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 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).

Adoption of the Amendment

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

PART 71—[AMENDED]

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; 14 CFR 11.69

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways

* * * * *

V–163 [Revised]

From Matamoros, Mexico; via Brownsville, TX; 27 miles standard width, 37 miles 7 miles wide (3 miles E and 4 miles W of centerline); Corpus Christi, TX; Three Rivers, TX; INT Three Rivers 345° and San Antonio, TX, 168° radials; San Antonio; Lampasas, TX; Glen Rose, TX; Millsap, TX; Bowie, TX; Ardmore, OK; to Will Rogers, OK. The airspace within Mexico is excluded.

* * * * *

V–194 [Revised]

From Cedar Creek, TX; College Station, TX; INT College Station 151° and Hobby, TX, 290° radials; Hobby; Sabine Pass, TX; Lafayette, LA; Baton Rouge, LA; McComb, MS; INT McComb 055° and Meridian, MS; 221° radials; Meridian. From Liberty, NC, via Raleigh-Durham, NC; Tar River, NC, Cofield, NC, to INT Cofield 077° and Norfolk, VA, 209° radials.

* * * * *

V–278 [Revised]

From Texico, NM, via Plainview, TX; Guthrie, TX; Bowie, TX; Bonham, TX; Paris, TX; Texarkana, AR; Monticello, AR; Greenville, MS; Sidon, MS; Bigbee, MS; to Vulcan, AL.

* * * * *

V–355 [Revised]

From Bowie, TX; to Wichita Falls, TX.

* * * * *

V–358 [Revised]

From San Antonio, TX, via Stonewall, TX; Lampasas, TX; INT Lampasas 041° and Waco, TX, 249° radials; Waco; Glen Rose, TX; Millsap, TX; Bowie, TX; Ardmore, OK; INT Ardmore 327° and Will Rogers, OK, 195° radials; to Will Rogers.

* * * * *

V–369 [Revised]

From Dallas-Fort Worth, TX; to Navasota, TX.

* * * * *

V–477 [Revised]

From Leona, TX; to Cedar Creek, TX.

* * * * *

V–568 [Revised]

From Corpus Christi, TX, via INT Corpus Christi 296° and Three Rivers, TX, 165° radials; Three Rivers; INT Three Rivers 327° and San Antonio, TX, 183° radials; San Antonio; Stonewall, TX; Llano, TX; INT Llano 026° and Glen Rose, TX, 216° radials; Glen Rose; Millsap, TX; to Wichita Falls, TX.

V–569 [Revised]

From Beaumont, TX, via INT Beaumont 338° and Lufkin, TX, 146° radials; Lufkin; Frankston, TX; to Cedar Creek, TX.

* * * * *

V–571 [Revised]

From Humble, TX, via Navasota, TX; Leona, TX; INT Leona 331° and Cedar Creek, TX, 186° radials; to Cedar Creek.

* * * * *

V–583 [Revised]

From Austin, TX; INT Austin 062° and College Station, TX, 270° radials; College Station; Leona, TX; Frankston, TX; Quitman, TX; Paris, TX; to McAlester, OK.

* * * * *

Issued in Washington, DC, on June 25, 1996.

Nancy B. Kalinowski,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 96–17040 Filed 7–2–96; 8:45 am]

BILLING CODE 4910–13–P

Office of the Secretary

14 CFR Parts 211 and 213

RIN 2105–AC53

Aviation Economic Regulations: Updates and Corrections

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Department is amending 14 CFR Parts 211 and 213 to eliminate obsolete provisions and references, to conform citations to the recodification by Pub. L. 103–272 of the Federal Aviation Act and other transportation statutes, and to update organizational titles.

EFFECTIVE DATE: The rule shall become effective on August 2, 1996.

FOR FURTHER INFORMATION CONTACT: George L. Wellington, Chief, Foreign Air Carrier Licensing Division (X–45), Office of International Aviation, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–2388.

SUPPLEMENTARY INFORMATION: In his Regulatory Reinvention Initiative Memorandum of March 4, 1995, President Clinton directed Federal agencies to conduct a page-by-page review of all of their regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.'' In response to that directive, the Department has undertaken a review of its aviation economic regulations as contained in 14 CFR Chapter II. This rule is one result of those efforts.

This rule eliminates obsolete provisions and references, conforms citations to the recodification by Pub. L. 103–272 of the Federal Aviation Act and other transportation statutes, and updates organizational titles. The Department finds that notice and comment are unnecessary and contrary to the public interest because of the editorial nature of these changes.

Executive Order 12866 (Regulatory Planning and Review)

The Department has analyzed the economic and other effects of the final rule and has determined that they are not ''significant'' within the meaning of Executive Order 12866. The rule has not, therefore, been reviewed by the Office of Management and Budget.

DOT Regulatory Policies and Procedures

The final rule is not significant under the Department's Regulatory Policies and Procedures, dated February 26, 1979, because it does not involve

important Departmental policies; rather, the changes are being made solely for the purposes of eliminating obsolete requirements, correcting out-of-date references, and enhancing the organization of the regulations used by the Department to administer its aviation economic regulatory functions. The Department has also determined that there will be no economic impact as a result of these changes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, I certify that the amendments will not have a significant economic impact on a substantial number of small entities. The changes are editorial in nature and will have no substantive impact.

Executive Order 12612 (Federalism)

The final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The Department has determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The amendments will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

National Environmental Policy Act

The Department has also analyzed the rule for the purpose of the National Environmental Policy Act. The rule will not have any significant impact on the quality of the human environment.

Paperwork Reduction Act

There are no reporting or recordkeeping requirements associated with the final rule.

Lists of Subjects

14 CFR Part 211

Foreign air carriers, Economic authority, Transportation Department.

14 CFR Part 213

Foreign air carriers, Economic authority, Transportation Department.

Final Rule

For the reasons set out in the preamble, Title 14, Chapter II of the Code of Federal Regulations is amended as follows:

PART 211—[AMENDED]

1. The authority citation for part 211 is revised to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 415, 417.

2. Throughout the part, remove the words ''Board'' and ''Board's'' wherever they appear, and add, in their place, the words ''Department'' and ''Department's.'' Remove the words ''Docket Section,'' and add, in their place, the words ''Docket Facility.''

§ 211.1 [Amended]

3. In § 211.1, remove the words ''section 402 of the Federal Aviation Act'' and add, in their place, the words ''section 41301 of Title 49 of the United States Code (Transportation).''

§ 211.10 [Amended]

4. In § 211.10(b), remove the words ''Regulatory Affairs Division, Bureau of International Aviation, Civil Aeronautics Board, Washington, DC 20428,'' and add, in their place, the words ''Foreign Air Carrier Licensing Division, Office of International Aviation, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.''

§ 211.20 [Amended]

5. In § 211.20(t), remove the words ''CAB form 263,'' and add, in their place, the words ''OST Form 4523.''

Subpart D—[Amended]

6. Throughout subpart D of part 211, remove the words ''overseas,'' ''overseas and interstate,'' ''overseas or interstate,'' ''interstate and overseas'', and ''interstate or overseas,'' wherever they appear, and add, in their place, the word ''interstate.''

§ 211.33 [Amended]

7. In § 211.33(c), remove the words ''section 801(a)'' and add in their place the words ''section 41307.''

PART 213—[AMENDED]

8. The authority citation for part 213 is revised to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 415, 417.

9. Throughout the part, remove the words ''Board'' and ''Board's'' wherever they appear, and add, in their place, the words ''Department'' and ''Department's.'' Remove the words ''Docket Section,'' and add, in their place, the words ''Docket Facility.''

§ 213.1 [Amended]

10. In § 213.1, remove the words ''section 402 permits authorizing foreign direct air carriers to engage in'' and add, in their place, the words ''foreign air carrier permits issued under section 41302 of Title 49 of the United States Code (Transportation) authorizing.'' Remove the entire sentence that begins with ''Notwithstanding.''

§ 213.3 [Amended]

11. In § 213.3(f), remove the words ''section 1005(b) of the Act,'' and add, in their place, the words ''49 U.S.C. 46103.''

§ 213.5 [Amended]

12. The heading of § 213.5 is revised to read as follows:

§ 213.5 Filing and service of schedules and applications for approval of schedules; procedure thereon.

* * * * *

13. In § 213.5(a), remove the words ''each airport notice or,'' and ''each application for permission to use an airport (§ 213.4(b)) or.'' Remove the words ''19 copies,'' and add, in their place, the words ''seven (7) copies.'' Remove the entire sentence that begins with ''Each airport notice or application . . .''

14. Section 213.5(b) is revised to read as follows:

* * * * *

(b) *Pleadings by interested persons.* Any interested person may file and serve upon the foreign air carrier a memorandum in opposition to, or in support of, schedules or an application for approval of schedules within 10 days of the filing opposed or supported. All memoranda shall set forth in detail the reasons for the position taken together with a statement of economic data and other matters which it is desired that the Department officially notice, and affidavits stating other facts relied upon. Memoranda shall contain a certificate of service as prescribed in paragraph (a) of this section. An executed original and seven (7) true copies shall be filed with the Department's Docket Facility. Unless otherwise provided by the Department, further pleadings will not be entertained.

* * * * *

15. In § 213.5(c), remove the words ''for permission to use an airport or.'' Remove the entire sentence beginning with ''Petitions for reconsideration of the Board'' determination on an application for permission to use an airport . . .''

§ 213.6 [Amended]

16. In § 213.6, remove the words ''Title IV of the Act'' and add in their place the words ''Subtitle VII of Title 49 of the U.S. Code.''

§ 213.7 [Amended]

17. In § 213.7, remove the abbreviation ''CAB'' before the word ''Agreement.'' Remove the words ''CAB form 263,'' and add, in their place, the words ''OST Form 4523'', and remove

the words ''Publications Services Division, Civil Aeronautics Board, Washington, DC 20428,'' and add in their place the words ''Foreign Air Carrier Licensing Division (X–45), Office of International Aviation, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.

Issued in Washington, DC, on May 31, 1996.

Charles A. Hunnicutt,

Assistant Secretary for Aviation and International Affairs.

[FR Doc. 96–16808 Filed 7–2–96; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 452

[Docket No. 96N–0117]

Antibiotic Drugs; Clarithromycin Granules for Oral Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to include accepted standards for clarithromycin for its use in a new dosage form of clarithromycin, clarithromycin granules for oral suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective August 2, 1996; comments, notice of participation, and a request for hearing by August 2, 1996; data, information, and analyses to justify a hearing by September 3, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James M. Timper, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2193.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations issued under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of clarithromycin, clarithromycin granules for oral suspension. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic dosage form are adequate to establish the safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 452 (21 CFR part 452) to include accepted standards for this product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because, when effective, it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, is effective August 2, 1996. However, interested persons may, on or before August 2, 1996, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before August 2, 1996, a written notice of participation and request for a hearing, and (2) on or before September 3, 1996, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for a hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 452

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 452 is amended as follows:

PART 452—MACROLIDE ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 452 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

§ 452.150a [Redesignated from § 452.150]

2. Section 452.150 is redesignated as § 452.150a and new §§ 452.150 and 452.150b are added to subpart B to read as follows:

§ 452.150 Clarithromycin oral dosage forms.

§ 452.150b Clarithromycin granules for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clarithromycin granules for oral suspension is a dry mixture containing clarithromycin-coated particles, suitable and harmless dispersing agents, diluents, preservatives, and flavorings. It contains the equivalent of 25 or 50 milligrams of clarithromycin activity per milliliter of the reconstituted suspension. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of clarithromycin that it is represented to contain. Its loss on drying is not more than 2.0 percent. When constituted as directed in the labeling, its pH is not less than 4.0 nor more than 5.4. The