

Proposed Rules

Federal Register

Vol. 60, No. 52

Friday, March 17, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 112

[Docket No. 93-167-1]

Viruses, Serums, and Toxins and Analogous Products; Master Labels

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the packaging and labeling of veterinary biologicals to require the use of a master label. The use of a master label system would: reduce the number of copies of labels that are required to be submitted for review and approval, and allow labels with certain minor revisions to be used sooner than would be possible without the use of a master label. A definition of "master label" would be added to the regulations. The proposed amendments are necessary in order to improve label approval procedures by establishing a master label system. The effect of the proposed amendment would be to streamline the procedure for requesting and receiving approval to use new or revised labels for veterinary biologicals.

DATES: Consideration will be given only to comments received on or before May 16, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 93-167-1, Animal and Plant Health Inspection Service, Policy and Program Development, Regulatory Analysis and Development, 4700 River Road Unit 118, Riverdale, MD 20737-1228. Please state that your comments refer to Docket No. 93-167-1.

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 (202) 690-2817) to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, MD 20737-1228, telephone number (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations pertaining to the packaging and labeling of veterinary biologicals are in 9 CFR part 112. The regulations require that all labels for veterinary biologicals be submitted and reviewed for compliance with the regulations and approved in writing prior to use. APHIS has issued licenses under the Virus-Serum-Toxin Act (21 U.S.C. 151-159) for some 2000 veterinary biological products. Each licensed biological product is required to have approved packaging and labeling applicable to a variety of container sizes, trade names, producers, subsidiaries, and distributors.

Current regulations require each product label to be reviewed and approved individually prior to use. Several nearly identical labels for one product are often required to be reviewed and approved by APHIS. A minor revision in the labeling of a product can result in the additional review and approval of all revised labels for that product.

Due to the large number of label submissions and the requirement for label review prior to the marketing of a biological product, an inordinate amount of program time and resources may be expended in the review and approval of label submissions. Many label submissions constitute only minor revisions.

An analysis of the time and resources currently required to review, file, and store label submissions involving minor revisions, and the accompanying delay experienced by some manufacturers in receiving approval and written notification suggest that the process by which labels are approved may be simplified. We propose to institute the use of a master label system that would reduce redundant review and approval of submissions involving only minor revisions of approved labels. Under the proposed master label system, only the

container and carton label for the smallest size final container that is approved by APHIS and any insert for the product would be required to be submitted for review, approval, and filing as master labels. Certain specified revisions could be made on labels under the Master Label system without prior written approval, provided that such revisions are submitted to APHIS for review, approval, and filing within 60 days of use of the revised label.

We are proposing to amend the definition in § 101.4 by adding a new paragraph (h) as follows:

(h) *Master label.* The finished carton, container, or enclosure label for the smallest size final container that is authorized for a biological product, that serves as the master template label applicable to all other size containers or cartons of the same product that is marketed by a licensee, subsidiary, division, or distributor.

We are also proposing to revise several paragraphs of the regulations in § 112.5 pertaining to the review and approval of labels to add specific provisions related to the use of master labels (see introductory paragraph, paragraphs (d)(1)(ii), (d)(1)(iv), (d)(3)(ii)(a), (d)(4), and (g)).

Certain revised labels could be used on products with approved master labels prior to review and approval by APHIS as provided under proposed paragraph (c) of § 112.5.

Two copies of master label sketches would be submitted for each enclosure and the labels for the smallest approved size of carton and container. A master label sketch would be held on file for one year, or as long as a license application was active.

For finished master labels, three copies of each enclosure and of each label for the smallest size carton and final container would be submitted. Labels for larger size containers or cartons of the same product would not be submitted, provided that the larger size container or carton is approved in the Outline of Production and the larger size container or carton is identified on the label mounting sheet. When the master label enclosure is used with more than one product, an extra copy of the enclosure for each additional product would have to be submitted. Finally, the information that must be submitted on the lower left hand corner of each page of the label submission

would include the reason for the submission, a reference to the master label, its replacement, and the dose sizes for which the master label is to be used.

We are proposing to add a provision in § 112.5(c) to allow for specified minor label changes without prior approval by APHIS for products with approved master labels. Minor label changes that would be allowed include changes in physical dimensions of the label or the color of the label print that do not affect legibility; the addition, deletion, or change of a trademark or registered symbol, label control number or bar code, or logo; and the correction of typographical errors. Such minor changes would, of course, not be appropriate if they cause the label to be false or misleading. In addition, there would be a requirement that a new master label bearing such minor changes be submitted to APHIS for review and written approval within 60 days of label use.

We are also proposing to revise § 112.5(d)(2)(iii)(a) to add a provision for the labeling of individual reagent containers included with diagnostic test kits. Such labeling of individual reagent containers would be mounted together on a single sheet of paper, when possible. Carton labels and enclosures would be mounted on separate individual sheets.

Finally, we are proposing to add a provision in § 112.5(g) that provides for inspection of labels and master labels by authorized inspectors.

We would also correct the references in § 112.7, paragraph (c)(2), by changing "§ 113.129" to read "§ 113.209" and in paragraph (d)(6) by changing "§ 113.147" to read "§ 113.312". In addition, in § 112.5(d), paragraph (2)(iii)(b) would be redesignated paragraph (2)(iii)(B), paragraph (3)(i)(a) would be redesignated paragraph (3)(i)(A), paragraph (3)(i)(b) would be redesignated paragraph (3)(i)(B), and paragraph (3)(ii)(b) would be redesignated paragraph (3)(ii)(B).

This proposed amendment was developed through the cooperative efforts of the manufacturers of veterinary biologicals, the Animal Health Institute, and APHIS. The overall effect of this regulation would be to simplify the process whereby labels are approved by reducing the number of copies of labels needed to be submitted for review.

Executive Order 12866 and Regulatory Flexibility Act

This 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 rule would amend the regulations for the review and approval of biological product labels by providing for a master label system. The current regulations in part 112 require the submission and approval of all labels for each biological product to be marketed. The approval of a prototype master label for each product would reduce the need for licensees producing veterinary biologicals to submit for approval additional copies of labels for each product.

The approval of a master label would apply to labels for larger container sizes of the same product, provided that the labels are identical to the master label, except for physical dimensions, and provided that additional container sizes are authorized in a filed Outline of Production.

This proposed rule would also allow certain approved labels with specified minor revisions to be used without prior written approval with the provision that new master labels be submitted to APHIS for review and approval within 60 days use of the revised label.

The proposed rule has its major effect in reducing the number of copies of labels that need to be submitted and reviewed. Most products are marketed in two or three different size containers. Currently, each label for each container must be submitted for approval. Under the proposed master label concept, only labels for the smallest size container would need to be submitted, thus reducing by two to three fold the number of labels that would need to be submitted by manufacturers and processed by APHIS.

The proposed rule would not have any adverse economic impact, since the submission of product labels for approval is already required under § 112.5 of the regulations, which currently specifies that all labels shall be reviewed and approved prior to use. The proposed amendments would simplify the process of label approvals and would reduce the time and expense necessary to get a product to market in the case of certain minor revisions of labels.

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 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 in conflict 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

The proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

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).

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 112

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

Accordingly, 9 CFR parts 101 and 112 would be amended as follows:

PART 101—DEFINITIONS

1. The authority citation for part 101 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 101.4 would be amended by adding a new paragraph (h) to read as follows:

§ 101.4 Labeling terminology.

* * * * *

(h) *Master label.* The finished carton, container, or enclosure label for the smallest size final container that is authorized for a biological product, that serves as the Master template label applicable to all other size containers or cartons of the same product that is marketed by a licensee, subsidiary, division, or distributor.

PART 112—PACKAGING AND LABELING

3. 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).

4. Section 112.5 would be amended as follows:

a. The introductory paragraph would be revised to read as set forth below.

b. Paragraph (c) would be revised to read as set forth below.

c. Paragraphs (d)(1)(i) and (d)(1)(ii) would be revised to read as set forth below.

d. Paragraphs (d)(1)(iii) and (d)(1)(iv) would be added to read as set forth below.

e. Paragraph (d)(2)(iii)(a) would be revised to read as set forth below.

f. Paragraph (d)(3)(ii)(a) would be revised to read as set forth below.

g. Paragraph (d)(4) would be revised to read as set forth below.

h. Paragraph (g) would be added to read as set forth below.

i. In § 112.5, paragraph (d)(2)(iii)(b) would be redesignated paragraph (d)(2)(iii)(B), paragraph (d)(3)(i)(a) would be redesignated paragraph (d)(3)(i)(A), paragraph (d)(3)(i)(b) would be redesignated paragraph (d)(3)(i)(B), and paragraph (d)(3)(ii)(b) would be redesignated paragraph (d)(3)(ii)(B).

§ 112.5 Review and approval of labeling.

Labels used with biological products prepared at licensed establishments or imported for general distribution and sale must be submitted to the Animal and Plant Health Inspection Service for review for compliance with the regulations and approval in writing prior to use, except under the master label system as provided in paragraph (c) of this section.

* * * * *

(c)(1) Labels must be submitted to the Animal and Plant Health Inspection Service for review and written approval. Only labels which are approved as provided in § 112.5 (d) may be used. When changes are made in approved labels, the new labels shall be subject to review and approval before use: *Provided*, That certain minor changes may be made in labels for products with approved master labels, and the revised labels, may be used prior to review by APHIS, with the provision that a new master label bearing these changes is submitted to APHIS for review and written approval within 60 days of label use, and that such minor changes do not render the product mislabeled or the label false and misleading in any particular.

(2) Minor label changes that may be made under the provision for products with approved master labels are:

(i) Changes in the physical dimensions of the label provided that such change does not affect the legibility of the label;

(ii) Change in the color of label print, provided that such change does not affect the legibility of the label;

(iii) The addition or deletion of a Trade Mark (TM) or Registered (R) symbol;

(iv) The correction of typographical errors;

(v) Adding or changing label control numbers or bar codes; and

(vi) Revising or updating logos.

* * * * *

(d) (1) * * *

(i) For label sketches, submit two copies of each sketch of a final container label, carton label, and enclosure. Sketches must be legible, and must include all information specified in § 112.2. One copy of each sketch will be returned with applicable comments, and one copy will be held on file by APHIS for no more than one year after processing, until replaced by a finished label: *Provided*, That sketches submitted in support of an application for a license or permit shall be held as long as the application is considered active.

(ii) For master label sketches, submit for each product two copies of each sketch of an enclosure, label for the smallest size final container, and carton label: *Provided*, That labels for larger size containers and/or cartons that are identical, except for physical dimensions, need not be submitted. One copy of each master label sketch will be returned with applicable comments, and one copy will be held on file by APHIS for one year after processing, until replaced by a finished master label that is submitted according to § 112.5(d)(1)(iii): *Provided*, That master label sketches submitted in support of an application for license or permit shall be held as long as the application is considered active.

(iii) For finished labels, submit three copies of each finished final container label, carton label, and enclosure: *Provided*, That when an enclosure is to be used with more than one product, one extra copy shall be submitted for each additional product. Two copies of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee. Labels to which exceptions are taken shall be marked as sketches and handled under § 112.5(d)(1)(i).

(iv) For finished master labels, submit for each product three copies each of the enclosure and the labels for the smallest size final container and carton. Labels for larger sizes of containers or cartons of the same product that are identical, except for physical dimensions, need not be submitted. Such labels become eligible for use, concurrent with the approval of the appropriate finished master label: *Provided*, That the marketing of larger sizes of final containers is approved in the filed Outline of Production, and the appropriate larger sizes of containers or

cartons are identified on the label mounting sheet. When a master label enclosure is to be used with more than one product, one extra copy of each additional product shall be submitted. Two copies of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee. Master labels to which exceptions are taken will be marked as sketches and handled under § 112.5(d)(1)(ii).

* * * * *

(2) * * *

(iii)(A) When two final containers are packaged together in a combination package, the labels for each shall be mounted on the same sheet of paper and shall be treated as one label. For diagnostic test kits, the labels for use on the individual reagent containers to be included in the kit shall be mounted together on a single sheet of paper, if possible; if necessary, a second sheet of paper may be used. The carton label and enclosure shall be mounted on separate individual sheets.

* * * * *

(3) * * *

(ii)(A) Designation of the specimen as a label or master label: sketch, final container label, carton label, or enclosure.

(B) If two final container labels or multiple parts are on one sheet, each shall be named, and the label or part being revised shall be designated.

(iii) Size of package (dose, ml., cc., or units) for which the labels or enclosures are to be used.

(4) To appear on the bottom of each page: The reason for and information relevant to the submission shall be stated in the lower left hand corner as:

(i) Master label dose sizes approved for code _____.

(ii) Replacement for label, master label, and/or sketch No. _____.

(iii) Reference to label or master label No. _____.

(iv) Addition to label No. _____.

(v) License Application Pending _____.

(vi) Foreign Language copy of label No. _____.

* * * * *

(g) At the time of an inspection, or when requested by APHIS, licensees or permittees shall make all labels and master labels, including labels approved for use but exempted from filing under the master label system, available for review by authorized inspectors. Such labels shall be identical to the approved label or master label except for physical dimensions, reference to recoverable volume or doses and/or certain minor differences permitted in accordance with § 112.5(c).

5. In § 112.7, paragraphs (c)(2) and (d)(6) would be revised as follows:

§ 112.7 Special additional requirements.

* * * * *

(c) * * *

(2) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.209, paragraphs (b) or (c), or both.

* * * * *

(d) * * *

(6) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.312, paragraphs (b) or (c), or both.

* * * * *

Done in Washington, DC, this 13 day of March 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-6650 Filed 3-16-95; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95-NM-02-AD]

Airworthiness Directives; Fokker Model F28 Mark 0100 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 certain Fokker Model F28 Mark 0100 series airplanes. This proposal would require repetitive checks to detect backlash in the elevator mechanical control system, and various follow-on actions. The proposed AD would also provide for an optional terminating action for the repetitive check requirements. This proposal is prompted by a report indicating that corrosion was found on the pivot bolts and bushings of the backlash remover lever mechanism on the elevator booster control unit (BCU) of a Model F28 Mark 0100 series airplane. The actions specified by the proposed AD are intended to prevent such corrosion, which could result in backlash in the elevator controls and reduced elevator control authority in the manual mode.

DATES: Comments must be received by May 12, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-02-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 Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (206) 227-2141; fax (206) 227-1100.

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 in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 95-NM-02-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the

FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-02-AD, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

Discussion

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, recently notified the FAA that an unsafe condition may exist on all Fokker Model F28 Mark 0100 series airplanes equipped with a certain Menasco Aerospace Elevator Booster Control Unit (BCU). The RLD advises that corrosion was found on the pivot bolts and bushings of the backlash remover lever mechanism on the elevator BCU of Model F28 Mark 0100 series airplanes. This mechanism prevents backlash in the elevator control forces when the elevator BCU is not hydraulically powered, providing the pilot with full manual control of the elevator system. Investigation revealed that corrosion on the pivot bolts and bushings causes the backlash remover mechanism to stick, which results in deteriorated elevator control when the BCU is in manual mode. This condition, if not corrected, could result in backlash in the elevator controls and reduced elevator control authority in the manual mode.

Fokker has issued Service Bulletin SBF100-27-052, Revision 1, dated March 29, 1994, which describes procedures for:

1. Performing repetitive operational checks to detect backlash in the elevator mechanical control system;

2. Performing an inspection to determine whether certain elevator BCU bolts rotate and slide freely, and to detect corrosion on the bolts of the backlash remover lever mechanism, if any backlash is detected; and

3. Replacing the elevator BCU or bolts with a serviceable part, if any anomaly is detected.

The RLD classified this service bulletin as mandatory and issued Dutch airworthiness directive BLA 93-051/3 (A), dated April 29, 1994, in order to assure the continued airworthiness of these airplanes in the Netherlands.

Additionally, Fokker has issued Service Bulletin SBF100-27-061, dated March 2, 1994, which provides instructions for accomplishing an optional modification of the affected elevator BCU, which would eliminate the need for the repetitive operational checks. This modification involves replacing two bolts in the elevator BCU with new bolts.

This airplane model is manufactured in the Netherlands and is type certificated for operation in the United States under the provisions of section