refund price computed pursuant to § 1309.2(e) by the producer's milk pounds, not to exceed $12,000.

Dated: March 2, 2000.

Kenneth M. Becker,

Executive Director.

[FR Doc. 00–5585 Filed 3–7–00; 8:45 am]

BILLING CODE 1650–01–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 95–066–1]

Viruses, Serums, Toxins, and Analogous Products; Autogenous Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations for autogenous biologics. The number of test summaries that autogenous biologics manufacturers must submit to the Animal and Plant Health Inspection Service would be reduced. In addition, we are proposing to amend the requirement concerning the submission to the Animal and Plant Health Inspection Service of containers selected from each serial of autogenous biologic that exceeds 50 containers. Manufacturers would be required to hold these containers and submission would not be required unless requested by the Animal and Plant Health Inspection Service. These actions would result in savings in time and resources for autogenous biologics manufacturers and the Animal and Plant Health Inspection Service without a significant reduction in regulatory oversight.

DATES: We will consider all comments that we receive by May 8, 2000.

ADDRESSES: Please send your comment and three copies to:

Docket No. 95–066–1, Regulatory Analysis and Development, PPD, APHIS Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 95–066–1.

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 rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html

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

SUPPLEMENTARY INFORMATION:

Background

The regulations in title 9, Code of Federal Regulations (9 CFR), part 113 contain standard requirements for the preparation of veterinary biological products. Section 113.113 of the regulations sets forth the requirements for autogenous biologics. Autogenous biologics are prepared from cultures of microorganisms that are isolated from sick or dead animals of a particular flock or herd. The cultures are used to produce an autogenous veterinary biological product that is administered to other animals of the originating flock or herd to prevent them from being affected by the same disease. Autogenous biologics may also be used in adjacent and nonadjacent herds under certain conditions, if approved by the Administrator of the Animal and Plant Health Inspection Service (APHIS).

Autogenous biologics are intended for use in isolated cases of diseases of animals when licensed products are not available or such products are unable to protect the vaccinated animals (*e.g.,* the strain of microorganism in the licensed product differs from the strain associated with the disease outbreak). Autogenous biologics can also be used to respond to emergency outbreaks of diseases of animals when the immediate need for the product is such that it precludes the usual route of vaccine development.

Given the special circumstances pertaining to the preparation and use of autogenous biologics, including the need for a rapid response to emergencies, special testing and serial release reporting requirements have been applied. In § 113.113, paragraph (c)(1)(ii) allows first serials or subserials of an autogenous biologic that are satisfactory after the third day of observation of purity test cultures and safety test animals to be released for shipment to the customer while the purity and safety tests are continued through the required period. Paragraph(c)(1)(iii) of § 113.113 provides that such serials must be immediately recalled if evidence of contamination occurs in the purity test cultures or if any of the test animals used to demonstrate product safety get sick or die during the observation period. However, because autogenous biologic products can be shipped prior to completion of testing, the products, in most cases, have been used in animals prior to the completion of testing. In addition, § 113.113(c)(1)(iv) requires autogenous biologics manufacturers to submit to APHIS the test summaries of the first serial or subserial within 4 days of the completion of the purity and safety tests. The test summaries must be submitted to APHIS in accordance with § 116.7 of 9 CFR part 116, ''Records and Reports.'' (Section 116.7, in short, provides the requirements for maintenance of detailed records of all tests conducted on each serial and subserial and the preparation and submission of summaries of such tests using APHIS Form 2008 or an equivalent prior to release of the serial or subserial.)

In 1993, the last year for which full data are available, veterinary biologics manufacturers submitted approximately 11,400 autogenous biologics first serial test summaries to APHIS for processing, and the number of reports has increased in succeeding years. However, we believe that the requirement to submit test summaries from the first serial or subserial of an autogenous biologic within 4 days of completion of purity and safety tests for serials that may have already been used in animals is unnecessary. We believe that these reports can be submitted on a quarterly basis without reducing our regulatory oversight. Therefore, we are proposing to revise § 113.113(c)(iv) to provide that test summaries must be submitted on a quarterly basis as summary reports by the 21st day of January, April, July, and October, or more often as required by the Administrator.

Because we would allow the submission of test summaries on a quarterly basis, we would no longer refer to § 116.7.

Reserve Samples

Manufacturers of autogenous biologics are required by § 113.3 to submit to APHIS samples from each serial or subserial of an autogenous biologic for confirmatory purity and safety testing. In § 113.3, paragraph (b)(8) states that, in the case of

autogenous biologics, 10 samples for submission to APHIS must be selected from each serial that exceeds 50 containers. Samples from serials containing 50 or fewer containers are required to be held and need not be submitted unless requested. Because purity testing can be conducted on any serial of comparable product, we do not believe that 10 samples from serials of autogenous biologics that exceed 50 containers need to be submitted to APHIS to maintain our current regulatory oversight. We believe that autogenous biologics manufacturers should maintain samples of the first serial or subserial in reserve and, if requested, submit them to APHIS when testing is necessary. However, samples of second serials and subsequent serials that exceed 50 containers will still be required to be submitted.

Therefore, we are proposing to revise § 113.3(b)(8) to provide that, with the exception of the first serial or subserial, 10 samples must be selected for submission to APHIS from each serial or subserial of autogenous biologic that exceeds 50 containers. For first serials or subserials with more than 50 containers, 10 samples would need to be selected and held in reserve for submission to APHIS upon request. For all serials or subserials with 50 or fewer containers, reserve samples would be handled as prescribed in § 113.3(e) of the regulations.

Miscellaneous

We are also proposing minor nonsubstantive and editorial changes to the regulations, as set out in the rule portion of this document. The main change would be in the APHIS address appearing in § 113.113(a)(2).

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.

We are proposing to amend the Virus-Serum-Toxin Act regulations for autogenous biologics. We are proposing to reduce the number of test summaries that autogenous biologics manufacturers must submit to APHIS. In addition, we are proposing to amend the requirement for the submission of samples of any autogenous biologic that exceeds 50 containers by requiring autogenous biologics manufacturers to hold samples of the first serial or subserial of the autogenous biologic in reserve. These actions would result in savings in time and resources for autogenous biologics manufacturers and APHIS without a significant reduction in regulatory oversight.

This proposed rule would affect all licensed veterinary biologics establishments that produce autogenous biologics. Currently, there are approximately 150 veterinary biologics establishments, and approximately 35 of these establishments produce autogenous biologics. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

By creating a system that allows the quarterly reporting of test results for first serials and subserials of autogenous biologics, APHIS would reduce paperwork submissions from autogenous biologics manufacturers by approximately 25 percent or more. This would reduce the industry's annual reporting burden by approximately 6,018 hours.

In addition, this proposed rule would allow autogenous biologics manufacturers to hold in reserve 10 samples from the first serial or subserial of any serial or subserial of an autogenous biologic with more than 50 containers. These manufacturers would no longer need to submit samples of the first serial or subserial to APHIS unless requested to do so. Allowing autogenous biologics manufacturers to hold these samples in reserve would save them the time and resources previously invested in shipping samples to APHIS.

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

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.*). This action would, in fact, reduce paperwork submissions from autogenous biologics manufacturers by approximately 25 percent or more. This would reduce the industry's annual reporting burden by approximately 6,018 hours.

List of Subjects 9 CFR Part 113

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

Accordingly, we propose to amend 9 CFR part 113 as follows:

PART 113—STANDARD REQUIREMENTS

1. 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 371.2(d).

2. In § 113.3, paragraph (b)(8) would be revised to read as follows:

§ 113.3 Sampling of biological products.

* * * * *

(b) * * *

(8) *Autogenous biologics.* With the exception of the first serial or subserial, 10 samples must be selected from each serial or subserial of an autogenous biologic that consists of more than 50 containers. For first serials or subserials with more than 50 containers, 10 samples from each serial or subserial must be selected and held in reserve for submission to the Animal and Plant Health Inspection Service upon request in accordance with paragraph (e)(4) of this section. For all serials or subserials with 50 or fewer containers, reserve samples must be selected and held as prescribed in paragraph (e) of this section.

* * * * *

3. In § 113.113, paragraphs (a)(2) introductory text and (c)(1)(iv) would be revised to read as follows:

§ 113.113 Autogenous biologics.

(a) * * *

(2) Under normal circumstances, microorganisms from one herd must not be used to prepare an autogenous biologic for another herd. The Administrator, however, may authorize preparation of an autogenous biologic for use in herds adjacent to the herd of origin, when adjacent herds are considered to be at risk. To request authorization to prepare a product for use in herds adjacent to the herd of origin, the establishment seeking

authorization must submit to the Administrator (in c/o the Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010–8197) the following information. (If any of the data are unavailable, the applicant for authorization should indicate that such data are unavailable and why.)

* * * * *

(c) * * *

(1) * * *

(iv) Test summaries must be submitted to the Administrator (in c/o the Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010–8197) on a quarterly basis by the 21st day of January, April, July, and October, or more often as required by the Administrator.

* * * * *

Done in Washington, DC, this 1st day of March, 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–5596 Filed 3–7–00; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ASW–33]

Proposed Realignment of Jet Route; TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to realign Jet Route 25 (J–25) in the vicinity of San Antonio, TX. This proposal would realign the affected jet route between the Corpus Christi Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) and the San Antonio VORTAC. The FAA is proposing this action to enhance the management of air traffic operations and allow for better utilization of navigable airspace in the San Antonio, TX, area.

DATES: Comments must be received on or before April 25, 2000.

ADDRESSES: Send comments on this proposal in triplicate to: Manager, Air Traffic Division, ASW–500, Docket No. 99–ASW–33, Federal Aviation Administration, 2601 Meacham Blvd; Fort Worth, TX 76193–0500.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, 2601 Meacham Blvd; Fort Worth, TX 76193–0500.

FOR FURTHER INFORMATION CONTACT: Sheri Edgett Baron, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 99–ASW–33.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

An electronic copy of this document may be downloaded using a modem and suitable communications software from the FAA regulations section of the Fedworld electronic bulletin board service (telephone: 703–321–3339) or the Government Printing Office's electronic bulletin board service (telephone: 202–512–1661).

Internet users may reach the FAA's web page at http://www.faa.gov or the Superintendent of Documents's webpage at http://www.access.gpo.gov/nara for access to recently published rulemaking documents.

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–8783. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should call the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

As a result of a recent airspace review, the FAA has determined that a segment of J–25, between the Corpus Christi VORTAC and the San Antonio VORTAC, requires realignment to allow for better utilization of the navigable airspace in the San Antonio, TX, area.

The Proposal

The FAA is proposing an amendment to part 71 of Title 14 Code of Federal Regulations to realign J–25 in the vicinity of San Antonio, TX. This proposal would realign the affected jet route between the Corpus Christi VORTAC and the San Antonio VORTAC. The FAA is proposing this action to enhance the management of air traffic operations and allow for better utilization of navigable airspace in the San Antonio, TX, area.

Jet routes are published in paragraph 2004 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The jet route listed in this document would be published subsequently in the Order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory