(b) * * *

(1) * * * The irradiation treatment must be carried out at an approved facility in Hawaii or, if authorized by a limited permit issued under paragraph (b)(7)(ii) of this section, on the mainland United States. * * *

* * * * *

(7) * * *

(ii) * * * Cut blooms of gardenia may be treated only in Hawaii and are not eligible for a limited permit for movement to the mainland United States for treatment.

* * * * *

8. A new 318.13–4j would be added to read as follows:

§ 318.13–4j Administrative instructions governing the interstate movement of cut blooms of gardenia from Hawaii.

Cut blooms of gardenia may be moved interstate from Hawaii if treated with irradiation in accordance with § 318.13–4f of this subpart or if grown and inspected in accordance with the provisions of this section.

(a) The grower's production area must be inspected annually by an inspector and found free of green scale. If green scale is found during an inspection, a 2-month ban will be placed on the interstate movement of cut blooms of gardenia from that production area unless the grower elects to treat the blooms with irradiation in accordance with § 318.13–4f. Near the end of the 2 months, an inspector will reinspect the grower's production area to determine whether green scale is present. If reinspection determines that the production area is free of green scale, shipping may resume. If reinspection determines that green scale is still present in the production area, another 2-month ban on shipping will be placed on the interstate movement of gardenia from that production area unless the grower again elects to treat the blooms with irradiation in accordance with § 318.13–4f. Absent irradiation, each ban will be followed by reinspection in the manner specified, and the production area must be found free of green scale prior to interstate movement.

(b) The grower must establish a buffer area surrounding gardenia production areas. The buffer area must extend 20 feet from the edge of the production area. Within the buffer area, the growing of gardenias and the following green scale host plants is prohibited: Ixora, ginger (*Alpina purpurata*), plumeria, coffee, rambutan, litchi, guava, citrus, anthurium, avocado, banana, cocoa, macadamia, celery, *Pluto indicia* (a weed introduced into Hawaii), mango, orchids, and annona.

(c) An inspector must visually inspect the cut blooms of gardenias in each shipment prior to interstate movement from Hawaii to the mainland United States. If the inspector does not detect green scale in the shipment, the inspector would issue a certificate for the shipment in accordance with § 318.13–4(a). If the inspector finds green scale in a shipment, that shipment must be treated with irradiation in accordance with § 318.13–4f to be eligible for interstate movement from Hawaii.

Done in Washington, DC, this 9th day of May 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–12135 Filed 5–14–02; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 112 and 113

[Docket No. 93–129–1]

Viruses, Serums, Toxins, and Analogous Products; Equine Influenza Vaccine, Killed Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning Standard Requirements for veterinary biologics by adding a Standard Requirement for Equine Influenza Vaccine, Killed Virus. This proposed rule would require that such vaccines be shown to protect vaccinates for at least 60 days based on a vaccination-challenge study conducted in horses. In addition, we would establish a serum hemagglutination inhibition test in guinea pigs as the serial release potency test for the vaccine; establish procedures for adding and removing strains of virus based on evidence of changes in the antigenic character of the equine influenza viruses in current circulation; and add labeling requirements to the regulations. The effect of these proposed changes would be to standardize purity, safety, potency, and efficacy requirements for equine influenza vaccine to ensure that such products will provide a minimum level of protection to vaccinated horses.

DATES: We will consider all comments we receive that are postmarked, delivered, or e-mailed by July 15, 2002.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 93–129–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 93–129–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 93–129–1'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) prescribe Standard Requirements for the preparation and testing of veterinary biological products. A Standard Requirement consists of test methods, procedures, and criteria that define the standards of purity, safety, potency, and efficacy for a given type of veterinary biological product. When a Standard Requirement for a product type does not exist, test methods, procedures, and criteria for evaluating the purity, safety, potency, and efficacy are provided in an Outline of Production for the product filed with the Animal and Plant Health Inspection Service (APHIS). Once uniform standards for a type of product are established, they are codified in the regulations as a Standard Requirement.

Because there is no Standard Requirement in 9 CFR part 113 for Equine Influenza Vaccine, each manufacturer of these products has devised its own procedures, which are a part of the Outline of Production, to meet the requirements of the Virus-Serum-Toxin Act that all veterinary biological products be pure, safe, potent, and efficacious. Although several equine influenza vaccines have been licensed, the lack of standardized procedures for updating such products to compensate for the short-lived antibody response in horses and the natural antigenic shift and drift that is characteristic of the influenza virus, has resulted in horse owners having to revaccinate their animals every 3 to 4 months in order to ensure protection. Therefore, we are proposing to add a new § 113.217 to the standards that would require uniform criteria, test methods, and procedures that would provide vaccine manufacturers a method by which to update their products to compensate for the natural evolution of the virus and ensure that equine influenza vaccines remain pure, safe, potent, and efficacious.

In the proposed Standard Requirement, equine influenza vaccine would be evaluated for immunogenicity by vaccinating susceptible horses at the minimum age recommended on the label and challenging those horses at least 60 days after the last vaccine dose using a relevant equine influenza challenge virus provided by or acceptable to APHIS. Protection would have to be demonstrated for at least one component strain of each equine influenza virus subtype present in the vaccine, and would be based on the demonstration of a statistically significant difference in the characteristic clinical signs of equine influenza virus infection in vaccinated horses as compared to non-vaccinated control horses. In addition, once host animal protection against challenge has been demonstrated for any strain of a particular equine influenza virus subtype, protection may be claimed for other strains of the same subtype contained in the same product by using hemagglutination titers to demonstrate an acceptable dose-response relationship between the challenge and non-challenge strain(s) in horses or guinea pigs. Hemagglutination inhibition titers (HI titers) could serve as a basis for adding or substituting strains of a particular subtype as long as at least one strain of each subtype present in the vaccine has been evaluated in a host animal challenge-protection study.

The proposed serial release potency test for equine influenza vaccine is a serum hemagglutination inhibition test performed in guinea pigs; other tests could be used if they were found by APHIS to be acceptable. We are proposing HI titers in guinea pigs as a serial release potency test based on our experience with such tests that indicates manufacturers should be able to develop the dose-response data and mean relative potency value needed to establish the required correlation between guinea pig titers and HI titers in horses.

In addition, we are proposing to add a new paragraph to the regulations in § 112.7 to require equine influenza vaccine labeling to list the subtype(s) and strain(s) of the virus used in the product.

This proposed Standard Requirement was developed with the cooperation of licensees, researchers, and scientists at APHIS' Center for Veterinary Biologics-Laboratory. The proposed Standard Requirement would establish uniform immunogenicity and potency criteria for equine influenza vaccine and improve the protection such vaccine provides.

Immunogenicity

We are proposing that equine influenza vaccine be evaluated for immunogenicity in horses. For at least one strain of each subtype of equine influenza virus contained in the vaccine, 15 equine influenza susceptible horses (10 vaccinates and 5 controls) of the minimum age recommended on the label would be vaccinated with equine influenza vaccine made with virus at the highest passage from Master Seed and at the minimum preinactivation titer provided in the filed Outline of Production.

Duration of Immunity

This proposed rule would also require equine influenza vaccine to protect horses against the characteristic signs of equine influenza for a minimum of 60 days. To demonstrate protection and duration of immunity, horses used in the immunogenicity study would be challenged not less than 60 days after vaccination with a representative strain of each equine influenza virus subtype present in the vaccine.

Potency

Under this proposed rule, the potency of each serial would have to be evaluated for potency in guinea pigs. Each strain of each subtype of equine influenza virus contained in the vaccine would be evaluated for potency using guinea pigs as test animals.

Safety

For safety, we are proposing that the guinea pigs used in the potency test be observed each day during the post-vaccination observation period for unfavorable reactions attributable to the vaccine.

Currently Licensed Vaccines

Veterinary biologics manufacturers that produce equine influenza vaccine under present standards described in their filed Outlines of Production would be allowed 2 years after the effective date of the final rule to come into compliance. In the interim, we would allow such manufacturers to continue to release serials of equine influenza vaccine using the standard described in their filed Outlines of Production, provided that such serials of product are shown to be effective and the labels for such products specify the demonstrated duration of immunity.

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 purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to amend the Virus-Serum-Toxin Act regulations in 9 CFR part 113 by adding a new Standard Requirement for Equine Influenza Vaccine, Killed Virus. This proposed rule would require equine influenza vaccines to protect against clinical signs of equine influenza virus infection for at least 60 days based on challenge protection studies performed in horses. In addition, this proposed rule would allow claims for protection to be made for other strains of the equine influenza virus of the same subtype contained in the same product provided that the manufacturer demonstrates an acceptable dose-response relationship between the challenge and non-challenge strain(s) in host animals or guinea pigs. This proposed Standard Requirement would affect all licensed manufacturers of veterinary biologics producing any new equine influenza vaccine by requiring manufacturers of equine influenza vaccine to incur the expense associated with demonstrating protection of horses against the characteristic signs of equine influenza for at least 60 days.

Currently, only 8 of the approximately 135 licensed veterinary biologics manufacturers produce equine influenza vaccine and would be affected by this proposal. According to the standards of the Small Business Administration,

most veterinary biologics establishments would be classified as small entities.

Veterinary biologics manufacturers that produce equine influenza vaccine that does not meet this proposed standard would be allowed 2 years from the effective date of the final rule to come into compliance. In the interim, we would allow such manufacturers to continue to release serials of equine influenza vaccine using the current standard described in their filed Outlines of Production.

We do not have an alternative option to this proposed rule in light of the ever-changing antigenic profile of the equine influenza virus, which has created a demand for equine influenza vaccine that provides better protection than the currently available products. This proposed rule, if adopted, would aid firms manufacturing equine influenza vaccines. The proposal contains a Standard Requirement for immunogenicity testing that would provide uniformity among firms instead of each firm having to meet APHIS' requirements by methods of its own design. This would reduce a firm's cost of research and development needed to design a method to test immunogenicity. In addition, once host animal protection has been demonstrated for any strain of a particular equine influenza virus subtype, non-host animal methods may be used to claim protection for other strains of the same subtype.

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 is listed in the category 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed 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

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, we propose to amend 9 CFR parts 112 and 113 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 2.22, 2.80, and 371.4.

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

§ 112.7 Special additional requirements.

* * * * *

(n) In the case of biological products containing equine influenza virus, all labels shall specify the subtype(s) and strain(s) of the virus used in the product and the revaccination recommendation as determined from the results of duration of immunity studies acceptable to the Animal and Plant Health Inspection Service.

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 2.22, 2.80, and 371.4.

4. Section 113.217 would be added to read as set forth below.

§ 113.217 Equine Influenza Vaccine, Killed Virus.

Equine Influenza Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed that has been established as pure, safe, and immunogenic may be used for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed. Firms currently producing equine influenza vaccine that does not satisfy this requirement have until [*Insert date 2 years from effective date of final rule*] to comply with this requirement unless granted an extension by the Administrator based on a showing by the firm seeking the extension that they have made a good faith effort with due diligence to achieve compliance.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.200.

(b) The immunogenicity of vaccine prepared from the Master Seed in accordance with the Outline of Production must be established by the method prescribed in this paragraph or other method acceptable to the Animal and Plant Health Inspection Service (APHIS). The vaccine used for this test must be at the highest passage from the Master Seed and at the minimum preinactivation titer provided in the Outline of Production. The test must establish that the vaccine when used as recommended on the label is capable of inducing an immune response that protects horses for at least 60 days following completion of the immunization regimen specified on the labeling.

(1) For at least one strain of each subtype of equine influenza virus contained in the vaccine, at least 15 susceptible horses of the minimum age recommended on the label shall be used as test animals. Horses are considered susceptible if the HI titer of individual serum samples taken from each animal is less than 1:10 using a constant virus, decreasing serum HI assay against 4 HA units of each strain of virus tested. The virus (antigen) may not be treated prior to the assay.

(2) At least 10 horses shall be vaccinated in accordance with the label recommendation, and at least 5 additional horses shall be held as unvaccinated controls. To demonstrate continued susceptibility, vaccinates must be negative for an anamnestic serologic response at 7 days after the first vaccination.

(3) Not less than 60 days after completion of the immunization regimen, the immunity of each of the vaccinates and the controls shall be challenged. At least 10 vaccinates and 5 controls must be challenged with a representative strain of each equine influenza virus subtype present in the vaccine in a manner acceptable to APHIS, and observed each day for 7 days for clinical signs of disease. Test animals must be bled immediately prior to challenge, and serum samples obtained for testing. If the controls are not seronegative at the time of challenge, the test is inconclusive and may be repeated.

(4) If a statistically significant ($p<0.05$) difference in clinical signs and temperature cannot be demonstrated between the vaccinates and controls using a scoring system acceptable to APHIS, the Master Seed is unsatisfactory.

(5) If the Master Seed immunogenicity test is satisfactory, other strains of equine influenza virus of the same subtype(s) may be added to the vaccine at any time by demonstrating that the added strain(s) elicits a serum HI titer either in horses or in guinea pigs that is equal to or greater than the titer elicited by the strain of the virus used in the challenge study. *Provided,* That:

(i) For each virus subtype claimed on the label for the product, the vaccine will at all times contain at least one strain of equine influenza virus whose immunogenicity has been determined in a host animal vaccination-challenge study.

(ii) Guinea pig HI titers may be used only if a satisfactory dose-response relationship correlated to host animal protection and a mean relative potency value of the vaccine in guinea pigs based on a minimum of 3 replicate tests conducted at the time of the efficacy study has been established or can be shown.

(c) *Test requirements for release.* Each serial must meet the applicable general requirements prescribed in § 113.200 and the special requirements for safety and potency provided in this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* The vaccinates used in the potency test in paragraph (c)(2) of this section shall be observed each day during the post vaccination observation period. If unfavorable reactions occur which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur that are not attributable to the vaccine, the test is inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial is unsatisfactory.

(2) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency as provided in this paragraph. For each fraction of each subtype contained in the product—subtype A1 or subtype A2—the serological interpretations required in this test shall be made independently.

(i) At least 12 guinea pigs, each weighing between 300 and 500 grams, shall be used as test animals.

(ii) A dose of product equivalent to one-half the recommended horse dose shall be administered by the recommended horse route to at least 10 animals. A second dose shall be administered by the same route 14 to 21 days later. At least two animals shall be held as unvaccinated controls.

(iii) Fourteen to 21 days after the second vaccination, the animals shall be bled and serum samples obtained. The samples from each animal shall be tested in an HI assay consistent with that described in the following paragraph or by an alternative method acceptable to APHIS.

(iv) The serum samples shall be treated with kaolin and chicken red blood cells prior to initiation of the assay. A constant-virus, decreasing-serum HI assay against four hemagglutination units of each virus fraction shall be employed. The antigens may not be treated prior to performance of the assay.

(v) *Test interpretation.* If the controls for a given test fraction have not remained seronegative at the lowest test dilution (1:10), the test is inconclusive and may be repeated. If the geometric mean titer (GMT) of vaccinates in a valid test is less than the guinea pig GMT correlated with protection of horses against the applicable virus subtype, the serial is unsatisfactory unless the test is repeated. If the second test meets the requirements for validity and the GMT of vaccinates from both tests is less than the guinea pig GMT correlated with protection of horses for that subtype, then the serial is unsatisfactory without further testing.

(d) If more than 60 days' duration of immunity is to be claimed for any fraction, it may be shown by vaccinating at least 10 horses as recommended on the label and demonstrating an HI titer that is equal to or greater than the titer achieved in the Master Seed immunogenicity study for the period of time claimed. Labels must specify revaccination every 60 days if longer duration of immunity is not shown. Although not required, horses used to establish the duration of immunity beyond the required minimum of 60 days may also be challenged.

Done in Washington, DC, this 9th day of May, 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–12134 Filed 5–14–02; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–48–AD]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Model BAe 146 and Avro 146–RJ Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all BAE Systems (Operations) Limited Model BAe 146 and Avro 146–RJ series airplanes. This proposal would require replacement of the existing ''Low Temp'' terminal blocks ''G'' with new, fireproof ceramic terminal blocks ''G'' in engine zones 412, 422, 432, and 442. This action is necessary to prevent failure of the engine fire detection and suppression systems to operate properly in the event of a fire due to failure of non-fireproof terminal blocks, which could result in an undetected and uncontrollable fire in an engine. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by June 14, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–48–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2002–NM–48–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the FAA, Transport Airplane Directorate,