PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 178.2010(b) by alphabetically inserting a new item in the list of substances to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* *
1,4-Benzenedicarboxylic acid, bis[2-(1,1-dimethylethyl)-6-[[3-(1,1-dimethylethyl)-2-hydroxy-5-methylphenyl]methyl]-4-methylphenyl]ester (CAS Reg. No. 57569-40-1)	For use only at levels not to exceed 0.075 percent by weight of olefin polymers complying with § 177.1520 of this chapter
* * *	* *

Dated: January 24, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-3150 Filed 2-12-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Amoxicillin Trihydrate and Clavulanate Potassium for Oral Suspension

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Beecham Laboratories, providing for use in cats of amoxicillin trihydrate and clavulanate potassium for oral suspension. The drug is indicated for treatment of certain skin and soft tissue infections.

EFFECTIVE DATE: February 13, 1986.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, TN 37620, filed NADA 55-103 which provides for use in cats of amoxicillin trihydrate and clavulanate potassium for oral suspension. The drug is available as a powder for reconstitution and oral administration for treatment of skin and soft tissue infections such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase producing *Staphylococcus aureus*, non-beta-lactamase producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida* and *Pasteurella* spp. The NADA is approved and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) (April 26, 1985; 50 FR 16636) 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.

List of Subjects in 21 CFR Part 540

Animal drugs, Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 540 is amended as follows:

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

1. The authority citation for 21 CFR Part 540 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. Section 540.103h is amended by adding paragraph (c)(3)(ii) to read as follows:

§ 540.103h Amoxicillin trihydrate and clavulanate potassium for oral suspension

* * * * *

(c) * * *

(3) * * *

(ii) *Cats*—(*a*) *Amount.* 62.5 milligrams (1 milliliter) twice daily (50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid).

(*b*) *Indications for use.* It is used in the treatment of feline skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of beta-lactamase (pencillinase) producing *Staphylococcus aureus*, non-beta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida*, and *Pasteurella* spp.

(*c*) *Limitations.* Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and reevaluate the case. Maximum duration of treatment should not exceed 30 days. Not for use in cats maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: February 3, 1986.

Gerald B. Guest,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 86-3152 Filed 2-12-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Amoxicillin Trihydrate and Clavulanate Potassium Film-Coated Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Beecham Laboratories to correct a discrepancy existing between the moisture content specifications for amoxicillin trihydrate and clavulanate potassium tablets for human and veterinary use. The moisture content limit for the veterinary tablets is being increased from not more than 7 percent to not more than 10 percent so that it will be consistent with the limit for human tablets which have the same concentration ratio between the two drug components.

EFFECTIVE DATE: February 13, 1986.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc.,

Bristol, TN 37620, is the sponsor of approved NADA 55–099 which provides for the use of amoxicillin trihydrate and clavulanate potassium tablets in treating dogs for certain skin infections. In the **Federal Register** of November 16, 1984 (49 FR 45420), the approval of the NADA was published along with a regulation (21 CFR 540.103g) which contains a moisture content specification for the tablets of not more than 7 percent. The moisture content is significantly influenced by the amoxicillin trihydrate component. Therefore, in the regulation for the human use tablets (21 CFR 440.103d(a)(1)), the moisture content specification is not more than 7 percent when the milligrams of amoxicillin (as the trihydrate) to milligrams of clavulanic acid ratio is 2 to 1, respectively, but is not more than 10 percent when the ratio is 4 to 1. All of the veterinary use tablets in § 540.103g (4 drug concentration levels) contain an amoxicillin to clavulanic acid ratio of 4 to 1. Therefore, the sponsor should have specified a moisture content limit of not more than 10 percent, but the sponsor inadvertently specified not more than 7 percent. Consequently, the firm filed a supplemental NADA requesting correction of the discrepancy. The supplement is approved and the regulations are amended accordingly. The freedom of information summary for original NADA 55–099, which published in the November 16, 1984, **Federal Register**, also applies to this approval.

List of Subjects in 21 CFR Part 540

Animal drugs, Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 540 is amended as follows:

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

1. The authority citation for 21 CFR Part 540 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 540.103g [Amended]

2. Section 540.103g *Amoxicillin trihydrate and clavulanate potassium film-coated tablets* is amended in paragraph (a)(1) by revising the fifth full sentence "Its moisture content is not more than 7 percent." to read "Its moisture content is not more than 10 percent."

Dated: February 3, 1986.

Marvin H. Norcross,

Acting Associate Director for New Animal Drug Evaluation.

[FR Doc. 86–3148 Filed 2–12–86; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Amoxicillin Trihydrate and Clavulanate Potassium Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Beecham Laboratories, providing for use of amoxicillin trihydrate and clavulanate potassium tablets in cats. The drug is labeled for the treatment of certain skin, soft tissue, and urinary tract infections.

EFFECTIVE DATE: February 13, 1986.

FOR FURTHER INFORMATION CONTACT: Sandra Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3420.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, TN 37620, filed NADA 55–102 for amoxicilin trihydrate and clavulanate potassium tablets for use in cats. The drug is for the treatment of skin and soft tissue infections due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus*, non-beta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. The drug is also for the treatment of urinary tract infections due to susceptible strains of *E. coli*. The firm presently holds an approval for use of the product in dogs. The application is approved and the regulations amended accordingly. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(4).

List of Subjects in 21 CFR Part 540

Animal drugs, Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 540 is amended as follows:

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

1. The authority citation for 21 CFR Part 540 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. Section 540.103g is amended by adding new paragraph (c)(3)(ii) to read as follows:

§ 540.103g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

* * * * *

(c) * * *

(3) * * *

(ii) *Cats*—(*a*) *Amount.* 62.5 milligrams twice daily (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid).

(*b*) *Indications for use.* It is used in the treatment of skin and soft tissue infections such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus*, non-beta-lactamase producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. It is also used in the treatment of urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

(*c*) *Limitations.* Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Urinary tract infections may require

treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 29, 1986.

Gerald B. Guest,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 86-3151 Filed 2-12-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1302, 1303, 1304, 1305, 1306, 1307, 1308, 1311, 1312 and 1316

Nomenclature and Other Changes

AGENCY: Drug Enforcement Administration.

ACTION: Final rule.

SUMMARY: This action updates Parts 1301 through 1316 of Title 21 of the Code of Federal Regulations. It contains no substantive changes in any regulation. Therefore, no comments have been solicited and the action is being issued as a final rule.

EFFECTIVE DATE: February 13, 1986.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Diversion Operations Section, Office of Diversion Control, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, telephone: (202) 633-1216.

SUPPLEMENTARY INFORMATION: This action changes certain office designations and titles which are currently listed in Parts 1301 through 1316 of Title 21 of the Code of Federal Regulations in order to accurately reflect the internal organization of the Drug Enforcement Administration. It also corrects several internal references, deletes sections no longer valid, reinserts a word deleted in a previous amendment, removes references to obsolete forms, and corrects the authority citations.

List of Subjects in 21 CFR Parts 1301-1316

Administrative practice and procedure, Drug Enforcement Administration, Drug traffic control, Security measures, Exports, Imports, Labeling, Packaging and containers, Reporting requirements, Prescription drugs, Narcotics, Research, seizures and forfeitures.

Therefore, pursuant to the authority vested in the Attorney General by 21 U.S.C. 821 and 871(b) as delegated by 28 CFR 0.100 to the Administrator of the Drug Enforcement Administration, the Administrator of DEA hereby orders that Parts 1301-1316 of Title 21 of the Code of Federal Regulations be amended as follows:

1. The authority citations for Parts 1302, 1303, 1306, 1311, 1312, and 1316 are revised to read as follows:

Part 1302

Authority: 21 U.S.C. 821, 825, 871(b), 958(e).

Part 1303

Authority: 21 U.S.C. 821, 826, 871(b).

Part 1306

Authority: 21 U.S.C. 821, 829, 871(b).

Part 1311

Authority: 21 U.S.C. 952, 956, 957, 958.

Part 1312

Authority: 21 U.S.C. 952, 953, 954, 958.

Part 1316

Subpart A

Authority: 21 U.S.C. 822(f), 871(b), 880, 958(f), 965.

Subpart B

Authority: 21 U.S.C. 871(b), 872(c), 872(d).

Subpart C

Authority: 21 U.S.C. 871(b), 883.

Subpart D

Authority: 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

Subpart E

Authority: 21 U.S.C. 871(b), 881, 965.

2. The authority citations for Parts 1301, 1304, 1305, 1307, and 1308 continue to read as follows:

Part 1301

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

Part 1304

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965.

Part 1305

Authority: 21 U.S.C. 821, 828, 871(b).

Part 1307

Authority: 21 U.S.C. 821, 822(d), 871(b).

Part 1308

Authority: 21 U.S.C. 811, 812, 871(b).

§§ 1301.03, 1301.32, 1301.33, 1301.34, 1301.61, 1305.05, 1305.12, 1307.14, 1311.03, 1311.32 and 1311.61 [Amended]

3. 21 CFR 1301.03, 1301.32(c), 1301.32(f), 1301.33(c), 1301.34(a), 1301.61, 1305.05(b), 1305.05(d), 1305.12(b), 1307.14(a), 1311.03, 1311.32(c), 1311.32(f), and 1311.61 are amended by removing the words "Registration Branch" and replacing them with the words "Registration Unit."

§ 1301.24 [Amended]

4. 21 CFR 1301.24(b) is amended by removing the phrase "(For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances if a pharmacy is so registered.)" and replacing it with the phrase, "(For example, a staff physician employed by a hospital need not be registered individually to administer and dispense, other than by prescribing, controlled substances within the hospital.)"

5. 21 CFR 1301.26(e), 1301.71(d), 1312.12(a), 1312.14(a), 1312.16(b) 1312.18(b), 1312.19(a), 1312.19(b) 1312.22(a), 1312.24(a), 1312.25, 1312.27(a), 1312.28(c), 1312.28(d), 1312.31(b), 1312.32(a) are amended by removing the words "Compliance Division" and replacing them with the words "Diversion Operations Section."

§ 1301.32 and § 1316.03 [Amended]

6. 21 CFR 1301.32(a)(7) and 1316.03(d) are amended by removing the words "BND Form" and replacing them with the words "DEA Form."

§ 1301.32 and § 1311.32 [Amended]

7. 21 CFR 1301.32(f) and 1311.32(f) are amended by deleting the phrase "on DEA (or BND) Form 231(a)."

§ 1301.64 [Removed]

8. 21 CFR 1301.64 is removed.

§§ 1303.12, 1303.22, 1303.27, 1304.35, 1304.41 and § 1308.24 [Amended]

9. 21 CFR 1303.12(b), 1303.12(d), 1303.22, 1303.27, 1304.35(a), 1304.41(a), 1308.24(d) are amended by removing the words "Regulatory Control Division" and replacing them with the words "Drug Control Section."

§§ 1304.31, 1304.32 and § 1304.36 [Amended]

10. Sections 1304.31, 1304.32 and 1304.36 (a) and (b) are removed.

§§ 1304.33, 1304.34 and 1304.35 [Redesignated as 1304.31, 1304.32 and 1304.33]

11. Sections 1304.33, 1304.34 and 1304.35 are redesignated as 1304.31, 1304.32 and 1304.33, respectively.

§§ 1304.37–1304.41 [Redesignated as §§ 1304.34–1304.38]

§ 1304.36 [Amended]

12. Sections 1304.37, 1304.38, 1304.39, 1304.40, and 1304.41 are redesignated as §§ 1304.34, 1304.35, 1304.36, 1304.37, 1304.38 and 1304.36(c) is redesignated as section 1304.34(c).

§ 1304.34 [Amended]

13. New section (as redesignated in 12 above) 1304.34 is amended by replacing the phrase "§§ 1304.38–1304.41" with the phrase §§ 1304.35–1304.38."

§ 1304.03 [Amended]

14. 21 CFR 1304.03(d) is amended by removing the citation "21 U.S.C. 335(i)" and replacing it with the citation "21 U.S.C. 355(i)".

§ 1304.04 [Amended]

15. Section 1304.04(f) is amended by adding the word "exporter" between the words "importer" and "narcotic treatment program."

16. Section 1304.04(g) is amended by removing the phrase "paragraph (b) of this section" and replacing it with the phrase "paragraph (f) of this section."

§ 1304.31 and § 1304.32 [Amended]

17. New sections 21 CFR 1304.31(a) and 1304.32(a) are amended by removing the words "Distribution Audit Branch" and replacing them with the words "Drug Control Section."

§ 1305.03 [Amended]

18. The internal reference in 21 CFR 1305.03(c) currently reading "1316.04(d)" is deleted and replaced by "1301.26(b)."

§ 1306.15 and § 1306.25 [Amended]

19. The internal reference in 21 CFR 1306.15 and 1306.25 currently given as "1304.04(d)" is deleted and replaced by "1304.04(h)."

§ 1306.23 [Amended]

20. 21 CFR 1306.23 is amended by removing the phrase "Schedule III, IV or V" and inserting in its place the phrase "Schedule III or IV."

§ 1306.31 [Amended]

21. 21 CFR 1306.31(a) is amended by removing the internal references to "1306.23" and "1306.24" and replacing them with "1306.24" and "1306.25", respectively.

§ 1308.04 [Amended]

22. 21 CFR 1308.04(a) is amended by removing the phrase "Regulatory Support Division" and replacing it with the phrase "Regulatory Support Section."

§ 1308.11 [Amended]

23. 21 CFR 1308.11(b)(16) is amended by removing the number "9618" and replacing it with the number "9168."

§ 1308.13 [Amended]

24. 21 CFR 1308.13(e)(3) and 1308.13(e)(4) are amended by adding the word "(hydrocodone)" after the word dihydrocodeinone.

§ 1311.32 [Amended]

25. 21 CFR 1311.32(b) and 1311.32(c) are amended by removing the number "227" and inserting in its place the number "225a."

§ 1311.64 [Removed]

26. 21 CFR 1311.64 is deleted.

§ 1312.02 [Amended]

27. 21 CFR 1312.02(b) is amended by removing the number "1002" and inserting in its place the number "102."

§ 1312.12 [Amended]

28. 21 CFR 1312.12(a) is amended by removing the phrase "(or BND) Form 85" and inserting in its place the phrase "Form 357."

It has been determined that this is an internal management matter not requiring consultation with the Office of Management and Budget (OMB). The Administrator of DEA hereby certifies that these matters will have no significant negative impact upon small businesses within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

Dated: February 7, 1986.

John C. Lawn,

Administrator.

[FR Doc. 86–2903 Filed 2–12–86; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8075]

Income Taxes; Treatment of Certain Hospital Services

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the treatment of certain hospital services furnished by one tax-exempt hospital to other such hospitals. Changes to the applicable tax law were made by the Tax Reform Act of 1976. The regulations affect those tax-exempt hospitals that furnish the services, and would provide the furnishing hospitals with the guidance needed to determine their unrelated business taxable income.

DATES: The regulations apply to taxable years beginning after December 31, 1953, and are effective after December 31, 1953.

FOR FURTHER INFORMATION CONTACT: Calder L. Robertson, Jr., of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, (Attention: CC:LR:T:EE–46–78) (202–566–3544) (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 13, 1982, the **Federal Register** published proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 513(e) of the Internal Revenue Code of 1954 (47 FR 55696). These proposed amendments conform the regulations to section 1311 of the Tax Reform Act of 1976 (90 Stat. 3526). The regulations are issued under the authority contained in section 513(e) and in section 7805(b) of the Internal Revenue Code of 1954 (90 Stat. 3526, 68A Stat. 917; 26 U.S.C. 513(e), 7805). There was only one request for a public hearing. No public hearing was held because the request was withdrawn. After consideration of all written comments received, the regulations are adopted with minor clarification by this Treasury decision.

Effective Date

The regulations are effective for all taxable years beginning after December 31, 1953.

Non-Applicability of Executive Order 12291

The Commissioner has determined that this Treasury decision is not subject to review under Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required.

Regulatory Flexibility Act

Although a notice of proposed rulemaking that solicited public comment was issued, the Internal Revenue Service concluded when the notice was issued that the regulations are interpretative and that the notice and public procedure requirements of 5 U.S.C. 553 did not apply. Accordingly, the final regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. Chapter 6).