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: Proposed rule

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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 § 330.1 (21 CFR 330.1) and in an applicable final OTC antibiotic drug monograph. Under the exemption, manufacturers would not be 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: Comments by September 20, 1985; requests for an informal conference by August 21, 1985.

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 Drug and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 7, 1982 (47 FR 39155), FDA amended § 433.1 of the regulations (21 CFR 433.1), which describes how antibiotic drugs can be exempted from the batch certification requirements of section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357). This regulation now provides that antibiotic drugs for human use are exempt from the batch certification requirements of the act if they are approved for marketing under an appropriate antibiotic Form 5 or Form 6 and meet certain other specified conditions. Because the act provides that an antibiotic drug that is a new drug exempted from the batch certification requirements is subject to the new drug approval requirements of section 505 of the act (21 U.S.C. 355), the regulations also provide that an approved antibiotic Form 5 is regarded as an approved new drug application, and

Part 330 of the regulations (21 CFR Part 330) contains procedures by which classes of OTC human drugs are generally recognized as safe and effective and not misbranded. Under these procedures, an OTC drug product, including an OTC antibiotic drug product, that conforms to each of the general conditions established in § 330.1, and to each of the conditions in an applicable final OTC drug monograph issued under § 330.10, is generally recognized as safe and effective and not misbranded. Because it is generally recognized as safe and effective, such a product is not subject to the new drug approval requirements of section 505 of the act. Accordingly, OTC antibiotic drug products that meet the conditions in Part 330 do not need approval for marketing in the form of an approved antibiotic Form 5 or Form 6.

The agency believes 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 would not meet one of the conditions necessary for exemption under § 433.1, as this section is presently written. Specifically, such drug products would not be approved for marketing under an appropriate antibiotic Form 5 or Form 6, 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 is proposing 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 is also proposing a conforming technical amendment to § 433.2(b).

Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(a) (8) and (9) (April 26, 1985; 50 FR 16636) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Impact

The agency has considered the economic impact of this proposed 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 proposed rule would allow 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 rulemaking, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Interested persons may, on or before September 20, 1985, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons may also, on or before August 21, 1985, submit to the Dockets Management Branch a request for an informal conference. The participants in a informal conference, if one is held, will have until September 20, 1985, or 30 days from the date of the conference, whichever is later, to submit their comments.

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 it is proposed that Part 433 be amended as follows:

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

1. The authority citation for 21 CFR Part 433 would continue to read as follows:

Authority: Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357), unless otherwise noted.

2. In Part 433 by revising §§ 433.1 and 433.2(b) 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 of 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 Form 5 or Form 6 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 Form 5 or Form 6 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 Form 5 or Form 6 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 Form 5 or Form 6 application.

(c) The over-the-counter antibiotic drug product for human use meets 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 Form 5 application is regarded to be an approved new drug application under § 314.50 of this chapter.

(2) An approved antibiotic Form 6 application is regarded to be an approved abbreviated new drug 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 the 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.

(g) Reporting/recordkeeping requirements contained in this Part 433 have been approved by the Office of Management and Budget and assigned approval numbers 0910-0007, 0910-0008, and 0910-0055.

§ 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 requirements 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 Commission 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 certifications 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 12, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-17281 Filed 7-19-85; 8:45 am]

BILLING CODE 4160-01-M