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

Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E, AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 2004—Jet Routes

* * * * *

J–25 [Revised]

From Matamoras, Mexico, via Brownsville, TX; INT of the Brownsville 358° and the Corpus Christi, TX, 178° radials; Corpus Christi; INT of the Corpus Christi 311° (302°M) and the San Antonio, TX, 174°(266°M) radials; San Antonio; Centex, TX; Waco, TX; Ranger, TX; Tulsa, OK; Kansas City, MO; Des Moines, IA; Mason City, IA; Gopher, MN; Brainerd, MN; to Winnipeg, MB, Canada. The airspace within Canada is excluded. The airspace within Mexico is excluded.

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Issued in Washington, DC, on March 2, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–5598 Filed 3–7–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 97P–0044]

New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of its proposed rule published in the **Federal Register** on March 6, 1998 (63 FR 11174). The document proposed to amend FDA's regulations on notice of certification of invalidity or noninfringement of a patent to provide additional methods for new drug and abbreviated new drug applicants to provide notice to patent owners and new drug application (NDA) holders, without removing the existing means. FDA is withdrawing this proposal based on comments regarding the inability of large corporations to track receipt of deliveries by means other than certified mail, return receipt requested.

DATES: The proposed rule is withdrawn March 8, 2000.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 6, 1998 (63 FR 11174), FDA proposed to permit new drug and abbreviated new drug applicants to provide notice of certification of invalidity or noninfringement of a patent to patent owners and NDA holders by overnight delivery service, facsimile, and electronic mail, in addition to U.S. Postal Service (USPS) registered or certified mail, return receipt requested, or another method approved in advance by the agency. Sections 314.52(c) and 314.95(c) (21 CFR 314.52(c) and 314.95(c)) set forth the content requirements of the notice of certification. Under §§ 314.52(e) and 314.95(e), applicants must amend their applications to document receipt of the notice of certification by each person provided the notice. Applicants must include a copy of the return receipt or other similar evidence of the date the notification was received. FDA accepts as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. Under §§ 314.52(e) and 314.95(e), applicants may rely on another form of documentation only if FDA has agreed to such documentation in advance. FDA reminds those providing notice of certification to application holders that if an application holder does not reside or maintain a place of business within the United States, notice must be sent to the application holder's U.S. attorney, agent, or other authorized official (§§ 314.52(a)(2) and 314.95(a)(2)). FDA also notes that the term ''registered or certified mail'' as used in §§ 314.52(a) and 314.95(a) means USPS registered or certified mail, and not equivalent delivery via foreign mail. Since the actual form of international registered or certified mail and receipt may vary from country to country, use of international mail could put a substantial burden on innovator companies to be alert to multiple forms of notice. Therefore, applicants must use USPS mail. Delivery by USPS mail should not be burdensome since applicants are required to have a U.S. agent.

II. Comments on the Proposed Rule

FDA received three comments on the proposed rule. The comments were from two large pharmaceutical companies and from the Pharmaceutical Research and Manufacturers Association. All of the comments stated that electronic methods of delivery, including facsimile and electronic mail, are too unreliable at this stage to be used to deliver notification.

One of the comments supported use of overnight and messenger delivery services. One comment stated that overnight delivery service would be acceptable only if the person receiving the notice signed a form verifying receipt of the notice. The other comment stated that overnight delivery services are not acceptable because deliveries are made in bulk, accompanied by a manifest that does not guarantee that each item listed is in fact in the bulk package and that individual items are not signed for.

All of the comments stated that the present system is workable.

III. Withdrawal of the Proposed Rule

After careful consideration of these comments, FDA has concluded that the current system, which requires only that an applicant send notice by USPS registered or certified mail, return receipt requested, is not overly