Proposed Rules

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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 116

[Docket No. 00–071–1]

Viruses, Serums, Toxins, and Analogous Products; Records and Reports

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning records and reports. First, we are proposing to require veterinary biologics licensees and permittees to record and submit reports to the Animal and Plant Health Inspection Service concerning adverse events associated with the use of biological products that they produce or distribute. Second, we are proposing to require veterinary biologics licensees and permittees to report to the Animal and Plant Health Inspection Service the number of doses of each licensed product that they distribute. Third, we are proposing to provide definitions for *adverse event* and *adverse event report*. These actions would assist the Animal and Plant Health Inspection Service in providing complete and accurate information to consumers regarding adverse reactions or other problems associated with the use of licensed biological products.

DATES: We will consider all comments we receive that are postmarked, delivered, or e-mailed by March 18, 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. 00–071–1, 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. 00–071–1. 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. 00–071–1'' 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, between 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, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD, 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 116 contain requirements for maintaining detailed records of information necessary to give a complete accounting of all the activities within a veterinary biologics establishment.

In this document, we are proposing amendments to that part. First, we are proposing to require veterinary biologics licensees and permittees to record and submit reports to the Animal and Plant Health Inspection Service (APHIS) concerning adverse events associated with the use of biological products that they produce or distribute. Second, we are proposing to require veterinary biologics licensees and permittees to report to APHIS the number of doses of each licensed product that they distribute. Third, we are proposing definitions for *adverse event* and *adverse event report.*

Definitions

The regulations at 9 CFR part 101 contain definitions of terms used in the regulations concerning veterinary biologics. The proposed changes to part 116 of the regulations would make it necessary for us to add definitions in § 101.2 for two terms used in the proposed regulations: *Adverse event* and *adverse event report.* We would define *adverse event* as ''any undesirable and unintended occurrence after the use of a biological product, whether or not the cause of the event is known. For products administered to animals, adverse events are those involving the health of the treated animal, including the apparent failure to protect against disease. For products intended to diagnose disease, adverse events refer to anything that hinders discovery of the correct diagnosis.'' We would define *adverse event report* as ''a communication concerning the occurrence of one or more adverse events which identifies the product(s), animal(s), and person making the report.'' The receipt of an adverse event report does not necessarily imply that the product caused the adverse event.

Adverse Event Records and Reports

Currently, § 116.1(a) requires each licensee, permittee, and foreign manufacturer of biological products imported into the United States to maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within each establishment. Section 116.1, paragraph (a), further states that such records must include, but are not limited to, the items listed in part 116, which are inventory and disposition records (§ 116.2), label records (§ 116.3), sterilization and pasteurization records (§ 116.4), product development and preparation and market suspensions and recalls (§ 116.5), animal records (§ 116.6), and test records (§ 116.7).

In addition, §§ 116.1(b) and 116.5(b) state that if at any time there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify APHIS concerning the circumstances and the action taken, if any.

However, the regulations in § 116.1(a) and (b) and § 116.5(b) do not explicitly require licensees and permittees to maintain records of reports of adverse events associated with the use of veterinary biologics, nor do the regulations provide specific guidance in determining when an adverse event report may raise questions regarding the purity, safety, potency, efficacy, preparation, testing, or distribution (PSPEPTD) of such product. Consequently, each veterinary biologics manufacturer makes independent determination concerning (1) whether an adverse event report raises PSPEPTD questions and (2) when and in what manner such report of the adverse event will be provided to APHIS.

To limit the harm to animals posed by unsatisfactory veterinary biologics, APHIS currently must rely primarily on adverse event reports provided by the manufacturer. Unexpected or unexplained adverse events associated with the use of veterinary biologics in animals are reported to the veterinary biologics manufacturer either by the consumer or in the form of a report from a technical service veterinarian employed by the manufacturer to monitor the performance of their products in the field.

Currently, licensees and permittees are using nonstandardized methods to record and submit reports regarding adverse events to APHIS. In addition, adverse event reports that may signal problems concerning the use of veterinary biologics products are not all being submitted to APHIS in a timely manner. Unless we have complete and timely reports, we may not be able to take expeditious action to limit the harm in animals caused by veterinary biological products that may be harmful or dangerous to animals. Therefore, we are proposing to add to the regulations a new § 116.9 for adverse event records. New § 116.9 would require licensees and permittees to record reports of all adverse events that they receive concerning the use of biological products that they produce or distribute and submit a summary of such reports to APHIS on an annual basis. Licensees and permittees would be required to record information concerning adverse events that includes: (1) The date of the report; (2) identification of the person initiating the report; (3) the true name of the product involved and product trade name; (4) the product serial number, if available; (5) a description of the adverse event; (6) the animal(s) involved; and (7) any other pertinent identifying information regarding the product.

In addition, in new § 116.9, we would propose that licensees and permittees prepare summaries of the adverse event report records for submission to APHIS. Beginning with the date the product is licensed, such summaries would have to include intervals of 6 months during the first year and intervals of 1 year thereafter. We would also require summaries to be received by APHIS within 30 days after the end of the interval.

We would require records for each 6-month interval after the product is licensed because little is known about newly licensed products, except for observations made during the immunogenicity studies, safety tests, and field trials for these products. We believe that more frequent reporting requirements for newly licensed products would ensure that we have adequate data to support a decision to take regulatory action against products that are associated with an unusual number of adverse event reports.

We are also proposing to revise §§ 116.1(a)(3) and 116.8 of the regulations to allow adverse event records to be excluded from the list of records to be completed before serials may be marketed because adverse event records cannot be completed before a product has been distributed and used in animals.

The proposed amendments would standardize the adverse event reporting system and the information that should be included when making records of adverse event reports.

Number of Doses Distributed

In order to provide an objective measure of when it may be necessary to take action against a veterinary biologic to limit the harm in animals, and as a component of the adverse event reporting system, we would use the number of doses of product distributed instead of the number of doses of product administered to animals to calculate the incidence of adverse events associated with a particular product. Typically, the number of doses of product administered to animals would be used to calculate incidence. Because we must take timely action and may not know precisely how many animals have been treated with a product, we believe that the number of marketed doses of a product should be representative of the number of doses that were administered to animals.

Currently, the regulations in part 116 do not require veterinary biologics manufacturers to report to APHIS the number of doses of each licensed product that are distributed. Therefore, we are proposing to add this requirement in new § 116.5(c). In addition, we are proposing that the records include the number of doses for each 6-month interval after the product is licensed during the first year and each yearly interval thereafter. We would also require the reports to be received within 30 days after the end of the interval.

We would require records for each 6-month interval after the product is licensed based on the reasons provided previously in this document under ''Adverse Event Reports.''

Miscellaneous

We are also proposing to make minor, nonsubstantive, editorial changes to the regulations, as set out in the rule portion of this document, for clarity.

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 the 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 for records and reports. First, we are proposing to require veterinary biologics licensees and permittees to record and submit reports to APHIS concerning adverse events associated with the use of biological products that they produce or distribute. Second, we are proposing to require veterinary biologics licensees and permittees to report to APHIS the number of doses of each licensed product that they distribute. Third, we are proposing to provide definitions for *adverse event* and *adverse event report.* These actions would assist us in providing complete and accurate information to consumers regarding adverse reactions or other problems associated with the use of licensed biological products.

This proposed rule would affect most, if not all, licensed manufacturers of veterinary biologics. Currently, there are approximately 150 veterinary biologics manufacturers, including permittees. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

We believe that this proposed rule would not have a significant effect on small entities because most veterinary biologics manufacturers currently maintain recordkeeping systems for adverse event reports, and this proposed rule does not restrict manufacturers from using their discretion to choose the most appropriate recordkeeping system

for maintaining records of these reports. However, one of the purposes of this proposed rule is to provide veterinary biologics manufacturers with criteria that should be included in the reports so that the reports are standardized from manufacturer to manufacturer and submitted to APHIS in a timely manner.

In addition, the proposed requirement that veterinary biologics manufacturers report the number of doses of each licensed or permitted product that has been distributed would not have a significant effect on small entities. Veterinary biologics manufacturers currently maintain records of the number of doses of a product produced and distributed. This proposed rule would only require veterinary biologics manufacturers to report the number of doses to APHIS as required by the proposed regulations.

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 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 Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 00–071–1. Please send a copy of your comments to: (1) Docket No. 00–071–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would require manufacturers of veterinary biological products to maintain records of adverse event reports that they receive concerning the use of veterinary biological products that they produce or distribute for 2 years or longer and submit a summary of such reports to APHIS. The reports would have to be submitted at 6-month intervals during the first year the product is licensed and at 1-year intervals thereafter. In addition, licensees and permittees would have to report to APHIS the number of doses of each licensed product distributed every 6 months during the first year the product is licensed or permitted and at 1-year intervals thereafter. These information collection and recordkeeping requirements would allow us to monitor and provide the appropriate level of regulatory oversight.

We are soliciting comments from the public (as well as affected agencies) concerning this proposed amendment to the records and reports requirements in the regulations. We need this outside input to help us:

(1) Evaluate whether the proposed information collection in the form of records and reports is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 1 hour per response.

Respondents: Veterinary biologics licensees and permittees.

Estimated annual number of respondents: 125.

Estimated annual number of responses per respondent: 8.

Estimated annual number of responses: 1,000.

Estimated total annual burden on respondents: 1,000 hours.

Copies of this information collection can be obtained from: Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 116

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR parts 101 and 116 as follows:

PART 101—DEFINITIONS

1. The authority citation for part 101 would be revised to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. In § 101.2, definitions of *adverse event* and *adverse event report* would be added in alphabetical order to read as follows:

§ 101.2 Administrative terminology.

* * * * *

Adverse event. Any undesirable and unintended occurrence after the use of a biological product, whether or not the cause of the event is known. For products administered to animals, adverse events are those involving the health of the treated animal, including the apparent failure to protect against disease. For products intended to diagnose disease, adverse events refer to anything that hinders discovery of the correct diagnosis.

Adverse event report. A communication concerning the occurrence of one or more adverse events which identifies the product(s), animal(s), and person making the report.

* * * * *

PART 116—RECORDS AND REPORTS

3. The authority citation for part 116 would be revised to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

4. In § 116.1, paragraph (a)(3) would be revised to read as follows:

§ 116.1 Applicability and general considerations.

(a) * * *

(3) Records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer, as the case may be, before any portion of a serial of any product

may be marketed in the United States or exported.

* * * * *

5. Section 116.5 would be amended by adding a new paragraph (c) to read as follows:

§ 116.5 Reports.

* * * * *

(c) The licensee and/or permittee must report to APHIS the number of doses of each licensed or permitted product that has been distributed. Reports must include the number of doses for each 6 month interval during the first year the product is licensed and at yearly intervals thereafter. Reports must be received by APHIS within 30 days after the end of the interval.

* * * * *

6. Section 116.8 would be revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records must be retained at the place of business for the licensee, permittee, or foreign manufacturer for a period of 2 years after the expiration date of a product or longer as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

7. A new § 116.9 would be added to read as follows:

§ 116.9 Adverse event records.

(a) A detailed record must be maintained for every adverse event report the licensee or permittee receives for any biological product it produces or distributes. Each record must include:

(1) The date of the report;

(2) The identification of the person initiating the report;

(3) The true name of the product involved and product trade name;

(4) The serial number(s) of the product(s), if available;

(5) A description of the adverse event;

(6) The animal(s) involved; and

(7) Any other pertinent identifying information regarding the product.

(b) For each product, summaries of adverse event report records must be compiled and submitted to APHIS. Beginning with the date the product is licensed, such summary compilations must cover intervals of 6 months during the first year the product is licensed and yearly intervals thereafter. Summaries must be received within 30 days after the end of the interval.

Done in Washington, DC, this 10th day of January, 2002.

W. Ron DeHaven,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–938 Filed 1–14–02; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NE–49–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney PW4000 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to supersede an existing airworthiness directive (AD), that is applicable to Pratt & Whitney PW4000 series turbofan engines. That AD currently requires operators to perform initial and repetitive inspections for cracking of high pressure compressor (HPC) front drum rotors based on cycle usage. That AD also requires the removal from service of any cracked HPC front drum rotors. This proposal clarifies inspection requirements for cracking of high pressure compressor (HPC) front drum rotors that have fewer than 1,000 cycles-since-new (CSN). This proposal is prompted by comments from operators seeking more clarity about the inspection requirements of paragraph (a)(1) of the current AD. The actions specified in the proposed AD are intended to prevent HPC drum rotor failure from cracks that could result in an uncontained engine failure and damage to the airplane.

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

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–NE–49–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location, by appointment, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: ''*9-ane-adcomment@faa.gov*''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in the proposed rule may be obtained from Pratt & Whitney, 400 Main Street, East Hartford, CT 06108. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Tara Goodman, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington MA 01803–5299; telephone: 781–238–7130, fax: 781–238–7199.

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 should 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 action 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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NE–49–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–NE–49–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

On October 12, 2001, the FAA issued AD 2001–20–13, Amendment 39–12461