

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

burdensome. This requirement is intended to provide maximum assurance that the notice will be received by the patent holder and the NDA holder, and that such receipt will be documented adequately. In addition, FDA has concluded that adding new methods of notification presents complications in ensuring that notification is received by sponsors. Accordingly, FDA is withdrawing its proposed rule 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 USPS registered or certified mail, return receipt requested, or another method approved in advance by the agency.

Dated: February 29, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00-5527 Filed 3-7-00; 8:45 am]

**BILLING CODE 4160-01-F**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[DA 00-168; MM Docket No. 00-15, RM-9804; MM Docket No. 00-16, RM-9805]

#### Radio Broadcasting Services; Susquehanna, PA; and Burke, SD

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes two new allotments at Susquehanna, Pennsylvania, and Burke, South Dakota. The Commission requests comments on a petition filed by Tammy M. Celenza proposing the allotment of Channel 227A at Susquehanna, Pennsylvania, as the community's second local FM transmission service. Channel 227A can be allotted to Susquehanna in compliance with the Commission's minimum distance separation requirements with a site restriction of 6.3 kilometers (3.9 miles) east to avoid short-spacings to the licensed sites of Station WBZD-FM, Channel 227B1, Muncy, Pennsylvania, and Station WKXZ(FM), Channel 230B, Norwich, New York. The coordinates for Channel 227A at Susquehanna are 41-55-44 North Latitude and 75-31-50 West Longitude. Since Susquehanna is located within 320 kilometers (200 miles) of the U.S.-Canadian border,

Canadian concurrence has been requested.

**DATES:** Comments must be filed on or before March 20, 2000, and reply comments on or before April 4, 2000.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, his counsel, or consultant, as follows: Michael Celenza, Celenza Communications, 41 Kathleen Crescent, Coram, New York 11727 (Consultant for Tammy M. Celenza); and Heather Drischel, General Partner, NationWide Radio Stations, 496 Country Road 308, Big Creek, Mississippi 38914 (Petitioner).

**FOR FURTHER INFORMATION CONTACT:**

Sharon P. McDonald, Mass Media Bureau, (202) 418-2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 00-15; and MM Docket No. 00-16, adopted January 19, 2000, and released February 4, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857-3800, 1231 20th Street, NW., Washington, DC 20036.

The Commission also requests comments on a petition filed by NationWide Radio Stations proposing the allotment of Channel 264A at Burke, South Dakota, as the community's first local aural transmission service. Channel 264A can be allotted to Burke in compliance with the Commission's minimum distance separation requirements with a site restriction of 3.5 kilometers (2.2 miles) east to avoid a short-spacing to the vacant allotment site for Channel 264A at Mission, South Dakota. The coordinates for Channel 264A at Burke are 43-11-06 North Latitude and 99-15-02 West Longitude.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

**John A. Karousos,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 00-5545 Filed 3-7-00; 8:45 am]

**BILLING CODE 6712-01-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

**RIN 1018-AF98**

#### Endangered and Threatened Wildlife and Plants; Proposed Determination of Critical Habitat for the Alameda Whipsnake (*Masticophis lateralis euryxanthus*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for the Alameda whipsnake (*Masticophis lateralis euryxanthus*). A total of approximately 164,663 hectares (406,708 acres) of land fall within the boundaries of the proposed critical habitat designation. Proposed critical habitat is located in Contra Costa, Alameda, San Joaquin, and Santa Clara counties, California. If this proposal is made final, section 7 of the Act, which prohibits destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency, would apply to the designated critical habitat for the Alameda whipsnake. Section 4 of the Act requires us to consider economic and other impacts of specifying any particular area as critical habitat.

We solicit data and comments from the public on all aspects of this proposal, including data on economic and other impacts of the designation and our approaches for handling habitat conservation plans (HCPs). We may revise this proposal to incorporate or address new information received during the comment period.

**DATES:** Comments from all interested parties must be received by May 8, 2000. Public hearing requests must be received by April 24, 2000.