(b). Tissue samples can provide additional

[1] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0036.*

certainty in diagnosing END; however, while the death loss rates in production flocks of poultry mean that tissue samples are normally available for testing, the death loss rates in flocks of ratites are much lower, meaning that tissue samples of ratites may be unavailable. For these reasons, no consensus exists on optimal surveillance techniques for END in live ratites. Given that and the other risk factors described above, we believe that the risk associated with the interstate movement of ratites is similar to that associated with the interstate movement of poultry, and that the same restrictions on that movement are warranted.

One commenter stated that her own research had not shown ostrich to be especially susceptible to END or to have been a factor for the spread of END during the 2002–2003 END outbreaks.

During the 2002–2003 END outbreaks, we required ratites moved interstate from the quarantined area to be moved directly to slaughter, based on a risk assessment we conducted. This risk assessment and our experience in the 2002–2003 END outbreak led us to propose this change. The fact that ratites were not a factor for the spread of END during the 2002–2003 outbreak is therefore not inconsistent with the change we proposed.

Two of these commenters provided additional information for the section of our economic analysis that addressed the potential economic impact of this change, mostly related to the size of the ratite industry. We have used this information to update our economic analysis.

The commenters additionally expressed concern that the change would have catastrophic economic effects on the ratite industry.

Whenever END is detected in the United States, we will pursue eradication of the disease. Any quarantine for END would be temporary and local, thus minimizing the number of ratite operations affected by the requirement that ratites that are moved from the quarantined area be moved directly to slaughter. (Ratite flock owners whose flocks are not known to be infected with or exposed to END could also keep their flock in place during the quarantine.) The potential economic effects of this change, in the event of an END outbreak, are discussed in more detail under the heading ''Executive Order 12866 and Regulatory Flexibility Act'' later in this document.

Our proposed changes classified birds that could be moved from the quarantined area as pet birds, other birds, and poultry and ratites. One commenter, a racing pigeon association, recommended that racing pigeons be considered ''other birds'' rather than pet birds. The commenter stated that pets are essentially animals that are kept by humans for companionship; pigeon fanciers do not keep racing pigeons as pets, but as the necessary element in their hobby of breeding and racing pigeons. Racing pigeons are highly trained, fed careful diets, kept on a strict sanitary and medical regimen, and much prized for their athletic accomplishments. Pigeon fanciers do not look to their loft of birds, typically 60 to 100 in number, for companionship. The commenter also stated that racing pigeons are thoroughbreds and that championship birds can be worth thousands of dollars.

We agree with the commenter. During the 2002–2003 END outbreak, we considered racing pigeons to be ''other birds,'' and we will do so if another END outbreak occurs in the United States. Because the definition of *pet bird* in § 82.1 reads ''Any bird that is kept for personal pleasure and is not for sale,'' and because the commenter has presented convincing evidence that racing pigeons meet neither of these criteria, we believe that the regulations already accommodate the policy suggested by the commenter.

Other Comments

One commenter stated that the proposed rule was not in accord with the Terrestrial Animal Health Code published by the World Organization for Animal Health (OIE), specifically Chapter 2.7.13, Newcastle Disease, and Chapter 1.3.5, Zoning and Compartmentalization.[2]

The Terrestrial Animal Health Code is designed to provide a science-based reference document for international trade in animals and animal products. OIE guidelines are not intended to be prescriptive; each member nation sets its regulatory policy based not only on the Code but also on, among other things, local conditions. The commenter did not specify what provisions of the proposed rule were inconsistent with the Terrestrial Animal Health Code. We believe the changes we proposed are appropriate for eradicating END within the United States. We are making no changes in response to this comment.

One commenter stated that poultry become infected with END when they are kept in conditions that adversely affect their welfare. This commenter also stated that the interstate movement of poultry should not be allowed for any reason.

Poultry become infected with END when they are exposed to its causal virus. We may restrict the movement of poultry or any other animal only to the extent that such restrictions are necessary to prevent the introduction or spread of a pest or disease of livestock.

One commenter recommended that we require the complete and immediate incineration of all poultry carcasses known to be infected with END. The commenter recommended that we accomplish this by requiring all poultry producers to have a dual-chambered, environmentally safe incinerator on their premises. The commenter stated that such a requirement would eliminate the risk associated with moving the carcasses of infected poultry from a premises to an incinerator.

The commenter is correct that such a policy would directly address the risk associated with the movement of carcasses of infected poultry. However, we believe that the movement of such carcasses to an incinerator can be done safely if biological security protocols are followed. Therefore, an on-premises incinerator requirement is unnecessary. We will continue to work with States and industry to determine the safest and most efficient ways to dispose of carcasses of poultry infected with or exposed to END and other highly virulent poultry diseases.

Miscellaneous Change

The regulations in 9 CFR 94.6 address the importation into the United States of carcasses of game birds from regions where END is considered to exist. Paragraph (b)(1) of this section allows the carcasses of game birds to be imported into the United States as long as they are eviscerated and their heads and feet have been removed. In the proposed rule, we stated that the importation of such carcasses poses a high risk of introducing END into the United States and proposed to remove and reserve paragraph § 94.6(b)(1).

Since the publication of the proposed rule, we have completed a more thorough risk assessment of the risk associated with importing carcasses of game birds, as part of a risk assessment supporting the development of regulations for the importation of poultry and poultry products from regions where highly pathogenic avian influenza exists. This risk assessment, which will be published in completed form along with a rule proposing such regulations, indicates that the risk of disease introduction associated with the importation of game bird carcasses under the conditions specified in

[2] The Terrestrial Animal Health Code can be viewed on the Internet at *http://www.oie.int/eng/normes/mcode/en_sommaire.htm.*

§ 94.6(b)(1) is actually low. The carcass preparation process for game birds makes the tissue unsuitable for virus survival, and game bird carcasses typically do not come into contact with poultry populations, because the carcasses are intended for home display. Therefore, this final rule withdraws that proposed amendment and leaves § 94.6(b)(1) unchanged.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the change discussed in this document.

This final rule also serves to affirm the last 4 interim rules in a series of 10 interim rules we published between November 2002 and September 2003. The first six interim rules amended the regulations in part 82 by adding portions of Arizona, California, Nevada, New Mexico and Texas to the list in § 82.3 of areas quarantined for END; the final four interim rules subsequently removed all those areas from that list. The 10 interim rules elicited a total of 11 comments, only 2 of which were germane to the action taken in the interim rule (*i.e.*, the addition or removal of an area from quarantine). In both cases, the commenters pointed out the need for adequate surveillance to ensure the complete eradication of END in an area before it is removed from quarantine. In this final rule, we supplement the conditions for removing an area from quarantine by requiring an additional surveillance period after those conditions have been met before the quarantine will be removed. As noted in the proposed rule, we made that amendment based on information gained during the 2002–2003 END outbreak, which includes the information contained in the comments we received on the interim rules.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are making several changes to the END domestic quarantine regulations, including adding an option for the movement of pet birds; adding restrictions on the interstate movement of live ratites out of quarantined areas; harmonizing our domestic and import regulations regarding the movement of dressed carcasses of dead birds and dead poultry; providing for the use of alternative procedures for treating manure and litter and for composting; and adding an additional surveillance period after the conditions for removing quarantine are met before quarantine is removed. We concluded that these changes are necessary based on our experiences during the eradication programs for the 2002–2003 outbreaks of END in California, Arizona, Nevada, and Texas. In the event of an END outbreak, these changes will help to ensure that END does not spread from quarantined areas and that END is eradicated within quarantined areas.

END, also known as velogenic viscerotropic Newcastle disease, is a highly contagious and fatal viral disease affecting all species of birds. END is one of the most infectious and virulent diseases of poultry in the world, and the infection often results in many birds dying before demonstrating any clinical signs of infection. In unvaccinated poultry flocks, END has a death rate of close to 100 percent. Moreover, the mortality rates in vaccinated flocks are 10 to 20 percent, clearly showing that vaccination does not guarantee complete protection against END.

END was first identified in the United States in 1950 in California. The outbreak was traced to game birds and pheasants imported from Hong Kong. The disease spread to five poultry farms in Contra Costa County, but was quickly eliminated by destroying infected chickens. In 1971, a major outbreak of END occurred in California commercial poultry and lasted for 2 years. As a result of that outbreak 1,341 infected flocks were identified, and almost 12 million birds were destroyed. The eradication program cost taxpayers $56 million ($228 million in 2002 dollars), severely disrupted the operations of many producers, and increased the prices of poultry and poultry products to consumers.

On October 1, 2002, END was confirmed in backyard poultry in Southern California. The disease spread from backyard poultry to commercial poultry operations in California, backyard poultry in Nevada and Arizona, and poultry in Texas. The U.S. Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS) took the lead in END eradication efforts. Immediately a task force of over 1,500 people from APHIS, the California Department of Food and Agriculture, and other State and Federal agencies combined forces to fight this devastating disease. Almost 4 million birds were destroyed to contain the spread of END.

Economic Analysis

The final rule change to the END regulations will have an effect on all persons and entities handling birds of any type, including farm and commercial operations, backyard flock owners and enthusiasts, and pet bird owners in an END quarantined area wishing to engage in interstate movement. While accurate statistics on farm and commercial operations in the United States are readily available, there is a significant information gap on the backyard flocks and pet bird owners. As such, we have no way of quantifying the true number of persons affected by these changes.

The United States is the world's largest producer of poultry meat and the second-largest egg producer behind China. Preliminary reports for the year 2005 indicate there were a total of 452.8 million chickens, excluding commercial broilers, with a cash value of over $1.133 billion. In 2004 broiler production, raised for the purpose of meat production, totaled 8.7 billion birds, with a combined live weight of over 45.7 billion pounds. The value of broiler production for that year was over $20.4 billion. In 2004, the last full report available, there were over 89 billion eggs produced with a cash value of over $5.3 billion.[3] Preliminary statistics for 2004 indicate that turkey production totaled over 264 million birds with a combined live weight of 7.3 billion pounds and a cash value of over $3 billion.[4]

The U.S. poultry industry plays a significant role in international trade. In fact, the United States is the world's largest exporter of turkey products, and the second largest exporter of broilers. In 2005, broiler exports totaled 5.1 billion pounds, valued at $2.1 billion.[5] Turkey exports for the same year totaled over 541 million pounds, with a total value of about $369 million. In addition, 61.8 million dozen shell eggs for consumption, and 55 million pounds of egg products were exported in 2005.[6] The presence of END in the United States would significantly reduce our ability to be competitive in international markets in the trade of poultry and poultry products. By extension, any efforts made to contain and prevent the spread of END throughout the United States would serve to enhance our reputation for providing high-quality products. Thus, the changes in this rule

[3] USDA, *Agricultural Statistics 2006*. Washington, D.C.: National Agricultural Statistics Service, 2006. Estimates cover the 12-month period, December 1 of the previous year through November 30.

[4] USDA, *Agricultural Statistics 2006*. Estimates based on turkeys placed September 1, 2003 through August 31, 2004 and excludes young turkeys lost.

[5] USDA–ERS, *Background Statistics on U.S. Broiler Industry*. Washington, D.C.: Economic Research Service, 2006.

[6] USDA–FAS, *U.S. Trade Statistics*. Washington, D.C.: Foreign Agricultural Service, 2006.

will benefit the commercial poultry industry by increasing product marketability, both domestically and internationally.

This final rule also impacts the movement of ratites out of a quarantined area. Ratites are a family of flightless birds with small wings and flat breastbones. Domestic production of ratites is limited to ostriches and emus. This alternative livestock industry is still in its infancy, so new in fact that ratites have only been under mandatory USDA inspection since April 22, 2002, and were first included as a separate line item in the 2002 USDA Census of Agriculture. Ostrich was the first ratite to be raised in the United States. According to the 2002 Census of Agriculture, there are 5,224 farms raising a total of 48,221 emus, and 1,643 farms holding an inventory of 20,560 ostriches. Additionally, there were 15,682 emus and 16,038 ostriches sold according to Census data.[7] Ostriches are raised primarily for meat, with an average bird yielding about 75–100 pounds of meat, whereas emus are raised primarily for oil. According to American Ostrich Association (AOA) estimates, approximately 500,000 to 750,000 pounds of ostrich meat were processed from domestically produced ostrich in 2005, with a slaughter price of $1 per pound live weight. Due to a fluctuating market for oil, the value of emu production is indeterminate at this time. While U.S. farms raising ratites can have an inventory ranging from 2 to 2,000 birds, the AOA estimates that there are probably less than a dozen farms in the United States with 100 or more birds.[8] Based on these estimates, as well as Census data, we can assume the majority of ratite farmers would be considered small entities by SBA standards.[9]

Comments on the interim rule expressed concern over the continued presence of the U.S. ratite industry in light of movement restrictions put in place by this rule. However, we feel confident in our position that the ratite industry will not be significantly affected by this rule, especially not to the extent that the industry will no longer be viable. This rule will only affect those ratite owners located in an area quarantined for END who wish to move their ratites interstate. It is important to note that any area deemed necessary to be quarantined will be as small as possible, and will only be quarantined for a limited period of time, until the disease is eradicated. Farms raising ostriches and emus within the quarantined area will have the option of moving their birds directly to slaughter. The rule will impact ratite owners located in a quarantined area that move day-old or infant ratite birds interstate to farms where the birds are then raised, but we do not believe this impact will be significant, especially considering the quarantine would be in place for a limited time.

In addition, the regulations will affect backyard poultry not kept for commercial sale and pet owners in the quarantined area, the number of which is indeterminate. Although the specific numbers of persons in this category are unknown, we feel safe in determining that the impact of this regulation will not be significant as it only affects those owners located within a quarantined area for the limited time the quarantine is actually in place. The remainder of this analysis will consider each of the major changes in the final rule individually and examine the expected benefits and costs.

Live Pet Birds

The regulations in § 82.5 have prohibited the movement of pet birds out of a quarantined area unless they have been in the owner's control for 90 days. The final rule adds a new option that allows pet birds, except those that are imported for eventual resale as pets, that have been in the owner's control for less than 90 days to be moved out of the quarantined area if they enter a 30-day quarantine at a USDA quarantine station outside of the quarantined area and meet all other requirements for movement. There is a user fee of $390 to enter into this 30-day USDA quarantine station. Entering into this quarantine station is voluntary and is meant to increase the flexibility for pet owners who have been in control of their pet birds for less than 90 days. Intuitively, we expect only those pet owners who consider the value of protecting and moving their birds out of the quarantine area to be higher than the expense of the $390 fee to voluntarily enter the USDA facility. While that does pose an expense to pet owners, in light of the fact that the option allows for interstate movement where the regulations otherwise do not, it is safe to assume the cost is not overly burdensome for those pet owners deciding to enter their birds into the USDA facility.

Those birds that are imported for eventual resale as pets, which fall under the added definition of commercial birds, are not bound by the restrictions in § 82.5(a). Current regulations require that commercial birds be imported from and into biologically secure facilities. As such, birds imported for eventual resale as pets have already met the necessary requirements to be determined free of END. This amendment is more of a clarification rather than an actual change in movement requirements. Generally, END regulations governing pet birds are more restrictive than for other birds due to the fact that there are fewer biological security measures in place, and pet birds are thus more vulnerable to contracting and spreading END.

Other Live Birds, Including Ratites

Ratites tend to be housed in outdoor pens or backyard flocks, thereby making surveillance of these birds for END more difficult. Also, virus detection techniques that are widely used to detect END were inconclusive when used on ratites. Combined, this creates a situation where infection of ratites in a quarantined area is highly possible and detection is uncertain, thus increasing the risk for widespread END dissemination. Consequently, this final rule amends § 82.5(b)(5) to prohibit interstate movement of ratites from an area quarantined for END unless they are moved to a recognized slaughtering establishment and slaughtered within 24 hours of arrival at that establishment.

Previously, ratites not known to be infected with or exposed to END were allowed to move interstate as long as they were accompanied by a permit. Coupled with the knowledge that epidemiological tests for END were inconclusive in ratites, this created a situation where the dissemination of END was possible. In situations where ratites were thought to be exposed to END, these flocks were depopulated and the owners were paid indemnity based on current market values. While this rule places additional restrictions on the movement of ratites from areas quarantined because of END, we do not believe the economic effects of this rule will be significant. Even though the interstate movement of ratites from a quarantined area must be directly to slaughter, the marketability of meat and oil, which are the primary markets for the ratite industry, are not adversely affected by this movement restriction. Essentially, this change in the regulations seeks to increase biological

[7] USDA, *2002 Census of Agriculture—Table 27*. Washington, D.C.: National Agricultural Statistics Service, 2006.

[8] Source: Dianna Westmoreland and Carole Price of the AOA, through submitted comments and personal communication.

[9] A small ratite farm is one having $750,000 or less in annual receipts. North American Industry Classification System (NAICS) code 112390, ''Other Poultry Production,'' which includes duck, emu, geese, ostrich, pheasant, quail and ratite production. Table of Size Standards based on NAICS 2002. Washington, D.C.: U.S. Small Business Administration, effective July 31, 2006.

security measures by restricting the movement of ratites from quarantined areas. We do not expect the economic impacts to affected producers of ratites to be significant.

Dressed Carcasses of Dead Birds and Dead Poultry

We will harmonize § 82.6 with the regulations in § 94.6 under which carcasses, and parts or products of carcasses, of birds and poultry may be imported into the United States from an area where END is considered to exist. The principal effect of this change will be to prohibit any movement of uncooked bird or poultry meat out of a quarantined area. Only meat that has both been packed in hermetically sealed containers and cooked by a commercial method after packing to produce articles that are shelf-stable without refrigeration, or cooked so that it has a thoroughly cooked appearance throughout, will be allowed to move from the quarantined area. The regulations had not required sealing and commercial cooking, so these new regulations are intended to provide a higher level of protection against the spread of END. The cost burdens of these changes are fairly obvious for those producers in a quarantined area engaged in the interstate movement of dead birds and poultry. Specifically, these costs include gathering materials to seal the dead birds or poultry; the expense of electricity and/or gas, and perhaps equipment, needed to commercially cook the dead birds or poultry, and the additional labor costs associated with this change. These costs vary by producer. We do not anticipate these costs will significantly impact producers, the majority of which are small entities. The major benefit of this change, outside of increasing safeguards against END, is to harmonize our domestic requirements for movement out of a quarantined area with our import requirements for dressed carcasses from regions where END is known to exist.

Manure and Litter

Previously the only way manure and litter used by birds and poultry not known to be infected with END could be moved interstate from a quarantined area was by heating throughout to a temperature of not less than 175 °F along with other requirements. This rule will provide producers with additional flexibility by providing for the use of any alternative treatment that is determined by the Administrator to be adequate in preventing the dissemination of END. This change would result in a potential decrease in cost, as we assume producers are profit-maximizing entities; hence, it is safe to assume any alternative treatment proposed and accepted will be cheaper than the heat treatment previously required. As such, it is hard to quantify the actual cost savings of this change in the regulations as it will vary based on the alternative chosen.

Also, this rule establishes a procedure under which composted manure and/or litter from infected premises will be allowed to move outside the quarantined area. The regulations in § 82.7(a)(2) have prohibited the movement from a quarantined area of any manure or litter from infected premises, so this amendment will allow producers greater flexibility. Thus, we expect that producers will benefit by having greater flexibility and the opportunity to decrease their present costs by looking into additional options for the disposal of manure and litter.

Eggs, Other Than Hatching Eggs

This final rule adds performance standards for processing plants that prepare eggs for eventual sale. In an effort to increase biological security at these sites, these processing plants will have to meet several standards, including:

- Physically separating processing and layer facilities, the incoming and outgoing eggs by quarantined and non-quarantined areas, and any flocks that may reside at the processing plant.
- Putting in place adequate controls to ensure processing plants are not exposed to END by any outside sources (i.e. those persons higher up in the vertical chain of production).
- Disinfecting equipment in accordance with 9 CFR part 71 at intervals deemed appropriate by the Administrator, so that there is less of a chance the equipment will transmit END to the eggs being processed.

Implementing these biological security standards will pose some burdens on processing plants. The actual cost imposed is indeterminable, because that will vary by processing plant. However, it is of note that the majority of these standards have to do with modifications in the procedures rather than any sort of capital investment. As such, it is not expected that processing plants will incur a significant economic burden by conforming to these standards.

Hatching Eggs

This change in the regulations will better harmonize domestic requirements for the movement of hatching eggs from a quarantined area with the import requirements for hatching eggs from regions where END is considered to exist. As a result, persons wishing to move hatching eggs out of a quarantined area must now follow the procedures in the National Poultry Improvement Plan for sanitizing hatching eggs, as found in 9 CFR 147.22 and 147.25. By harmonizing our domestic requirements with our import requirements, the conditions governing the movement of hatching eggs out of quarantined areas will be slightly more restrictive. However, this change is not expected to pose a significant economic burden upon affected entities.

Removal of Quarantine

Finally, before the quarantine is lifted, birds and poultry that died from any cause other than slaughter, along with accompanying manure and litter generated by these birds and poultry, must be disposed of using an approved method, including composting. This final rule will allow the use of any alternative composting treatment that is determined by the Administrator to be adequate to prevent the dissemination of END. This amendment is expected to produce cost savings, as we would expect producers to only adopt alternative treatment mechanisms that are cheaper than those currently prescribed. In addition, the regulations will require follow-up surveillance after a quarantined area has fulfilled all requirements to have the quarantine lifted. The time period necessary to conduct this follow-up surveillance will be determined by the Administrator of APHIS. This additional observation period will ensure the quarantine is not lifted prematurely.

Impact on Small Entities

This final rule's amendments to the regulations are intended to ensure that any future END outbreaks in the United States are contained to as small an area as possible while allowing emergency authorities the flexibility to choose the methods best suited to meet that goal. Costs of complying with the regulations are relatively minimal and for the most part are not borne by producers. Specifically, there will be a user fee of $390 to enter the 30-day USDA quarantine station for those pet owners in control of their pets for less than 90 days wishing to move their birds interstate. In order to comply with those regulatory changes that will harmonize domestic and import regulations for END, producers located within the quarantined area wishing to engage in interstate movement of dead birds and poultry must sustain the costs relating to sealing and commercially cooking the birds. In the case of processing plants,

the costs inherent in complying with the change in the regulations are not expected to require capital investment; rather, there will be the cost of extra labor and materials required with respect to meeting the amended standards. Finally, State and/or Federal Governments, depending on the type of quarantine, must shoulder the cost of inspection and certification of hatching eggs from a quarantined area. The benefits of the changes in this rule aimed at ensuring more efficient and effective END containment and eradication efforts are numerous. In many cases, the actual benefit in monetary terms is not possible to quantify. For example, pet bird owners in control of their pets for less than 90 days are afforded the opportunity to move their pets from the quarantined area. Alternative treatment procedures for moving manure and litter from a quarantined area will be considered and accepted by APHIS, thus lifting some of the cost burdens previously faced by producers. Most importantly, the changes in this final rule are intended to reduce and even eliminate biological security hazards associated with END. The costs of compliance are insignificant in comparison to the benefits of containing and eradicating END in domestic flocks. Therefore, APHIS believes the net benefit of this rule will be positive.

The Regulatory Flexibility Act requires that agencies consider the economic impact of a regulation on small entities. The 2002 Agricultural Census estimated there were 83,381 domestic poultry and egg farms, with a total market value over $23.9 billion. Unfortunately, concrete information on the size distribution is unknown, but the census does indicate that only 8,791, or 10.5 percent, of those poultry operations have sold between $500,000 and $999,999 in market value of agricultural products.[10] Also, as was mentioned on the outset, the ratite farming industry is in its infancy. Therefore, it would be safe to assume that the majority of poultry operations in the United States are classified as small entities.[11] While we acknowledge that these small entities will incur some costs of compliance, we do not believe these costs are significant. Further, it is vital to remember that this final rule affects only those small poultry operations located within an area quarantined for END, and only for as long as the quarantine is in place.

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 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 in conflict 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 final 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 for 9 CFR Part 82

Animal diseases, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 9 CFR part 82 as follows:

PART 82—EXOTIC NEWCASTLE DISEASE (END) AND CHLAMYDIOSIS

■ 1. The authority citation for part 82 continues to read as follows:

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

■ 2. Section 82.1 is amended as follows:

■ a. By removing the definition of *pet bird*.

■ b. By adding, in alphabetical order, definitions of *commercial birds, pet birds*, and *ratites* to read as set forth below.

■ c. By revising the definition of *dressed carcasses* to read as set forth below.

§ 82.1 Definitions.

* * * * *

Commercial birds. Birds that are moved or kept for resale, breeding, public display, or any other purpose, except pet birds.

Dressed carcasses. Carcasses of birds or poultry that have been eviscerated, with heads and feet removed, or parts or products of such carcasses.

* * * * *

Pet birds. Birds, except ratites, that are kept for the personal pleasure of their individual owners and are not intended for resale.

* * * * *

Ratites. Cassowaries, emus, kiwis, ostriches, and rheas.

* * * * *

§ 82.4 [Amended]

■ 3. In § 82.4, paragraph (a)(2) is amended by adding the words ‘‘, except as provided in § 82.7(b)’’ after the word ‘‘END’’.

■ 4. Section 82.5 is amended as follows:

■ a. By revising paragraph (a) and the introductory text of paragraph (b) to read as set forth below.

■ b. In paragraph (b)(5), by adding the words ‘‘or ratites’’ after the word ‘‘poultry’’ each time it occurs.

§ 82.5 Interstate movement of live birds and live poultry from a quarantined area.

(a) *Pet birds.* An individual may move his or her pet birds interstate from a quarantined area only if the birds are not known to be infected with or exposed to END and the following requirements are fulfilled:

(1) *Epidemiological and testing requirements.* For all pet birds moved interstate, epidemiological evidence must indicate that the birds are not infected with any communicable disease.

(i) *Pet birds that have been under the control and ownership of the owner for at least 90 days.* Pet birds that have been under the ownership and control of the individual to whom the permit is issued for the 90 days before interstate movement, show no clinical signs of sickness (such as diarrhea, nasal discharge, ocular discharge, ruffled feathers, or lack of appetite) during the 90 days before interstate movement, and have been maintained apart from other birds and poultry in the quarantined area during the 90 days before interstate movement may be moved to a location outside the quarantined area for subsequent examination. The individual to whom the permit is issued must maintain ownership and control of the birds and maintain them apart from other birds and poultry from the time they arrive at the place to which the individual is taking them until a Federal

[10] USDA, *2002 Census of Agriculture, Table 56.* Washington, DC: National Agricultural Statistics Service, 2006.

[11] A small chicken egg operation is one having $10.5 million or less in annual receipts. All other poultry products and meat operations are small if they have $750,000 or less in annual receipts. Table of Size Standards based on NAICS 2002. Washington, DC: U.S. Small Business Administration, effective July 31, 2006.

representative or State representative [3] examines the birds and determines that the birds show no clinical signs of END. The examination will not be less than 30 days after the interstate movement. The individual to whom the permit is issued must allow Federal representatives and State representatives to examine the birds at any time until they are declared free of END by either a Federal veterinarian or a State veterinarian.

(ii) *All other pet birds.* Pet birds that do not meet the criteria in paragraph (a)(2)(i) of this section may only be moved to a USDA-approved quarantine facility outside the quarantined area for a 30-day quarantine before being released. The individual to whom the permit is issued must maintain ownership and control of the birds and maintain them isolated from other birds or poultry until the time they arrive at the USDA-approved quarantine facility. The pet bird owner is responsible for all costs associated for keeping his or her pet birds at the USDA-approved quarantine facility for the 30-day quarantine period.

(2) *Movement restrictions.* All pet birds must be moved interstate from a quarantined area under the following conditions:

(i) The birds are accompanied by a permit obtained in accordance with § 82.11.

(ii) The birds are moved interstate by the individual to whom the permit is issued.

(iii) The birds are caged while being moved interstate.

(iv) Within 24 hours of a bird's dying or showing clinical signs of sickness (such as diarrhea, nasal discharge, ocular discharge, ruffled feathers, or lack of appetite), the individual to whom the permit is issued notifies the veterinarian in charge or the State animal health official [4] in the State to which the birds are moved.

(v) The individual to whom the permit is issued submits copies of the permit so that a copy is received by the State animal health official and the veterinarian in charge for the State of destination within 72 hours of the arrival of the birds at the destination listed on the permit.

(b) *Other birds (including commercial birds) and poultry.* Except as provided for pet birds in paragraph (a) of this section, a person may move live birds (including commercial birds) and live poultry that are not known to be infected with or exposed to END interstate from a quarantined area only if:

* * * * *

■ 5. In § 82.6, paragraph (b) is revised to read as follows.

§ 82.6 Interstate movement of dead birds and dead poultry from a quarantined area.

* * * * *

(b) Dressed carcasses from birds and poultry that are not known to be infected with END may be moved interstate from a quarantined area only if:

(1) The dressed carcasses are from birds or poultry that were slaughtered in a recognized slaughtering establishment; [6]

(2) The dressed carcasses have been processed in one of the following ways:

(i) They are packed in hermetically sealed containers and cooked by a commercial method after such packing to produce articles which are shelf-stable without refrigeration; or

(ii) They have been thoroughly cooked and have a thoroughly cooked appearance throughout;

(3) If the dressed carcasses are from poultry, the processing establishment that treats the dressed carcasses in accordance with paragraph (b)(2) of this section employs the following safeguards:

(i) If receiving or handling any live poultry, there must be complete separation between the slaughter portion of the establishment and the portions of the establishment in which further processing takes place;

(ii) If the plant processes dressed carcasses from both quarantined and nonquarantined areas, all areas, utensils, and equipment likely to contact the poultry carcasses to be processed, including skimming, deboning, cutting, and packing areas, are cleaned and disinfected in accordance with part 71 of this chapter between the processing of dressed poultry carcasses from the quarantined area and the processing of dressed poultry carcasses from nonquarantined areas;

(iii) The dressed carcasses are stored in a manner that ensures that no cross-contamination with potentially infectious materials, such as raw or unprocessed products, occurs;

(4) The dressed carcasses are accompanied by a permit obtained in accordance with § 82.11;

(5) The dressed carcasses are moved in a means of conveyance either under official seal or accompanied by a Federal representative;

(6) The dressed carcasses are not unloaded until their arrival at the destination listed on the permit required by paragraph (b)(4) of this section;

(7) The dressed carcasses are moved, without stopping, to the destination listed on the permit required by paragraph (b)(4) of this section, except for normal traffic conditions, such as traffic lights and stop signs; and

(8) Copies of the permit accompanying the dressed carcasses are submitted so that a copy is received by the State animal health official and the veterinarian in charge for the State of destination within 72 hours of the arrival of the dressed carcasses at the destination listed on the permit required by paragraph (b)(4) of this section.

* * * * *

■ 6. Section 82.7 is amended as follows:

■ a. By redesignating paragraphs (a), (b), (c), and (d) as paragraphs (a)(1), (a)(2), (a)(3), and (a)(4), respectively, and designating the introductory text of the section as paragraph (a).

■ b. In newly redesignated paragraph (a)(2), by adding the words ''or subjected to any other treatment approved by the Administrator as being adequate to prevent the dissemination of END'' after the words ''not less than 175 °F (79.4 °C)''.

■ c. By adding a new paragraph (b) to read as set forth below.

§ 82.7 Interstate movement of manure and litter from a quarantined area.

* * * * *

(b) Compost derived from manure generated by and litter used by birds or poultry known to be infected with END may be moved interstate from a quarantined area only if:

(1) The manure and litter is accompanied by a permit obtained in accordance with § 82.11;

(2) All birds and poultry have been removed from the premises where the manure or litter is held;

(3) After all birds are removed from the premises where the manure or litter is held, all manure and litter inside and outside the bird or poultry house remains undisturbed for at least 28 days before being moved from the infected premises for composting;

(4) Composting is done at a site approved by the Administrator and under a protocol approved by the Administrator as being adequate to prevent the dissemination of END. All

[3] The location of Federal representatives and State representatives may be obtained by writing to Emergency Programs, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road, Unit 41, Riverdale, MD 20737–1231.

[4] The location of the veterinarian in charge or the State animal health official may be obtained by writing to Emergency Programs, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road, Unit 41, Riverdale, MD 20737–1231, or by referring to the local telephone book.

[6] See footnote 5 to § 82.5.

manure and litter from the infected premises must be moved to the composting site at the same time;

(5) Following the composting process, the composted manure or litter remains undisturbed for an additional 15 days before movement;

(6) After this 15-day period, all of the composted manure or litter from the infected site is removed at the same time;

(7) The resulting compost must be transported either in a previously unused container or in a container that has been cleaned and disinfected, since last being used, in accordance with part 71 of this chapter;

(8) The vehicle in which the resulting compost is to be transported has been cleaned and disinfected, since last being used, in accordance with part 71 of this chapter; and

(9) Copies of the permit accompanying the compost derived from the manure and the litter are submitted so that a copy is received by the State animal health official and the veterinarian in charge for the State of destination within 72 hours of arrival of the compost at the destination listed on the permit.

■ 7. Section 82.8 is amended as follows:

■ a. In paragraph (a)(2), by removing the citation ''7 CFR part 59'' and adding the citation ''9 CFR part 590'' in its place.

■ b. By revising paragraph (a)(3) to read as set forth below.

§ 82.8 Interstate movement of eggs, other than hatching eggs, from a quarantined area.

(a) * * *

(3) The establishment that processes the eggs, other than hatching eggs, for sale establishes procedures adequate to ensure that the eggs are free of END, including:

(i) The establishment separates processing and layer facilities, the incoming and outgoing eggs at the establishment, and any flocks that may reside at the establishment;

(ii) The establishment implements controls to ensure that trucks, shipping companies, or other visitors do not expose the processing plant to END;

(iii) Equipment used in the establishment is cleaned and disinfected in accordance with part 71 of this chapter at intervals determined by the Administrator to ensure that the equipment cannot transmit END to the eggs, other than hatching eggs, being processed; and

(iv) The eggs are packed either in previously unused flats or cases, or in used plastic flats that were cleaned or disinfected since last being used, in accordance with part 71 of this chapter;

* * * * *

■ 8. Section 82.9 is amended as follows:

■ a. In paragraph (b), by removing the word ''and'' at the end of the paragraph.

■ b. By redesignating paragraph (c) as paragraph (d).

■ c. By adding a new paragraph (c) to read as set forth below.

§ 82.9 Interstate movement of hatching eggs from a quarantined area.

* * * * *

(c) The hatching eggs have been kept in accordance with the sanitation practices specified in § 147.22 and § 147.25 of the National Poultry Improvement Plan; and

* * * * *

■ 9. Section 82.14 is amended as follows:

■ a. In paragraph (c)(2), in the introductory text, by revising the second sentence to read as set forth below.

■ b. In paragraph (e)(2), by removing the first sentence and by adding two new sentences in its place to read as set forth below.

■ c. By adding a new paragraph (i) to read as set forth below.

§ 82.14 Removal of quarantine.

* * * * *

(c) * * *

(2) * * * The birds and poultry must be composted according to the following instructions or according to another procedure approved by the Administrator as being adequate to prevent the dissemination of END:

* * * * *

(e) * * *

(2) *Composting*. If the manure and litter is composted, the manure and litter must be composted in the quarantined area. The manure and litter must be composted according to the following method, or according to another procedure approved by the Administrator as being adequate to prevent the dissemination of END: Place the manure and litter in rows 3 to 5 feet high and 5 to 10 feet at the base. * * *

* * * * *

(i) After the other conditions of this section are fulfilled, an area will not be released from quarantine until followup surveillance over a period of time determined by the Administrator indicates END is not present in the quarantined area.

* * * * *

Done in Washington, DC, this 20th day of May 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–11741 Filed 5–23–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2006–P–0404] (Formerly Docket No. 2006P–0487)

Food Labeling: Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting as a final rule, without change, the provisions of the interim final rule that amended the regulation authorizing a health claim on noncariogenic carbohydrate sweeteners and dental caries, i.e., tooth decay, to include isomaltulose as a substance eligible for the health claim. FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective May 27, 2008.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 2007 (72 FR 52783), FDA published an interim final rule to amend the regulation in part 101 (21 CFR part 101) that authorizes a health claim on the relationship between noncariogenic carbohydrate sweeteners and dental caries (§ 101.80) to include the noncariogenic sugar isomaltulose. Under section 403(r)(3)(B)(i) and section 403(r)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i) and 343(r)(7)), FDA issued this interim final rule in response to a petition filed under section 403(r)(4) of the act. Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue a