(11) The name, mailing address, and telephone number of the person to whom the hedgehog or tenrec will be delivered in the United States.

(12) The location of the place where delivery will be made in the United States.

(13) Any remarks regarding the shipment.

(d) *What will happen to the application for an import permit.* Upon receipt of the application, APHIS will review the application. If the hedgehog or tenrec appears to be eligible to be imported into the United States, APHIS will issue an import permit indicating the applicable requirements under this subpart for the importation of the hedgehog or tenrec. Even though an import permit has been issued for the importation of a hedgehog or tenrec, the animal may enter the United States only if all applicable requirements of this subpart have been met.

§ 92.705 Health certificate.

A hedgehog or tenrec may not be imported into the United States unless accompanied by a health certificate either issued by a full-time salaried veterinary officer of the national government of the exporting country, or issued by a veterinarian authorized or accredited by the national government of the exporting country and endorsed by a full-time salaried veterinary officer of the national government of that country. The health certificate must contain the names and street addresses of the consignor and consignee and must state:

(a) That the hedgehog or tenrec originated in a country that has been recognized as free of foot-and-mouth disease by the USDA;

(b) That the hedgehog or tenrec has never been in a country where foot-and-mouth disease exists;

(c) That the hedgehog or tenrec has not been commingled with any other hedgehog or tenrec that originated in or has ever been in a country where foot-and-mouth disease exists;

(d) That the hedgehog or tenrec was inspected by the individual issuing the health certificate and was found free of any ectoparasites not more than 72 hours before being loaded on the means of conveyance which transported the animal to the United States;

(e) That all body surfaces of the hedgehog or tenrec were treated for ectoparasites under the supervision of the veterinarian issuing the health certificate at least 3 days but not more than 14 days before being loaded on the means of conveyance that transported the animal to the United States;

(f) That the pesticide and the concentration used was adequate to kill the types of ectoparasites likely to infest the animal to be imported;

(g) That the hedgehog or tenrec, after being treated for ectoparasites in accordance with paragraphs (e) and (f) of this section, had physical contact only with, or shared a pen or bedding materials only with, treated hedgehogs or tenrecs in the same shipment to the United States; and

(h) The name and concentration of the pesticide used to treat the hedgehog or tenrec.

§ 92.706 Notification of arrival.

Upon the arrival of a hedgehog or tenrec at the port of first arrival in the United States, the importer or his or her agent must present the import permits and health certificates required by this subpart to the collector of customs for the use of the inspector at that port.

§ 92.707 Inspection at the port of first arrival.

(a) A hedgehog or tenrec from any part of the world must be inspected by an APHIS inspector at the port of first arrival. Subject to the other provisions in this subpart, a shipment of hedgehogs or tenrecs may enter into the United States only if each hedgehog or tenrec in the shipment is found free of ectoparasites and any clinical signs of communicable diseases.

(b) If any hedgehog or tenrec in a shipment is found to be infested with ectoparasites or demonstrates any clinical signs of communicable diseases, then the entire shipment will be refused entry. The importer will be given the following options:

(1) Remove the shipment from the United States; or

(2) Release the shipment to the U.S. Department of Agriculture. The Administrator will destroy or otherwise dispose of the shipment as necessary to prevent the possible introduction into the United States of communicable animal diseases.

Done in Washington, DC, this 27th day of April 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–11374 Filed 5–8–95; 8:45 am]

BILLING CODE 3410–34–P

9 CFR Parts 112 and 113

[Docket No. 94–046–1]

Viruses, Serums, Toxins, and Analogous Products; Marek's Disease Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the standard requirements for Marek's disease vaccines by including vaccines prepared from any of the three Marek's disease virus serotypes, and by defining the identity, safety, and efficacy requirements for vaccines prepared from each serotype or combinations of serotypes. The proposed rule would also amend the requirements for labeling Marek's disease vaccines. These proposed amendments are necessary based on the evolution of the disease in the field, advances in the types of vaccines currently prepared to prevent the disease, and advances in the methods of evaluating such vaccines. The effect of the proposed rule would be to save licensees time during the application process by clarifying and codifying the guidelines developed for licensing these products over the past several years.

DATES: Consideration will be given only to comments received on or before July 10, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket 94–046–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 94–046–1. 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. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD, 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

Veterinary biologics are regulated under the Virus-Serum-Toxin Act of 1913, as amended by the Food Security Act of 1985 (21 U.S.C. 151–159, hereinafter referred to as the Act). In accordance with this Act, the Animal

and Plant Health Inspection Service (APHIS) promulgates standard requirements that establish the purity, safety, potency, and efficacy requirements for these products.

The current standard requirements in § 113.330 (hereinafter referred to as the regulations) for licensing Marek's disease vaccines were promulgated at a time when only Serotype 3 Marek's disease vaccines were prepared. Also, the standard requirements did not include a standard for evaluating vaccine efficacy. Since that time, vaccines for Serotypes 1 and 2 have been developed, very virulent forms of the field virus have emerged, and other advances in our understanding of this virus have occurred. In response to these changes, APHIS has developed guidelines over the past several years for licensing these products. APHIS now proposes to amend the standard requirement for Marek's disease vaccines to include Serotypes 1 and 2, and to codify appropriate efficacy standards and guidelines which license applicants currently utilize.

Although all three Marek's disease virus serotypes have been used to prepare licensed vaccines, the current true names found on the labels of Marke's disease vaccines do not contain this information. Therefore, we propose to add new § 112.7(m) which would require that the true names of all Marke's disease vaccines specify the virus serotypes contained in the product (e.g., ''Serotype(s) 1, 2, and/or 3, Live Virus''). Also, the true names currently found on labels of many of these products include the final form in which the product is prepared (e.g., ''Cell Associated'' or ''Cell Free''). The reference to final form in the current true name is not consistent with the labeling of other live virus vaccines. Therefore, APHIS would no longer include references to ''Cell Associated'' or ''Cell Free'' when assigning true names for Marek's disease vaccines.

The current standard requirements limit the preparation of Marek's disease vaccines to five passages from the master seed virus (*see* § 113.330, introductory paragraph). A number of exemptions from this requirement, however, have been granted to accommodate production problems, particularly in the propagation of Serotype 2 viruses. Therefore, we propose to remove the five-passage restriction from the introductory paragraph of § 113.330. Licensees, however, would still be required to specify the highest passage, established by efficacy data, that may be contained in the final product for each master seed virus pursuant to § 113.330(c) of the regulations.

Due to the lack of an acceptable identity test at the time the current standard requirements were published, the current regulations provide in paragraph (a) and introductory paragraph (d) of § 113.330 an exemption from identity testing for Marek's disease master seed viruses and final products that is no longer appropriate. Current vaccines contain any of the three Marek's disease virus serotypes, and the reagents and techniques to identify the different serotypes are available. Therefore, the proposed rule would remove the identity test exemption in paragraph (a) and the introductory paragraph (d) of § 113.330 and would require a serotype-specific identity test in proposed paragraph (a) and introductory paragraph (d) of § 113.330.

Sections 113.330 (a) and (d)(1) of the current standard requirements permit applicants to disregard lesions typical of turkey herpes virus when evaluating master seed viruses and final products for extraneous agents in the chicken embryo inoculation test prescribed in § 113.37. Such lesions may arise when a vaccine virus override occurs during the performance of this test. This exemption for herpes virus lesions is inconsistent with the evaluation of other master seed viruses and products, which are typically evaluated in the chicken inoculation test prescribed in § 113.36 when a vaccine virus override occurs. Therefore, APHIS would require in proposed paragraphs (a) and (d)(1) of § 113.330 that the chicken inoculation test be conducted if a vaccine virus override occurs during the chicken embryo inoculation test for a Marek's disease virus master seed or vaccine serial.

The current regulations do not contain an efficacy standard for Marek's disease vaccines. APHIS addressed the need for such standard by issuing Veterinary Biologics Memorandum No. 800.82 on January 19, 1993. This memorandum prescribed efficacy criteria on the basis that Serotype 1 and 2 vaccines typically provide protection against a more (''very'') virulent challenge, while the Serotype 3 vaccines typically provide protection against a less (''standard'') virulent challenge. The proposed rule would codify the efficacy guidelines found in that memorandum in proposed § 113.330(c)—Immunogenicity. Furthermore, because licensees have obtained approval for label claims for both subcutaneous and *in ovo* routes of administration for these products, the proposed efficacy standard has been written to include the requirements for either route.

The master seed virus safety test found in § 113.330(b) of the current standard requirements requires modification in order to adequately evaluate all three Marek's disease virus serotypes. As with the efficacy standard, the safety test is addressed in the Veterinary Biologics Memorandum No. 800.82. The memorandum describes the appropriate challenge virus for the positive control group and adds a contact control group for the evaluation of Serotype 1 viruses, which have an increased potential for horizontal spread. This proposed rule would codify these guidelines with some modifications. Also, this proposed rule would expand the safety test to cover the use of embryos as well as chickens as test subjects (*See* proposed § 113.330(b).

Because Marek's disease vaccines may include more than one serotype in each final container, the proposed rule would require that the potency test for the final product be serotype-specific for all products containing more than one serotype. Also, the acceptable virus titers for product release and expiration would be based on the titers used in the efficacy study for each serotype, with specified minimum titers (*See* proposed § 113.330(d)(3)).

Executive Order 12866 and Regulatory Flexibility Act

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

The proposed amendments to the standard requirements for Marek's disease vaccines would codify guidelines developed for licensing these products over the past several years. These amendments would affect all (currently a total of eight) manufacturers of Marek's disease vaccines, some of which may be small businesses. By clarifying licensing requirements for Marek's disease vaccines, the proposed rule would save time during the application process and would cause no adverse economic impact on the regulated industry.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would 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 proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed 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

9 CFR part 112

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

9 CFR part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 112 and 113 would be amended as follows:

PART 112—PACKAGING AND LABELING

1. The authority citation for part 112 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 112.7 would be amended by adding paragraph (m) to read as follows:

§ 112.7 Special additional requirements.

* * * * *

(m) In the case of biological products containing Marek's disease virus, all labels shall specify the Marek's disease virus serotype(s) used in the product.

PART 113—STANDARD REQUIREMENTS

3. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

4. Section 113.330 would be revised to read as follows:

§ 113.330 Marek's Disease Vaccines.

Marek's disease vaccine shall be prepared from virus-bearing tissue culture cells. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.300, and the requirements prescribed in this section. The identity test required in § 113.300(c) shall be conducted in a serotype-specific manner by a method acceptable to APHIS. Each lot of Master Seed Virus shall also be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(b) *Safety test.* The Master Seed Virus shall be nonpathogenic for chickens as determined by the following procedure:

(1) Specific pathogen free chickens or embryos, negative for Marek's disease virus antibodies, and from the same source, shall be isolated into the following groups:

(i) *Group 1.* At least 50 test subjects shall be inoculated with 10 times as much viable virus as will be contained in one dose of vaccine, by the route recommended for vaccination.

(ii) *Group 2.* At least 50 test subjects shall be injected with a very virulent Marek's disease virus provided or approved by APHIS, at a dosage level that will cause gross lesions of Marek's disease in at least 80 percent of the chickens within 50 days.

(iii) *Group 3.* Fifth uninoculated controls. For *in ovo* studies, this group should receive a sham inoculation of diluent.

(iv) *Group 4.* For studies evaluating Serotype 1 Master Seed Viruses a group of 50 uninoculated control chickens shall be housed in contact with the group 1 vaccinated chickens.

(2) At least 40 chickens in each group shall survive to 5 days of age. All chickens that die shall be necropsied an examined for lesions of Marek's disease and cause of death. The test shall be judged according to the following criteria:

(i) At 50 days of age, the remaining chickens in group 2 shall be killed and examined for gross lesions of Marek's disease. If at least 80 percent of this group do not develop Marek's disease, the test is inconclusive and may be repeated.

(ii) At 120 days of age, the remaining chickens in groups 1, 3, and 4 shall be weighed, killed, and necropsied. If less than 30 of the chickens in group 3 survive the 120 day period, or if any of the chickens in group 3 have gross lesions of Marek's disease at necropsy, the test is declared inconclusive. If less than 30 chickens in groups 1 and 4 survive the 120 day period; or if any of the chickens in groups 1 and 4 have gross lesions of Marek's disease at necropsy; of if the average body weight of the chickens in groups 1 or 4 is significantly (statistically) different from the average in group 3 at the end of the 120 days, the lot of Master Seed Virus is unsatisfactory.

(3) For tests involving *in ovo* innoculation, hatchability results shall also be reported for each group.

(c) *Immunogenicity.* Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity at the highest passage level allowed for the product, and the virus dose to be used shall be established as follows:

(1) Specific pathogen free chickens or embryos, negative for Marek's disease antibodies, and from the same source, shall be isolated into the following groups:

(i) *Group 1.* A minimum of 35 test subjects shall be inoculated with the vaccine, using the recommended route, at 1 day of age for chicks or 18 days of embryonation for embryos. The dose used shall be established by 5 replicate virus titrations conducted by a cell culture system or other titration method acceptable to APHIS.

(ii) *Group 2.* A minimum of 35 nonvaccinated test subjects shall be held as challenge controls.

(iii) *Group 3.* A minimum of 25 nonvaccinated test subjects shall be held as nonchallenge controls.

(iv) *Group 4.* Except for studies evaluating vaccines which contain only a Serotype 3 virus as the Marek's disease fraction, a minimum of 35 chicks shall be vaccinated at 1 day of age with a licensed Serotype 3 vaccine, in order to document the severity of the very virulent challenge.

(2) At least 30 chickens in groups 1, 2, and 4, and at least 20 chickens in group 3, shall survive to 5 days of age. All chickens in groups 1, 2, and 4 shall be challenged at 5 days of age in the following manner:

(i) For studies evaluating vaccines which contain only a Serotype 3 virus as the Marek's disease fraction, groups 1 and 2 shall be inoculated with a standard virulent challenge virus provided or approved by APHIS.

(ii) For all other Marek's disease vaccines, groups 1, 2, and 4 shall be inoculated with a very virulent

challenge virus provided or approved by APHIS.

(3) All chickens shall be observed until 7 weeks of age, necropsied, and examined for grossly observable lesions consistent with Marek's disease. All chickens dying before the end of the 7 week observation period shall be necropsied and evaluated for gross lesions of Marek's disease. Any chickens not so examined shall be scored as positive for Marek's disease.

(4) For a valid test, at least 80% of the chickens in group 2 must develop grossly observable lesions, none of the chickens in group 3 shall develop grossly observable lesions, and (when included) at least 20% of the chickens in group 4 must develop grossly observable lesions.

(5) For a valid test to be considered satisfactory, at least 80% of the chickens in group 1 must remain free of grossly observable lesions. the appropriate product claim resulting from a satisfactory test would be to aid in the prevention of Marek's disease, for vaccines containing only a Serotype 3 virus as the Marek's disease fraction, or to aid in the prevention of very virulent Marek's disease, for all other vaccines.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable requirements prescribed in § 113.300. The identity test required in § 113.300(c) shall be conducted in a serotype-specific manner by a method acceptable to APHIS. Final container samples of completed product shall also meet the requirements in paragraphs (d)(1), (2), and (3) of this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* The chicken embryo inoculation test prescribed in § 113.37 shall be conducted, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(2) *Safety test.* At least 25 one-day-old, specific pathogen free chickens shall be injected, by the subcutaneous route, with the equivalent of 10 chicken doses of virus (vaccine concentrated 10X). The chickens shall be observed each day for 21 days. Chickens dying during the period shall be examined, cause of death determined, and the results recorded.

(i) If at least 20 chickens do not survive the observation period, the test is inconclusive.

(ii) If lesions of any disease or cause of death are directly attributable to the vaccine, the serial is unsatisfactory.

(iii) If less than 20 chicks survive the observation period and there are no deaths or lesions attributable to the vaccine, the test may be repeated one time, *Provided,* that if the test is not repeated, the serial shall be declared unsatisfactory.

(3) *Potency test.* The samples shall be titrated using a cell culture system or other titration method acceptable to APHIS. For vaccines composed of more than one Marek's disease virus serotype, each fraction shall be titrated in a serotype-specific manner.

(i) Samples of desiccated vaccine shall be incubated at 37°C for 3 days before preparation for use in the potency test. Samples of desiccated or frozen vaccine shall be reconstituted in diluent according to the label recommendations, and held in an ice bath at 0°C to 4°C for 2 hours prior to use in the potency test.

(ii) For a serial or subserial to be eligible for release, each serotype contained in the vaccine shall have a virus titer per dose which is at least 3 times greater than the number of plaque forming units (pfu) used in the immunogenicity test prescribed in paragraph (c) of this section, but not less than 1000 pfu per dose.

(iii) When tested (without the pretest incubation of desiccated products) at any time within the expiration period, each serotype contained in the vaccine shall have a virus titer per dose which is at least 2 times the number of pfu used in the immunogenicity test, but not less than 750 pfu per dose.

Done in Washington, DC, this 28th day of April 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–11375 Filed 5–8–95; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94–NM–135–AD]

Airworthiness Directives; British Aerospace Model Viscount 744, 745D, and 810 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain British Aerospace Model Viscount 744, 745D, and 810 airplanes, that currently establishes time-in-service limits for components of the fuselage pressure vessel, and requires modifications and inspections of various fuselage components to assure the continued structural integrity of these airplanes through the manufacturer's design life goal. This action would require additional modifications and inspections of the fuselage pressure vessel to extend the fuselage pressure vessel life from 30 to 45 years since new. This proposal is prompted by results of a review of fatigue test findings, stress analysis, and in-service history associated with pressure vessel components. The actions specified by the proposed AD are intended to prevent reduced structural capability of the fuselage pressure vessel.

DATES: Comments must be received by June 20, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–135–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from British Aerospace Regional Aircraft Ltd., Engineering Support Manager, Military Business Unit, Chadderton Works, Greengate, Middleton, Manchester M24 1SA, England. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2148; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained