overlap. Substitute domestic fruits whose markets might be affected by the importation of honeydew melons from Brazil would likely be other domestic melons, such as cantaloupe and watermelon. However, domestic cantaloupe and watermelon have the same growing/shipping season as domestic honeydew melons. Hence, their seasons also do not overlap with the season for honeydew melons from Brazil.

Therefore, it can be determined that allowing honeydew melons to be imported from Brazil will have no significant impact on U.S. producers, large or small. This is the case because the estimated amount of imports is very small in comparison to domestic production and also will be shipped after the U.S. growing season has come to an end.

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 12778

This final rule allows honeydew melons to be imported into the United States from Brazil. State and local laws and regulations regarding honeydew melons imported under this rule will be preempted while the fruit is in foreign commerce. Fresh honeydew melons are generally imported for immediate distribution and sale to the consuming public, and will remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases will be addressed on a case-by-case basis. No retroactive effect will be given to this rule; and this rule will not require administrative proceedings before parties may file suit in court.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule will be submitted for approval to the Office of Management and Budget.

List of Subjects in 7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, the regulations in 7 CFR part 319 are amended to read as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167; 21 U.S.C. 136a; 7 CFR 2.17, 2.51, and 371.2(c), unless otherwise noted.

2. In subpart—Fruits and Vegetables, to part 319, a new § 319.56–2aa is added to read as follows:

§ 319.56–2aa Administrative instructions governing the entry of honeydew melons from Brazil.

Honeydew melons may be imported into the United States from Brazil only under permit, and only in accordance with this section and all other applicable requirements of this subpart:

(a) *Area considered free of the South American cucurbit fly.* The honeydew melons must have been grown in the area of Brazil considered by the Animal and Plant Health Inspection Service to be free of the South American cucurbit fly, (*Anastrepha grandis*), in accordance with § 319.56–2(e)(4) of this subpart. In addition, all shipments of honeydew melons must be accompanied by a phytosanitary certificate issued by the Departamento de Defenso Sanitaria Vegetal (the Ministry of Agriculture of Brazil) that includes a declaration indicating that the melons were grown in this area. The following area is considered free of the South American cucurbit fly: that portion of Brazil bounded on the north by the Atlantic Ocean; on the east by the River Assu (Acu) from the Atlantic Ocean to the city of Assu; on the south by Highway BR 304 from the city of Assu (Acu) to Mossoro, and by Farm Road RN–015 from Mossoro to the Ceara state line; and on the west by the Ceara state line to the Atlantic Ocean.

(b) *Shipping requirements.* The honeydew melons must be packed in an enclosed container or vehicle or under tarpaulin cover while in transit from the area of Brazil considered free of the South American cucurbit fly to the United States, to prevent exposure of the fruit to insect pests.

(c) *Labelling.* All shipments of honeydew melons must be labelled in accordance with § 319.56–2(g) of this subpart.

Done in Washington, DC, this 19th day of February 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–4347 Filed 2–24–93; 8:45 am]

BILLING CODE 3410–34–M

9 CFR Part 78

[Docket 92–184–1]

Validated Brucellosis-Free States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: We are amending the brucellosis regulations concerning the interstate movement of swine by adding Mississippi and Missouri to the list of validated brucellosis-free States. We have determined that they meet the criteria for classification as validated brucellosis-free States. This action relieves certain restrictions on moving breeding swine from Mississippi and Missouri.

DATES: Interim rule effective on February 25, 1993. Consideration will be given only to comments received on or before April 26, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–184–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Delorias M. Lenard, Senior Staff Veterinarian, Swine Health Staff, VS, APHIS, USDA, room 736, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7767.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and man, caused by bacteria of the genus *Brucella*. The brucellosis regulations contained in 9 CFR part 78 (referred to below as the regulations) prescribe conditions for the interstate movement of cattle, bison and swine.

Under the swine brucellosis regulations, States, herds, and individual animals are classified according to their brucellosis status. Interstate movement requirements for swine are based upon the disease status of the herd or the State from which the animal originates.

We are amending § 78.43 of the regulations, which lists validated brucellosis-free States, to include Mississippi and Missouri. Validated brucellosis-free status is based on a State having:

(1) The necessary authorities for classification as a validated brucellosis-free State for swine;

(2) No known focus of swine brucellosis at the time of validation and completion of one of several methods of surveillance; or no diagnosed case of swine brucellosis in the 12-month period preceding the classification, and a statistical analysis of the combined results of certain tests that indicate the testing is equivalent to either complete herd testing or slaughter surveillance during a 1- or 2-year period, as chosen by the State; and

(3) Certification by the appropriate State animal health official, the Veterinarian in Charge and the Administrator.

After reviewing the brucellosis program records of Mississippi and Missouri, we have concluded that these States meet the criteria for classification as validated brucellosis-free States. Therefore, we are adding Mississippi and Missouri to the list of States in § 78.43. This action relieves certain restrictions on moving breeding swine interstate from Mississippi and Missouri.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause to publish this rule without prior opportunity for public comment. Immediate action is warranted to remove unnecessary restrictions on the interstate movement of breeding swine from Mississippi and Missouri.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 to make it effective upon publication. We will consider comments received within 60 days of publication of this interim rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register** including a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

This action will affect herd owners in Mississippi and Missouri by allowing breeding swine to be moved interstate without being tested for brucellosis. Approximately 20,900 swine are tested annually for brucellosis in Mississippi and Missouri, at an average cost to the seller of $5.00 per test, in order to be eligible for interstate movement. Using these numbers, we estimate that removing the testing requirement would result in a potential annual savings of $104,500 for swine herd owners in Mississippi and Missouri. Of the approximately 3,000 swine herd owners nationwide who regularly ship breeding swine interstate, approximately 50 regularly ship breeding swine interstate from Mississippi and 1,000 from Missouri. All of these herd owners would be considered small entities.

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 12778

This rule has been reviewed under Executive Order 12778, 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 rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 78 is amended as follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 continues to read as follows:

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

§ 78.43 [Amended]

2. Section 78.43 is amended by adding "Mississippi, Missouri," immediately after "Minnesota,".

Done in Washington, DC, this 19th day of February, 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–4349 Filed 2–24–93; 8:45 am]

BILLING CODE 3410–34–M

9 CFR Part 94

[Docket No. 92–147–2]

Change In Disease Status of Spain Because of Rinderpest, Foot-and-Mouth Disease, Hog Cholera, and Swine Vesicular Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are declaring Spain free of rinderpest, foot-and-mouth disease (FMD), hog cholera, and swine vesicular disease (SVD). Rinderpest and SVD have never been reported in Spain, and the last outbreaks of FMD and hog cholera took place, respectively, in 1986 and 1985. These changes in the animal disease status of Spain relieve certain prohibitions and restrictions on the importation into the United States of ruminants and swine and animal products of ruminants and swine from Spain. Restrictions on dairy products are being lifted.

Because Spain accepts ruminant and swine meat and meat products from countries where FMD, hog cholera, and SVD exist, however, the importation from Spain of ruminant and swine meat and meat products continues to be subject to certain restrictions because of these diseases. Also, because African swine fever continues to exist in Spain, certain pork and pork products continue to be prohibited.

EFFECTIVE DATE: March 29, 1993.

FOR FURTHER INFORMATION CONTACT:
Dr. Harvey A. Kryder, Chief Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 756–A, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7885.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation into the United States of specified animals and animal products in order to prevent the introduction of various diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever, hog cholera, and swine vesicular disease (SVD). These are dangerous and destructive communicable diseases of ruminants and swine.

On October 19, 1992, we published a document in the **Federal Register** (57 FR 47578–47580, Docket No. 92–147–1) in which we proposed to revise the regulations by declaring Spain free of rinderpest, FMD, hog cholera, and SVD. Accordingly, we proposed to add Spain to the list of countries in §§ 94.1(a)(2), 94.9(a), 94.10(a), and 94.12(a) of the regulations that have been declared free of rinderpest, FMD, hog cholera, and SVD. We proposed these changes in the animal disease status of Spain at the request of the Government of Spain, after determining that rinderpest and SVD have never been reported in Spain, and that the last Spanish outbreaks of FMD and hog cholera occurred, respectively, in 1986 and 1985.

At the same time, we proposed adding Spain to the list of countries in §§ 94.11 and 94.13 that, although free of rinderpest and FMD, in the first case, and free of SVD in the second, are, under certain circumstances, subject to special restrictions on the importation into the United States of their meat and meat products.

We solicited comments on the proposed rule, to be received on or before December 18, 1992. We received 1 comment, from a professional association, before the comment period closed.

The commenter opposed the proposed changes, claiming that Spain's failure to eradicate African swine fever and African horse sickness reflects unfavorably on Spain's ability to control animal diseases. The commenter expressed concern that, despite the regulations, ruminant and swine meat and meat products from Spain might be commingled with meat and meat products from countries where FMD, hog cholera, and SVD exist. Despite the special restrictions to which meat and meat products imported into the United States from Spain would be subject, the commenter feared a disease risk.

APHIS has determined that the surveillance measures of the animal health officials of the Government of Spain are sufficient to ensure compliance with all provisions of the regulations. We believe the regulatory safeguards discussed in the proposed rule are sufficient to prevent meat and meat products from Spain from introducing FMD, hog cholera, or SVD into the United States, and are adopting the provisions of the proposed rule as a final rule based on the rationale set forth in the proposed rule and in this document.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This rule eliminates certain requirements concerning the importation of ruminants and swine, ruminant meat and dairy products, and port and pork products from Spain into the United States. However, other requirements continue to restrict the importation of live swine and the meat and meat products of ruminants and swine.

Even without considering the export-constraining effects of the restrictions that remain in effect, it is unlikely that the changes in Spain's disease status will noticeably affect U.S. markets for ruminants, swine, meat or dairy products. In 1989, the total value of meat and meat products (excluding poultry) from Spain to the United States was only $11,000. Dairy exports from Spain to the United States were worth $1,052,000. These amounts represented only 0.0004 percent and 0.1 percent, respectively, of total U.S. imports for these commodity categories.

Before Spain's potential exports to the United States of meat, meat products, and dairy products would reach significant magnitude, an excess domestic supply of these commodities in Spain would be expected. Spain is a net importer worldwide of these commodities, however, receiving from other countries approximately three times as much as it exports. As Spain's per capita income rises, domestic supplies of meat, meat products, and dairy products can be expected to be consumed domestically, further limiting potential exports.

Given Spain's negative trade balance for meat, meat products, and dairy products and the relative insignificance of its exports of these commodities, the economic impact of the regulatory changes will have an insignificant effect on U.S. businesses, including small entities. Importers of dairy products might marginally benefit from the changes.

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 12778

This rule has been reviewed under Executive Order 12778, 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

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0015.

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, 9 CFR part 94 is amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, 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. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

§ 94.1 [Amended]

2. In § 94.1, paragraph (a)(2) is amended by adding "Spain," immediately after "Papua New Guinea,".

§ 94.9 [Amended]

3. In § 94.9, paragraph (a) is amended by adding "Spain," immediately after "Republic of Ireland,".

§ 94.10 [Amended]

4. In § 94.10, paragraph (a) is amended by adding "Spain," immediately after "the Republic of Ireland,".

§ 94.11 [Amended]

5. In § 94.11, paragraph (a) is amended by adding "Spain," immediately after "Papua New Guinea,".

§ 94.12 [Amended]

6. In § 94.12, paragraph (a) is amended by adding "Spain," immediately after "Rumania,".

§ 94.13 [Amended]

7. In § 94.13, the first sentence of the introductory text is amended by adding "Spain," immediately after "Republic of Ireland,".

Done in Washington, DC, this 19th day of February 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–4348 Filed 2–24–93; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Part 124

[Docket No. 90–011–2]

Patent Term Restoration for Veterinary Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This rule establishes procedures for the restoration of the time lost to the terms of veterinary biologics patents while awaiting premarket government approval. The effect of the rule is to enable veterinary biologics producers to apply for the restoration of such lost time. The rule is necessary in order to implement the patent term extension provisions of the Generic Animal Drug and Patent Term Restoration Act of 1988.

EFFECTIVE DATE: March 29, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Y. Tang, Biotechnologist, BCTA, BBEP, APHIS, USDA, room 851, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–4833.

SUPPLEMENTARY INFORMATION:

Background

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Term Restoration Act of 1988. Title II of this act (35 U.S.C. 156, as amended by Pub. L. 100–670) (the "Act") amended the U.S. patent laws to enable owners of patents relating to certain animal drugs and veterinary biological products, and the owners of patents relating to methods of using or manufacturing them, to apply for extension of the patent term to recover some of the time lost while awaiting premarket government approval. Patents concerning veterinary biologics subject to the Virus-Serum-Toxin Act (VSTA), as amended, 21 U.S.C. 151–159, are covered by the Act. Patents on products primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site-specific genetic manipulation techniques are not eligible for patent term restoration under the Act.

United States patents are effective for 17 years from the date they are issued. A patent gives an inventor the right to exclude others from making, using, or selling the patented invention within the United States (*See* 35 U.S.C. 154.) This exclusive right is designed to encourage innovation and development of new products by protecting the patent holder from direct competition for a period of time. However, a patent does not automatically give an inventor the right to actually make, use, or sell the invention. Federal law requires some inventions, such as veterinary biological products, to be Federally approved before they are manufactured or marketed. For these inventions, a portion of the 17 years of protection afforded by a patent may be lost waiting for Federal review and approval.

The Virus-Serum-Toxin Act, among other things, prohibits the preparation, sale, barter, or exchange of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, in places under Federal jurisdiction. It also prohibits the shipment of such products anywhere in or from the United States. The VSTA also states that it is unlawful for anyone to prepare, sell, barter, or exchange in places under Federal jurisdiction, or ship in or from the United States, any virus, serum, toxin, or analogous product unless it is prepared in compliance with USDA regulations at an establishment holding a valid USDA license (21 U.S.C. 151). Therefore, veterinary biological products cannot be marketed until these requirements are met. It takes time to satisfy the regulations and standards under the VSTA which are designed to assure that only pure, safe, potent, and effective biological products are marketed. If a product is covered in any way by a patent, the time spent waiting for Federal review and approval reduces the effective length of the patent. Profits therefore are reduced, along with the incentive to develop new veterinary biological products. The Generic Animal Drug and Patent Term Restoration Act is designed to restore these incentives.[1]

The Generic Animal Drug and Patent Term Restoration Act of 1988

The Generic Animal Drug and Patent Term Restoration Act of 1988 contains two titles: Title I, among other things, authorizes the Food and Drug Administration to approve abbreviated new drug applications for generic animal drugs; Title II allows patent term restoration for certain patents covering animal drugs and veterinary biological products.

Administrative responsibility for Title II of the Act is divided among the Food and Drug Administration (FDA) of the Department of Health and Human Services, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), and the Patent and Trademark Office (PTO) of the United States Department of Commerce.

Under the Act, applications for patent term extension are submitted to PTO for a determination whether a patent is eligible for extension. USDA assists PTO by determining the length of the regulatory review period for any veterinary biological product involved; FDA does the same for animal drugs. In addition, APHIS and FDA are responsible for determining, if they are petitioned to do so, whether the applicant for patent term restoration

[1] In September, 1984, a similar statute, The Drug Price Competition and Patent Term Restoration Act (Pub. L. 98–417) became law. This Act, which allows patent term restoration to holders of patents claiming human drug products (including biologics and antibiotics), medical devices, food additives and color additives, became law in September, 1984. Regulations have been issued under this Act by both the Food and Drug Administration (FDA) and the Patent and Trademark Office (PTO). The FDA regulations appear at 21 CFR part 60. The PTO regulations appear at 37 CFR part 1.

acted with due diligence to obtain approval from the Agency involved with the animal drug or veterinary biological product. A notice of a Memorandum of Understanding between the PTO and APHIS concerning implementation of procedures in determining a veterinary biological product's eligibility for patent term extension under 35 U.S.C. 156 was published in the **Federal Register** on June 23, 1989 (see 54 FR 26399). PTO issued regulations (see 54 FR 30375, July 20, 1989), governing the format, content, and submission of patent term restoration applications. The PTO regulations are codified at 37 CFR 1.710–1.785. Regulations covering FDA responsibilities for patent term extension for animal drugs have been finalized by that agency (see 57 FR 56260–56262, November 27, 1992).

On July 13, 1992, we published in the **Federal Register** a proposed rule on patent term restoration for veterinary biologics (see 57 FR 30926–30932, Docket No. 90–011). We proposed adding a new part 124 to our existing regulations in title 9, chapter I, Code of Federal Regulations. Subpart A of the regulations contains general provisions. Subpart B provides for APHIS to assist PTO in determining a patent holder's eligibility for patent term restoration. Subpart C contains regulations governing the determination of regulatory review periods. Subpart D provides for filing due diligence petitions; that is, challenging a regulatory review period determination on the grounds that an applicant did not diligently pursue premarketing approval. Standards for determining due diligence are also included in subpart D. Subpart E contains regulations governing informal hearings on the issue of due diligence.

We solicited comments for 60 days with the comment period ending September 11, 1992.

Summary and Analysis of Comments

We received comments from one trade association. Those comments and our response to them are discussed below. We have made changes to the proposed rule in response to the commenter and the changes are identified below. Based on the rationale set forth in the proposed rule and in this document in response to comments, we are adopting the provisions of the proposed rule as a final rule with changes made in response to the comments as well as minor editorial changes.

The commenter requested that in § 124.21(b)(2), the term "generic name" be changed to "true name" to be consistent with APHIS terminology in 9 CFR 101.4(d). APHIS agrees with this comment and has amended § 124.21(b)(2) accordingly.

The comment further requested that the term "any interested person" in §§ 124.22(a) and 124.40(a) be defined under *Definitions* in § 124.2. The term "person" is undefined even though it is used in the regulations. "Person" will therefore be added to the definition and shall mean "[A]ny individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing, or any agency, officer, or employee of any thereof." The term "interested person" is intended to have a broad meaning and includes any person interested in the subject matter who has information bearing on a regulatory review period or due diligence petition.

The commenter also requested that the applicant be notified and allowed an opportunity for comment prior to a revision of a regulatory review period. APHIS agrees with this request and has amended the proposal in § 124.22 accordingly in response to this comment.

The commenter also requested that the applicant for patent term extension be granted 30 days (rather than the 10 days in the proposed rule) in which to respond to a due diligence petition because the applicant has to prove due diligence.

In response to this request, APHIS agrees to grant the applicant an additional 10 days in which to respond to a due diligence petition. This should be sufficient time to reply. At the same time, APHIS should have adequate time, before the statutory limit of 90 days after its receipt of a due diligence petition, in which to evaluate the information which is submitted to the Agency, to conduct an investigation, to resolve any differences in information submitted by the petitioner and the applicant, to determine whether the period of time alleged in which the applicant did not act with due diligence will affect the maximum patent term extension to which the applicant is entitled, to publish a notice of the Agency's determination in the **Federal Register** along with the factual and legal basis for its determination, and to provide written notification of its determination to PTO, the applicant, and the petitioner.

Finally, the commenter requested that the word "initially" be added before the word "submitted" in § 124.20(a)(1), in order to be consistent with the language in § 124.20(a)(2). APHIS agrees with this request and has amended the regulations accordingly.

Executive Order 12291 and Regulatory Flexibility Act

This rule has been reviewed in accordance with Executive Order 12991 and Departmental Regulation 1512–1 and has been determined to be a non-major rule since it does not meet the criteria for a major regulatory action. Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The patent extension provision in 35 U.S.C. 156 (as amended by Title II of Pub. L. 100–670) benefits the patent holder by restoring to the patent holder that part of the term of the patent which has been lost due to regulatory review of the patented product. Thus the statute results in a net economic benefit to the patent holder. The final rule merely implements the statute. The rule provides procedures to allow APHIS to assist PTO in carrying out the requirements of the Act. An application for patent term restoration is made voluntarily by the patent holder. The time and cost required to comply with the regulation is far outweighed by the benefit conferred by patent term restoration to the patent holder.

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 as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or

recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) and assigned OMB control no. 0579–0013.

List of Subjects in 9 CFR Part 124

Animal biologics, Patents.

Accordingly, we are amending 9 CFR, chapter I, subchapter E by adding a new part 124 to read as follows:

PART 124—PATENT TERM RESTORATION

Subpart A—General Provisions

Sec.

Subpart B—Eligibility Assistance

Subpart C—Regulatory Review Period

Subpart D—Due Diligence Petitions

Subpart E—Due Diligence Hearing

Authority: 35 U.S.C. 156; 7 CFR 2.17, 2.51, and 371.2(m).

Subpart A—General Provisions

§ 124.1 Scope.

(a) This parts sets forth procedures and requirements for APHIS review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156—Extension of patent term. Responsibilities of APHIS include:

(1) Assisting PTO in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to APHIS's regulatory review period determinations; and

(4) Conducting hearings to review initial APHIS findings on due diligence challenges.

(b) The regulations in this part are designed to be used in conjunction with regulations issued by PTO concerning patent term extension which may be found at 37 CFR 1.710 through 1.785.

§ 124.2 Definitions.

Animal and Plant Health Inspection Service (APHIS). The agency in the Department of Agriculture responsible for licensing veterinary biological products under the Virus-Serum-Toxin Act.

Applicant. Any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking extension of the term of a patent.

Due diligence petition. A petition submitted under § 124.30 of this part.

Informal hearing. A hearing which is not subject to the provisions of 5 U.S.C. 554, 556, and 557 and which is conducted as provided in 21 U.S.C. 321(y).

License applicant. Any person who, in accordance with part 102 of this chapter, submits an application to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture for a U.S. Veterinary Biological Product License.

Patent. A patent issued by the Patent and Trademark Office of the United States Department of Commerce.

Person. Any individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

PTO. The Patent and Trademark Office of the United States Department of Commerce.

Subpart B—Eligibility Assistance

§ 124.10 APHIS liaison with PTO.

Upon receipt of a copy of an application for extension of the term of a veterinary biologic patent from PTO, APHIS will assist PTO in determining whether a patent related to a biological product is eligible for patent term extension by:

(a) (1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) Determining whether the permission for commercial marketing or use of the product after the regulatory review period was the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, and, if so, whether it was the first permitted commercial marketing or use of the veterinary biological product for administration to a food-producing animal;

(3) Ascertaining whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use; and

(4) Providing such other information as may be necessary and relevant to PTO's determination of whether a patent related to a product is eligible for patent term restoration.

(b) APHIS will notify PTO of its findings in writing, send a copy of this notification to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Subpart C—Regulatory Review Period

§ 124.20 Patent term extension calculation.

(a) As provided in 37 CFR 1.779 of PTO's regulations, in order to determine a product's regulatory review period, APHIS will review the information in each application to determine the lengths of the following phases of the review period, and will then find their sum:

(1) The number of days in the period beginning on the date authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was initially submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(b) A license application is "initially submitted" on the date it contains sufficient information to allow APHIS to commence review of the application. A product license is issued on the date of the APHIS letter informing the applicant of the issuance. The issuance of a license releases the product for commercial marketing or use.

§ 124.21 Regulatory review period determination.

(a) Not later than 30 days after the receipt of an application from PTO, APHIS shall determine the regulatory review period. Once the regulatory review period for a product has been determined, APHIS will notify PTO in writing of the determination, send a copy of the determination to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

(b) APHIS will also publish a notice of the regulatory review period

determination in the **Federal Register**. The notice will include the following:

(1) The name of the applicant;

(2) The trade name and true name of the product;

(3) The number of the patent for which an extension of the term is sought;

(4) The approved indications or uses for the product;

(5) The regulatory review period determination, including a statement of the length of each phase of the review period and the dates used in calculating each phase.

§ 124.22 Revision of regulatory review period determination.

(a) Any interested person may request a revision of the regulatory review period determination within the 30 day period beginning on its publication in the **Federal Register**. The request must be sent to Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

The request must specify the following:

(1) The identity of the product;

(2) The identity of the applicant for patent term restoration;

(3) The docket number of the **Federal Register** notice announcing the regulatory review period determination; and

(4) The basis for the request for revision, including any documentary evidence.

(b) If APHIS decides to revise its prior determination, APHIS will notify PTO of the decision, and will send a copy of notification to the applicant and the person requesting the revision (if different from the applicant) with a request for comments within 10 days of notification. If no comment on the proposed revision is received, APHIS will publish the revision in the **Federal Register**, and include a statement giving the reasons for the revision. If comment is received, APHIS will make a final determination regarding the revision based on such comment and will then publish the revision in the **Federal Register**, giving reasons for its determination.

§ 124.23 Final action on regulatory review period determination.

APHIS will consider its regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under § 124.30 unless it receives:

(a) New information from PTO records, or APHIS records, that affects the regulatory review period determination;

(b) A request § 124.22 for revision of the regulatory review period determination;

(c) A due diligence petition filed under § 124.30; or

(d) A request for a hearing filed under § 124.40.

Subpart D—Due Diligence Petitions

§ 124.30 Filing, format, and content of petitions.

(a) Any interested person may file a petition with APHIS, no later than 180 days after the publication of a regulatory review period determination under § 124.21, alleging that a license applicant did not act with due diligence in seeking APHIS approval of the product during the regulatory review period.

(b) The petition must be filed with APHIS under the docket number of the **Federal Register** notice of the agency's regulatory review period determination. The petition must contain any additional information required by this subpart.

(c) The petition must allege that the applicant failed to act with due diligence sometime during the regulatory review period and must set forth sufficient facts to merit an investigation by APHIS of whether the applicant acted with due diligence.

(d) The petition must contain a certification that the petitioner has served a true and complete copy of the petition on interested parties by certified or registered mail (return receipt requested) or by personal delivery.

§ 124.31 Applicant response to petition.

(a) The applicant may file with APHIS a written response to the petition no later than 20 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent term extension application.

(c) If the applicant does not respond to the petition, APHIS will decide the matter on the basis of the information submitted in the patent term restoration application, the due diligence petition, and APHIS records.

§ 124.32 APHIS action on petition.

(a) Within 90 days after APHIS receives a petition filed under § 124.30, the Assistant Secretary for Marketing and Inspection Services shall make a determination under paragraphs (b) or (c) of this section or under § 124.33 whether the applicant acted with due diligence during the regulatory review period. APHIS will publish its determination in the **Federal Register** together with factual and legal basis for the determination, notify PTO of the determination in writing, and send copies of the determination to PTO, the applicant, and the petitioner.

(b) APHIS may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 124.30;

(2) The petition does not contain information or allegations upon which APHIS may reasonably determine that the applicant did not act with due diligence during the applicable regulatory review period; or

(3) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence so that, even if the petition were granted, the petition would not affect the maximum patent term extension which the applicant is entitled to under 35 U.S.C. 156.

§ 124.33 Standard of due diligence.

(a) In determining the due diligence of an applicant, APHIS will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. APHIS will take into consideration all relevant factors, such as the amount of time between the approval of an experimental use permit and licensure of the veterinary biological product.

(b) For purposes of this Part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearing

§ 124.40 Request for hearing.

(a) Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination by APHIS in accordance with § 124.32, that APHIS conduct an informal hearing on the due diligence determination.

(b) The request for a hearing must:

(1) Be in writing;

(2) Contain the docket number of the Federal Register notice of APHIS's regulatory review period determination;

(3) Be delivered to the Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782;

(4) Contain a full statement of facts upon which the request for hearing is based;

(5) Contain the name, the address, and the principal place of business of the person requesting the hearing; and

(6) Contain a certification that the person requesting the hearing has served a true and complete copy of the request upon the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail (return receipt requested) or by personal service.

(c) The request must state whether the requesting party seeks a hearing not later than 30 days after the date APHIS receives the request, or, at the request of the person making the request, not later than 60 days after such date.

§ 124.41 Notice of hearing.

No later than ten days before the hearing, APHIS will notify the requesting party, the applicant, the petitioner, and any other interested person of the date, time, and location of the hearing.

§ 124.42 Hearing procedure.

(a) The presiding officer shall be appointed by the Administrator of APHIS from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(b) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(c) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and any general summary of the information which will be presented at the hearing in support of such action.

(d) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral and written information relevant to such action.

(e) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(f) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(g) The due diligence hearing will be conducted in accordance with rules of practice adopted for the proceeding. APHIS will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing. The standard of due diligence set forth in § 124.33 will apply at the hearing. The party requesting the due diligence hearing will have the burden of proof at the hearing.

§ 124.43 Administrative decision.

Within 30 days after completion of the due diligence hearing, the Assistant Secretary for Marketing and Inspection Services, taking into consideration the recommendation of the Administrator, will affirm or revise the determination made under § 124.32. APHIS will publish the due diligence redetermination in the **Federal Register**, notify PTO of the redetermination, and send copies of the notice to PTO and the requesting party, the applicant, and the petitioner.

Done in Washington, DC, this 19th day of February 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Service.

[FR Doc. 93–4345 Filed 2–24–93; 8:45 am]

BILLING CODE 3410-34-M

FARM CREDIT ADMINISTRATION

12 CFR Part 614

RIN 3052–AB34

Loan Policies and Operations; Collateral Evaluation Requirements, Actions on Applications, and Review of Credit Decisions; Correction

AGENCY: Farm Credit Administration.

ACTION: Final rule; correcting amendments.

SUMMARY: The Farm Credit Administration (FCA), by the Farm Credit Administration Board (Board), adopted on November 12, 1992, a final regulation amending FCA regulations relating to collateral evaluation requirements for Farm Credit System (FCS or System) institutions engaged in lending or leasing. This regulation was published as a final regulation on November 20, 1992, 57 FR 54683, but will not become effective until March 1, 1993. The FCA Board now publishes corrections and a clarifying change to the regulation which will make it clear that for certain loans, transactional independence between the credit decision and the collateral evaluation where the same employee or officer is responsible for both can be satisfied by providing for prior approval or post-review of the credit decision by the senior management or the board of directors.

DATES: The regulation shall become effective March 1, 1993, or upon the expiration of 30 days after November 20, 1992 during which either or both houses of Congress are in session, whichever is later. Notice of the effective date will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Dennis K. Carpenter, Senior Policy Analyst, Regulation Development Division, Office of Examination, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4498, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: The preamble to the final regulation (57 FR 54683) discussed evaluator independence requirements for collateral evaluations not requiring an appraisal. In such cases, the preamble stated that a loan officer could prepare the collateral evaluation and complete the credit decision if the final credit decision was also reviewed by the FCS institution's senior management and/or board of directors. However, the regulatory language did not accurately reflect the Board's intention. In addition, the preamble did not specify whether the review must be a prior approval or a post-review.

Section 614.4255 Independence requirements is corrected to indicate that if an employee or officer of the institution prepares the collateral evaluation as well as approves the credit decision, the institution's internal control procedures required by § 618.8430 of this chapter must provide for either a prior approval or a post-review of the credit decision.

In the case of a director of the institution, the regulation would still prohibit the director from performing