

where the corrections are made all apply to Volume 49, Number 36, of the Federal Register. For purposes of this notice, a line in the Federal Register upon which no letters or characters appear is not counted as a line number.

Such corrections are as follows:

§ 12.10 [Corrected]

1. On page number 6625, in the second column, at line number 14, the words "Proof of filing shall be made by attaching to the document for filing an affidavit certifying that the attached document was deposited in the mail, with first-class postage prepaid, addressed to the Proceedings Clerk, Office of Proceedings, 2033 K Street, NW., Washington, D.C. 20581, on the date specified in the affidavit." are inserted between the words "for filing" and the words "Proof of service";

§ 12.13 [Corrected]

2. On page number 6626, in the first column, after line number 37, a new line is inserted containing the words: "(1) Content. Each complaint shall include:". Also on page number 6626, in the second column, at line number 62, the words "before the Director may make a determination pursuant to § 12.26 (a), (b), or (c)," are inserted between the words "the United States," and the words "the complainant shall";

§ 12.25 [Corrected]

3. On page number 6629, in the third column, at line number 35, the words "summary decisional procedure or the formal" are inserted between the words "answer, has elected the" and the word "decisional";

§ 12.26 [Corrected]

4. On page number 6631, in the first column, at line number 5, the word "Motions" is deleted, and the words, "In a proceeding commenced pursuant to § 12.26(c) of these rules, motions" are inserted between the words "(30) days," and the words "for any additional";

§ 12.101 [Corrected]

5. On page number 6632, in the third column, at line number 62, the word "or" is deleted. At line number 63 of the same page number and column, the word "notice" is deleted;

§ 12.201 [Corrected]

6. On page number 6634, in the first column, at line number 10, the words "or request" are deleted;

§ 12.209 [Corrected]

7. On page number 6635, in the third column, at line number 11, the term "§ 12.313(f)" is deleted, and the term "§ 12.312(f)" is substituted for the

deleted term. At line number 48 of the same page number and column, the words "at least five days" are inserted between the words "unless a party," and the words "prior to";

§ 12.302 [Corrected]

8. On page number 6637, in the second column, at line number 24, the word "or" is deleted. At line number 25 of the same page number and column, the word "request" is deleted. At line number 27 of the same page and column, the term "§ 12.201" is deleted, and the term "§ 12.301" is substituted for the deleted term;

§ 12.312 [Corrected]

9. On page 6639, in the third column, at line number 59, the symbol "(f)" is deleted, and the symbol "(e)" is substituted therefor;

§ 12.313 [Corrected]

10. On page 6640, in the second column, at line number 54, the word "are" is deleted, and the word "is" is substituted for the deleted word;

§ 12.314 [Corrected]

11. On page 6641, in the second column, at line number 29, the words "prejudgment interest," are inserted between the word "Costs." and the words "Except as provided in". At line number 35 of the same page number and column, the words "and, if warranted as a matter of law under the circumstances of the particular case, prejudgment interest," are inserted between the words "attorney's fees)" and the words "to the party in whose";

§ 12.400 [Corrected]

12. On page 6641, in the third column, at line number 23, the words "Subparts D and E" are deleted, and the terms "§ 12.26 (b) and (c)" are substituted for the deleted words. At line number 28 of the same page number and column, the words "Subpart C" are deleted, and the term "§ 12.26(a)" is substituted for the deleted words. At line number 49, the word "An" is deleted and the words "A non-refundable" are substituted for the deleted word;

§ 12.407 [Corrected]

13. On page 6643, in the first column, at line number 51, the words "or (b)" are inserted between the words "with paragraph (a)" and the words "of this." At line number 67 of the same page number and column, the words "or (b)" are inserted between the words "in paragraph (a)" and the words "of this";

§ 12.407 [Corrected]

14. On page 6643, in the third column, at line number 51, the words "Part 12

of", appearing between the words "in accordance with," and the word "these" are deleted, and the words "Part 12" are inserted after the word "these".

Issued in Washington, D.C. on April 10, 1984.

Jane K. Stuckey,

Secretary of the Commission.

[FR Doc. 84-10107 Filed 4-16-84; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

[T.D. 84-84]

Change in the Customs Service Field Organization—Springfield, Missouri

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to establish a permanent Customs port of entry at Springfield, Missouri, in the St. Louis, Missouri, Customs district. The Springfield port of entry has been operating on an experimental basis since March 8, 1982, to see if it could meet the criteria for establishing and staffing a port of entry. As a result of a recently completed review, it has been concluded that the workload will be sufficient to meet the established criteria. The change is part of a continuing program to obtain more efficient use of Customs personnel, facilities, and resources, and to provide better service to carriers, importers, and the public.

EFFECTIVE DATE: May 17, 1984.

FOR FURTHER INFORMATION CONTACT: Richard C. Coleman, Office of Inspection, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, (202-566-8157).

SUPPLEMENTARY INFORMATION:

Background

As part of a continuing program to obtain more efficient use of its personnel, facilities, and resources, and to provide better service to carriers, importers, and the public, by a document published in the Federal Register on February 5, 1982, as T.D. 82-30 (47 FR 5406), Springfield, Missouri, was designated as a Customs port of entry in the St. Louis, Missouri, Customs district, on a 2-year experimental basis starting on March 5, 1982. T.D. 82-30 provided that, at the conclusion of the 2-year period Customs would make an

evaluation of the continued need for Customs services in the area, and the adequacy of Customs facilities. If the extent of the business or the adequacy of the facilities failed to meet the criteria used by Customs to determine port of entry eligibility, the designation of Springfield as a port of entry would be revoked.

Customs has recently completed its review of the status of the workload through the temporary Customs port of Springfield, Missouri. As a result of this review, Customs has concluded that the workload will exceed the established criteria. Because it has met the established criteria and all of the facilities are satisfactory, Springfield is being designated as a permanent port of entry.

Geographical Description

The geographical boundaries of the Springfield, Missouri, port of entry include all the territory within Greene and Christian Counties, Missouri.

Authority

Customs ports of entry are established under the authority vested in the President by section 1 of the Act of August 1, 1914, 38 Stat. 623, as amended (19 U.S.C. 2) and delegated to the Secretary of the Treasury by Executive Order No. 10289, September 17, 1951 (3 CFR Parts 1949-1953 Comp., Ch. II), and pursuant to authority provided by Treasury Department Order No. 101-5 (47 FR 2449).

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Imports, Organization.

Amendment to the Regulations

PART 101—GENERAL PROVISIONS

To reflect the establishment of a permanent Customs port of entry at Springfield, Missouri, the list of Customs regions, districts, and ports of entry in section 101.3(b), Customs Regulations (19 CFR 101.3(b)), is amended by removing "T.D. 82-30" and inserting, in its place, "T.D. 84-84" following "Springfield, Missouri, including all of the territory within Greene and Christian Counties, Missouri" under the column headed "Ports of Entry" in the St. Louis, Missouri, Customs district.

Executive Order 12291

Because this amendment relates to the organization of the Customs Service, pursuant to section 1(a)(3) of E.O. 12291, it is not subject to that E.O.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this amendment. Customs routinely establishes, expands, and consolidates Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Although this change may have a limited effect upon some small entities in the Springfield, Missouri area, the establishment of Customs ports of entry in other locations has not had a significant economic impact on a substantial number of small entities to the extent contemplated by the Regulatory Flexibility Act. Furthermore, Springfield has been operating as a port of entry since 1982. Accordingly, it is certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the amendment will not have a significant economic impact on a substantial number of small entities.

Drafting Information

The principal author of this document was Glen E. Vereb, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

William von Raab,
Commissioner of Customs.

Approved: April 6, 1984.
John M. Walker, Jr.,
Assistant Secretary of the Treasury.

[FR Doc. 84-10211 Filed 4-16-84; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 155 and 156

[Docket No. 77P-0090]

Tomato Concentrates, Catsup, and Tomato Juice; Definitions and Standards of Identity, Quality, and Fill of Container; Confirmation of Effective Date and Further Amendments

AGENCY: Food and Drug Administration.
ACTION: Final rule and confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date for compliance, but for two exceptions, with all provisions of the final rule amending and establishing certain definitions and standards for

canned vegetables and vegetable juices published in the Federal Register of January 28, 1983. One exception concerns § 155.191(a) (2) and (3) (21 CFR 155.191(a) (2) and (3)). These paragraphs are revised: (1) To provide for spices and flavoring as optional ingredients in tomato puree and to require that added spice or flavoring that characterizes tomato puree be declared as part of the name or in close proximity to the name of the food, (2) to clarify the use of the term "for manufacturing purposes only" for the labeling of "tomato concentrate," (3) to permit alternate methods to convey adequate directions for dilution of concentrated tomato juice in containers larger than No. 10 containers, and (4) to exempt from ingredient declaration water added to adjust the final composition of tomato concentrates. The other exception is for § 155.194(a)(1) (21 CFR 155.194(a)(1)) which is being revised: (1) To provide for the use in catsup of tomato concentrate containing lemon juice, concentrated lemon juice, or safe and suitable organic acids in quantities no greater than necessary to adjust pH, and (2) to clarify that salt is an optional ingredient in catsup.

DATES: Compliance with the provisions being revised herein may begin June 18, 1984. The provisions revised in this document are effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Objections to the provisions being revised herein by May 17, 1984.

Compliance with the provisions of Parts 155 and 156 amended in the Federal Register of January 28, 1983 (48 FR 3946) may have begun March 29, 1983, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply.

For exceptions to these effective dates regarding information collection requirements, see "Paperwork Reduction Act of 1980" appearing in the preamble of this document.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0107.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 28, 1983 (48 FR 3946), FDA issued a final regulation

amending the definition section for canned vegetables, establishing a separate definition section for vegetable juices, and amending the standards of identity and establishing standards of quality and fill of container for tomato concentrates, catsup, and tomato juice. The amendments included: (1) Establishing separate standards for tomato concentrates to include tomato puree, tomato paste, and concentrated tomato juice; (2) providing for the use of tomato concentrates and safe and suitable nutritive carbohydrate sweeteners in catsup; (3) providing for the use of concentrated tomato juice to prepare "tomato juice from concentrate" and establishing a minimum tomato soluble solids requirement of 5.0 percent by weight for "tomato juice from concentrate"; and (4) providing for safe and suitable organic acids in tomato juice and tomato juice from concentrate. Also, the amendments removed the standard of identity for yellow tomato juice (21 CFR 156.147). The final rule provided that any person who would be adversely affected could at any time, on or before February 28, 1983, file written objections and request a hearing on the specific provisions to which there were objections.

One objection and request for a hearing and five comments were filed in response to the final rule.

Under section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)), FDA has considered the comments and the objection and request for a hearing and its conclusions are as follows:

Tomato Puree—Spices and Flavoring

1. An objection and request for a hearing were received concerning the exclusion of spices and flavorings as optional ingredients in tomato puree. The objection stated that the excluded ingredients have long been allowed in tomato paste without causing deception or consumer confusion and that, therefore, there is no reason to prohibit their use in tomato puree. The objection further stated that consumers, as well as the industry, differentiate between tomato puree and tomato paste on the basis of solids content and not on the presence or absence of spices or flavoring. Finally, the objection pointed out that the growing concern about reducing sodium intake creates a need for exploring alternatives means of adding flavor to foods.

FDA is persuaded by these comments that the use of spices and flavoring in tomato puree should be permitted. Therefore, FDA has amended § 155.191(a)(2) to permit the use of the ingredients and has amended

§ 155.191(a)(3)(ii)(c) to provide that the use of any spice or flavoring that characterizes the product must be declared as part of or in close proximity to the name of the food.

Tomato Concentrate—For Manufacturing Purposes Only

2. One comment stated that tomato concentrate in large containers, such as 50-gallon drums, should not be required to bear the statement "for remanufacturing purposes only."

FDA advises that it never intended that containers that are larger than No. 10 containers be required to bear the statement "for remanufacturing purposes only." FDA has revised § 155.191(a)(3)(i)(c) to reflect this fact.

Concentrated Tomato Juice—Label Declaration for Dilution of Concentrate

3. One comment requested that, for large nonretail containers, alternative methods be permitted to convey adequate dilution directions.

FDA agrees and § 155.191(a)(3)(iii) is revised accordingly.

Tomato Concentrates—Label Declaration of Added Water

4. One comment stated water added to adjust the concentration of tomato soluble solids in certain tomato concentrates should not be required to be listed in the ingredient statement because the amount of added water is less than the amount of water in the original unconcentrated product. The comment stated that the requirement will permit a manufacturer of 8.0 percent tomato puree which has never been concentrated beyond that point to state only "tomato concentrate" in the ingredient statement while a manufacturer of a tomato puree of 12 percent tomato soluble solids prepared from 18 percent tomato soluble solids and water will be required to label his/her product with an ingredient statement reading "tomato concentrate and water."

FDA agrees that water need not be listed as an optional ingredient where the tomato soluble solids of tomato concentrates are adjusted with water within the range of soluble solids levels permitted for these foods. FDA believes that consumers are aware that such foods as tomato puree and tomato paste are concentrated products whether or not water has been used to adjust the final soluble solids level. FDA considers this use to differ in principle from the reconstitution of concentrated tomato juice with water to a level of soluble solids equivalent to that of the juice from which the concentrate was prepared. Therefore, FDA will continue

to require that water used in the preparation of tomato juice from concentrate be declared in the ingredient statement. However, FDA has revised § 155.191(a)(3)(iv) to exempt from the labeling requirement of Part 101 (21 CFR Part 101) water as an optional ingredient when it is needed to adjust the tomato soluble solids of the final composition of tomato concentrates.

Catsup—Lemon Juice or Organic Acids

5. Two comments requested clarification as to whether concentrates containing lemon juice or organic acids are prohibited from use in catsup when added in small quantities sufficient to control the pH of the concentrates or whether they are prohibited only when added in amounts that characterize the flavor of catsup. One comment stated that safe and suitable organic acids should not replace vinegar as the characteristic acidulant in catsup, but that it is important to permit tomato concentrates containing small amounts of organic acids to be used for making catsup in order to avoid unnecessary and costly burdens to both manufacturers and distributors of concentrates, as well as industrial users who may purchase concentrates for the purposes of manufacturing both catsup and noncatsup products. The comment pointed out that acidified and nonacidified concentrates would have to be produced, inventoried, stored, labeled, and shipped separately and could not be freely diverted from one manufacturing use to another if the need arose.

FDA agrees that it is reasonable to permit tomato concentrate to which lemon juice, concentrated lemon juice, or safe and suitable organic acids have been added in quantities no greater than necessary to adjust the pH of the tomato concentrate as an optional ingredient in catsup and § 155.194(a)(1)(i) is revised accordingly.

Catsup—Salt

6. One comment stated that the final regulation implies that only the food ingredients used to make catsup may contain added salt and that salt may not be added directly to catsup. The comment suggested that § 155.194(a)(1)(iv) be amended to read "The food may contain salt (sodium chloride formed during acid neutralization or present in any ingredient shall be considered added salt) * * *."

FDA agrees with the comment but does not believe that the suggested addition to the parenthetical statement, i.e. (or present in any ingredient), is

needed. FDA has revised § 155.194(a)(1) accordingly.

Catsup—Acidification

7. One comment stated that acetic acid, in addition to vinegar, should be provided for as an acidulant in catsup because acetic acid is the active component of vinegar and is as effective as vinegar in ensuring the stability and preservation of catsup.

FDA proposed in the Federal Register of May 9, 1978 (43 FR 19864), to broaden the choice of acidulants permitted for use in catsup to include lemon juice, concentrated lemon juice, and safe and suitable organic acids. Two comments on that proposal favored retention of the provision for the use of vinegar in catsup. One comment opposed permitting the use of the other acidulants because vinegar has been effective as a preservative while the stability and preserving qualities of other acidulants in catsup are not known. Both comments asserted that the use of acidulants other than vinegar would change the basic characteristics of catsup because the fermentation of vinegar produces certain natural flavors which appear to enhance the flavor of catsup. On this basis, FDA did not provide for acidulants other than vinegar in the final rule published in the Federal Register of January 28, 1983. The comments and the agency's response are discussed fully in the preamble to that final rule. Further, FDA does not consider diluted acetic acid to be vinegar and, therefore, acetic acid may not be substituted for vinegar in products that consumers customarily expect to be prepared with vinegar. Because no data have been submitted to demonstrate that acetic acid is a suitable alternate acidulant for vinegar in catsup, no change is made in the regulation.

Catsup—Label Declaration of Tomato Ingredient

8. One comment stated that catsup is produced from either fresh tomatoes or tomato paste and that the maintenance of separate labels to cover the specific tomato ingredient used in catsup will be expensive. The comment suggested that the regulation permit a single ingredient declaration as "Tomatoes or Concentrated Tomatoes" to cover both circumstances.

FDA's policy for the label declaration of optional ingredients was discussed fully in the preamble to the January 28, 1983 final rule (48 FR 3951; item 31), and FDA is not persuaded that to permit such collective ingredient labeling would be in the best interest of consumers. However, FDA advises that

any interested person who wishes to pursue this matter may submit a petition requesting that § 101.4 (21 CFR 101.4) be amended to provide for the desired collective ingredient labeling.

Paperwork Reduction Act of 1980

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the collection of information requirements in § 155.191 (a)(3) (ii)(c), (iii), and (iv) in this regulation as well as the collection of information requirements in §§ 155.191(a)(3), (b)(4), 155.194(a)(3), and 156.145(b)(2) as amended in the Federal Register of January 28, 1983, (48 FR 3946), will be submitted for approval to the Office of Management and Budget (OMB). These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register prior to July 1, 1984.

List of Subjects

21 CFR Part 155

Canned vegetables, Food standards, Vegetables.

21 CFR Part 156

Food standards, Vegetable juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that Parts 155 and 156, as amended in the Federal Register of January 28, 1983, will become effective July 1, 1985, except that §§ 155.191 and 155.194 are amended as follows:

PART 155—CANNED VEGETABLES

1. In § 155.191 by revising paragraph (a)(2) and (3)(i)(c), (ii)(c), (iii), and (iv), to read as follows:

§ 155.191 Tomato concentrates.

(a) * * *

(2) *Optional ingredients.* One or any combination of two or more of the following safe and suitable ingredients may be used in the foods:

(i) Salt (sodium chloride formed during acid neutralization shall be considered added salt).

(ii) Lemon juice, concentrated lemon juice, or organic acids.

(iii) Sodium bicarbonate.

(iv) Water, as provided for in paragraph (a)(1) of this section.

(v) Spices.

(vi) Flavoring.

(3) * * *

(i) * * *

(c) The name "tomato concentrate" may be used in lieu of the name "tomato puree," "tomato pulp," or "tomato paste" whenever the concentrate complies with the requirements of such foods; except that the label shall bear the statement "for remanufacturing purposes only" when the concentrate is packaged in No. 10 containers (3.1 kilograms or 109 avoirdupois ounces total water capacity) or containers that are smaller in size.

* * *

(ii) * * *

(c) A declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product, e.g., "Seasoned with _____," the blank to be filled in with the words "added spice" or, in lieu of the word "spice," the common name of the spice.

(iii) The label of concentrated tomato juice shall bear adequate directions for dilution to result in a diluted article containing not less than 5.0 percent by weight tomato soluble solids; except that alternative methods may be used to convey adequate dilution directions for containers that are larger than No. 10 containers (3.1 kilograms or 109 avoirdupois ounces total water capacity).

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter; except that water need not be declared in the ingredient statement when added to adjust the tomato soluble solids content of tomato concentrates within the range of soluble solids levels permitted for these foods.

* * *

2. In § 155.194 by revising paragraph (a)(1)(i) and the undesignated text following (a)(1)(iv) to read as follows:

§ 155.194 Catsup.

(a) * * *

(1) * * *

(i) Tomato concentrate as defined in § 155.191(a)(1), except that lemon juice, concentrated lemon juice, or safe and suitable organic acids may be used in quantities no greater than necessary to adjust the pH, and in compliance with § 155.191(b).

* * *

Such liquid is strained so as to exclude skins, seeds, and other coarse or hard substances in accordance with current good manufacturing practice. Prior to straining, food-grade hydrochloric acid may be added to the tomato material in an amount to obtain a pH no lower than

2.0. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2 ± 0.2 . The final composition of the food may be adjusted by concentration and/or by the addition of water. The food may contain salt (sodium chloride formed during acid neutralization shall be considered added salt) and is seasoned with ingredients as specified in paragraph (a)(2) of this section. The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

Any person who will be adversely affected by the foregoing amendments to the final regulation may, in accordance with 21 CFR 12.22, at any time on or before May 17, 1984 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to the amendments that may be stayed by the filing of proper objections, compliance with these amendments to the final regulation may begin June 18, 1984. The mandatory compliance date for these amendments shall be July 1, 1985. Notice of the filing of objections or lack thereof will be published in the *Federal Register*. Accordingly, except as to the provisions herein amended, the effective date of Parts 155 and 156 as amended in the *Federal Register* of January 28, 1983

(48 FR 3946) is confirmed as follows: Compliance with this regulation, including any required labeling changes, may have begun on March 29, 1983, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: April 6, 1984.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 84-8770 Filed 4-16-84; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 430, 436, 440, 450, 455, and 555

[Docket No. 83N-0395]

Antibiotic Drugs; Updating and Technical Changes; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the document that amended certain antibiotic regulations by making updating and noncontroversial technical changes. This document corrects typographical errors.

EFFECTIVE DATE: April 17, 1984.

FOR FURTHER INFORMATION CONTACT: Joan M. Eckert, Center for Drugs and Biologics (formerly National Center for Drugs and Biologics) (HFN-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: In FR Doc. 84-4353, appearing on page 6090, in the issue for Friday, February 17, 1984, the following corrections are made on page 6093: In the first column under § 450.220 *Dactinomycin for injection* in paragraph (b)(1)(ii)(c), "455-nanometer" is corrected to read "445-nanometer" and "§ 450.20(b)(6)(i)" is corrected to read "§ 450.20(b)(4)(i)"; and in paragraph (b)(4), "§ 450.20(b)(4)" is corrected to read "§ 450.20(b)(2)".

Dated: April 11, 1984.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 84-10196 Filed 4-16-84; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[T.D. 7950]

Exhaustion of Administrative Remedies

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the circumstances in which a party normally will be considered to have exhausted the administrative remedies available within the Internal Revenue Service for purposes of the recovery of court costs and certain fees in a civil tax proceeding brought in a court of the United States (including the Tax Court). Changes to the applicable tax law were made by the Tax Equity and Fiscal Responsibility Act of 1982. The regulations apply to parties to civil tax proceedings and provide them with guidance concerning circumstances in which the Internal Revenue Service normally will consider a party's administrative remedies exhausted.

DATES: The regulations are effective April 17, 1984, and apply to civil tax proceedings commenced after February 28, 1983, and before January 1, 1986.

FOR FURTHER INFORMATION CONTACT: C. Scott McLeod of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224, Attention, CC:LR:T, 202-566-3288 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

On March 25, 1983, the *Federal Register* published proposed amendments to the Regulations on Procedure and Administration (26 CFR Part 301) under section 7430 of the Internal Revenue Code of 1954 (48 FR 12560). The amendments were proposed to reflect the changes made by section 292(a) of the Tax Equity and Fiscal Responsibility Act of 1982 (96 Stat. 572). After consideration of all comments, the proposed amendments are adopted as revised by this Treasury decision.

In general, the rules in this Treasury decision are the same as those in the notice of proposed rulemaking. Those rules are explained in the preamble of the notice of proposed rulemaking under the heading, **SUPPLEMENTARY**