Commerce, P.O. Box 273, Washington, DC 20044.

3. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

4. This rule involves a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0625–0001.

List of Subjects in 15 CFR Part 399

Exports, Reporting and recordkeeping requirements.

PART 399—[AMENDED]

Accordingly, Part 399 of the Export Administration Regulations (15 CFR Parts 368–399) is amended as follows:

1. The authority citation for Part 399 continues to read as follows:

Authority: Pub. L. 96–72, 93 Stat. 503, 50 U.S.C. App. 2401 *et seq.*, as amended by Pub. L. 97–145 of December 29, 1981 and by Pub. L. 99–64 of July 12, 1985; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95–23, 50 U.S.C. 1701 *et seq.*, E.O. 12532 of eptember 9, 1985 (50 FR 36861, September 10, 1985).

§ 399.1 [Amended]

2. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1572A is amended by adding as the first note a new Note under paragraph (d), reading as follows:

1572A Recording or reproducing equipment, and specially designed components therefore.

* * * * *

(d) * * *

Note.—A validated export license is required only for Country Groups S and Z for exports of computer flexible disc cartridges designed for digital recording and reproduction having a "gross capacity" less than 17 million bits.

(Released from export controls by this Note are:

(1) Single or double side *or* single or double density 8-inch "floppy" diskettes that do not exceed 48 tracks per inch;

(2) Single or double side *or* single or double density 5.25-inch "floppy" diskettes that do not exceed 96 tracks per inch; and

(3) Single or double side *or* single or double density 3.5-inch "floppy" diskettes that do not exceed 135 tracks per inch.)

* * * * *

Dated: July 9, 1986.

Paul Freedenberg,

Assistant Secretary for Trade Administration.

[FR Doc. 86–15814 Filed 7–14–86; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 433

[Docket No. 84N–0373]

Antibiotic Drug Products for Over-the-Counter Human Use; Exemption From Certification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to specifically exempt from batch certification antibiotic drug products for over-the-counter (OTC) human use that meet all of the conditions in 21 CFR 330.1 and in an applicable final OTC antibiotic drug monograph. Under the exemption, manufacturers are not required to obtain, before marketing, certification of each batch of an OTC antibiotic drug that is generally recognized as safe and effective and not misbranded.

DATES: Effective August 14, 1986; notice of participation and request for hearing by August 14, 1986; data, information, and analyses to justify a hearing by September 15, 1986.

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

FOR FURTHER INFORMATION CONTACT: Robert J. Meyer, Center for Drugs and Biologics (HFN–362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8049.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of July 22, 1985 (50 FR 29702), FDA proposed to amend the antibiotic drug regulations to specifically exempt from batch certification antibiotic drug products for OTC human use that meet all of the conditions in § 330.1 (21 CFR 330.1) and in an applicable final OTC antibiotic drug monograph.

As discussed in the proposal, § 433.1 of the regulations (21 CFR 443.1) provides that antibiotic drugs for human use are exempt from the batch certification requirements of section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) if they are approved for marketing under an appropriate antibiotic application (formerly a Form 5) or an abbreviated antibiotic application (formerly a Form 6) and meet certain other specified conditions. Part 330 of the regulations contains procedures by which classes of OTC human drugs are generally recognized as safe and effective and not misbranded. The agency has determined that an OTC antibiotic drug product that meets the requirements of Part 330 also should be exempted from the batch certification requirements of section 507 of the act. However, such drug products do not meet one of the conditions necessary for exemption under § 433.1, as this section is currently written. Specifically, such drug products are not approved for marketing under an appropriate antibiotic application or an abbreviated antibiotic application, as § 433.1 now requires. FDA did not intend to exclude OTC antibiotic drugs that are generally recognized as safe and effective from the exemption from batch certification. Therefore, the agency proposed that § 433.1 be revised to exempt from the requirements of batch certification all OTC antibiotic drug products that conform to each of the general conditions established in § 330.1 of the regulations and to each of the conditions in an applicable final OTC drug monograph issued under § 330.10. The agency also proposed a conforming technical amendment to § 433.2(b).

Interested persons were given until September 20, 1985, to submit written comments on the proposal and until August 21, 1985, to submit requests for an informal conference. No comments or requests for an informal conference were received in response to the proposal.

In the **Federal Register** of February 22, 1985 (50 FR 7452), FDA revised its regulations governing the approval of new drugs and antibiotic drugs for human use. Under that final rule, FDA amended the antibiotic regulations in § 431.50 (21 CFR 431.50) by removing the terms antibiotic Form 5 and antibiotic Form 6 because they were superseded by the new terms "antibiotic application" and "abbreviated antibiotic application," respectively. In order to update these regulations, conforming amendments have been made in the final rule.

Economic Impact

The agency has considered the economic impact of this final rule and has determined that it does not require a

regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). Specifically, the final rule allows OTC antibiotic drugs that are generally recognized as safe and effective to be marketed without obtaining certification of each batch of antibiotic drug, thus eliminating the cost of this certification for the manufacturers of OTC antibiotic drugs that will be marketed under an applicable final OTC drug monograph. Accordingly, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Filing Objections

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 14, 1986, a written notice of participation and request for hearing; and (2) on or before September 15, 1986, 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 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 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 433

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 433 is amended as follows:

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

1. The authority citations under 21 CFR 433.1 and 433.2 are removed and the authority citation for 21 CFR Part 433 is revised to read as follows:

Authority: Secs. 505, 507, 52 Stat. 1050–1053 as amended, 59 Stat. 463 as amended (21 U.S.C. 355, 357); 21 CFR 5.10.

2. By revising § 433.1 to read as follows:

§ 433.1 Exemption of antibiotic drugs for human use from batch certification requirements.

(a) Antibiotic drugs for human use are exempt from the batch certification requirements of Part 431 of this chapter if the conditions of paragraph (b) of this section are met; or, in the case over-the-counter antibiotic drugs subject to an over-the-counter drug monograph in this chapter, if the conditions of paragraph (c) of this section are met.

(b) The conditions are as follows:

(1) The antibiotic drug is approved for marketing under an appropriate antibiotic application or abbreviated antibiotic application or is the subject of review under the Drug Efficacy Study Implementation Program.

(2) The antibiotic drug is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic application or abbreviated antibiotic application.

(3) The bulk antibiotic drug used in preparing the antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application or abbreviated antibiotic application.

(4) The antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application or abbreviated antibiotic application.

(c) The over-the-counter antibiotic drug product for human use is required to meet the general conditions established in § 330.1 of this chapter, and the conditions specified in an applicable over-the-counter drug monograph in this chapter.

(d) In accordance with the provisions of section 507(e) of the act, an antibiotic-containing drug for human use exempt from the requirements for batch certification under paragraph (b) of this section is subject following its approval to section 505 of the act and applicable regulations for new drugs, generally Parts 310 through 314 of this chapter. For each antibiotic drug subject to an exemption under paragraph (b) of this section:

(1) An approved antibiotic application is regarded to be an approved application under § 314.50 of this chapter.

(2) An approved abbreviated antibiotic application is regarded to be an approved abbreviated application under § 314.55 of this chapter.

(e) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic drug for human use subject to an exemption under this section as provided in section 507(c) of this act.

(f) All exemptions from batch certification requirements for antibiotic drugs for human use under this section are subject to the conditions of effectiveness under § 433.2.

(Approved by the Office of Management and Budget under control number 0910–0001.)

3. By revising § 433.2(b) to read as follows:

§ 433.2 Conditions on the effectiveness of exemptions of antibiotic drugs for human use from batch certification requirements.

* * * * *

(b) If the Commissioner finds that the person granted an exemption from batch certification requirments for an antibiotic drug for human use has failed either to comply with the requirements of section 505 of the act and the regulations promulgated thereunder or to meet the general conditions established in § 330.1 of this chapter and the conditions specified in an applicable over-the-counter drug monograph in this chapter; or if the Commissioner finds that the requirements of § 433.1 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the drug until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

* * * * *

Dated: July 8, 1986.

James W. Swanson,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-15850 Filed 7-14-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF LABOR

Wage and Hour Division, Employment Standards Administration

29 CFR Part 697

Industries in American Samoa; Wage Order

Correction

In FR Doc. 86-14072 beginning on page 22517 in the issue of Friday, June 20, 1986, make the following corrections to § 697.1(h)(1) on page 22518:

§ 697.1 [Corrected]

1. In the fourth line change "July 5, 1986" to read "January 5, 1987".
2. In the fifth line change "July 6, 1986" to read "July 6, 1987".
3. In the sixth line change "July 4, 1988" to read "January 4, 1988".

BILLING CODE 1505-01-M

VETERANS ADMINISTRATION

38 CFR Part 21

Subsistence Allowance for Dependents and Incarcerated Veterans; Correction

AGENCY: Veterans Administration.

ACTION: Final rules; correction.

SUMMARY: The Veterans Administration recently published final rules on the payment of subsistence allowance to incarcerated veterans and for payment of the portion of subsistence allowance payable to the veteran's dependents. These rules were published in the **Federal Register** of June 23, 1986, at pages 22807 and 22808. This document is to correct the text of § 21.324(n)(2).

EFFECTIVE DATE: October 14, 1982.

FOR FURTHER INFORMATION CONTACT: Morris Triestman, Vocational Rehabilitation Policy and Program Development, Department of Veterans Benefits (282), Veterans Administration, 810 Vermont Avenue NW., Washington, DC 20420, (202) 389-2866.

Dated: July 8, 1986.

Marjorie Leandri,

Acting Chief, Directives Management Division.

On page 22808 of the **Federal Register** of June 23, 1986, Volume 51, § 21.324(n)(2) is correctly revised to read as follows:

§ 21.324 Reduction or termination dates of subsistence allowance.

* * * * *

(n) *Incarceration in prison or jail.*

* * *

(2) *Halfway house or work-release program.* The subsistence allowance of a veteran in a halfway house or work release program as a result of conviction of a felony will not be reduced under the provisions of § 21.276 the date on which the Federal Government or a State or local government pays all of the veteran's living expenses. (38 U.S.C. 1508(g).)

* * * * *

[FR Doc. 86-15876 Filed 7-14-86; 8:45 am]

BILLING CODE 8320-01-M

POSTAL SERVICE

39 CFR Part 111

Domestic Mail Manual; Eligibility of Separate Publications to Mail at Second-Class Rates

AGENCY: Postal Service.

ACTION: Interim rule.

SUMMARY: This rule adds a new section to the Domestic Mail Manual (DMM) in respect to § 200.012 of the Domestic Mail Classification Schedule (DMCS), which makes publications primarily designed for advertising purposes or for free circulation ineligible for second-class privileges. So-called "Plus" publications regularly published on the same day as another regular issue of a parent periodical may, in certain circumstances described in § 200.0123 of the DMCS, be ineligible for second-class privileges under the permit of the parent periodical. See 51 FR 19831-33. The new rule makes it explicit that, in appropriate circumstances, "Plus" publications may be considered separate publications even though they are not regularly published on the same day as another regular issue of the parent periodical.

This interim rule is set forth below for comment and suggested revision prior to adoption in final form.

DATES: The interim rule will take effect on July 20, 1986. Comments must be received on or before August 14, 1986.

ADDRESS: Written comments should be directed to the Director, Office of Classification and Rates Administration, U.S. Postal Service, Room 8430, 475 L'Enfant Plaza, SW., Washington, D.C. 20260-5360. Copies of all written comments will be available for inspection and photocopying between 9:00 a.m. and 4:00 p.m., Monday through Friday, in Room 8430 at the above address.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Beller, (202) 268-5166.

SUPPLEMENTARY INFORMATION: As noticed in the **Federal Register** on June 3, 1986, new DMM § 425.225 became effective on June 8, 1986, in order to give effect to new Domestic Mail Classification Schedule (DMCS) § 200.0123, which also became effective on that date. 51 FR 19831-33. These new sections described conditions under which a so-called "Plus" issue will be deemed to be a separate publication if published at a regular frequency on the same day as another regular "issue" of the publication.

In its Opinion and Recommended Decision in Docket No. C85-1, however, the Commission stated plainly that the "on the same day" condition was set forth "solely because it is daily newspapers who, because of an improper administrative construction of the DMCS, are being permitted to enter Plus publications as second class even though they are not eligible." Opinion and Recommended Decision, Complaint of Advo-System, Inc., Docket No. C85-1, at 41-42 (January 24, 1986). The Commission emphasized that "[o]ur opinion does *not* authorize non-daily newspapers to mail total market coverage products and such materials akin to Plus publications would not be eligible for second-class." *Id.*, at 39-40 (Emphasis in original).

The Commission noted that the intent of its recommendations would be circumvented if "publications having the characteristics of Plus publications [were] entered as second class on days not used for publishing by newspapers which do not publish on a daily basis." *Id.* at 40. It added, however, that "[i]f this practice should develop, we believe that with the guidelines provided herein the Postal Service could handle it administratively, or if necessary, propose additional clarifying DMCS language." *Id.* It reiterated:

> Furthermore while the language of the proposed amendment is limited to daily newspapers, we assume that this opinion will assist the Postal Service in distinguishing whether printed matter is an issue of a particular publication or a separate publication.

Id. at 42.

The new DMM § 425.226, follows the Commission's guidelines to determine whether an "issue" which is not regularly published on the same day as another "issue" of a publication should