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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 436 and 442

[Docket No. 94N-0352]

Antibiotic Drugs; Cefuroxime Axetil 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 the accepted standards for cefuroxime axetil for its use in a new dosage form of cefuroxime axetil, cefuroxime axetil for oral suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 22, 1995; written comments, notice of participation, and requests for a hearing by June 22, 1995; data, information, and analyses to justify a hearing by July 24, 1995.

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

FOR FURTHER INFORMATION CONTACT: James Timper, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6714.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated 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

cefuroxime axetil, cefuroxime axetil for oral suspension. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in parts 436 and 442 (21 CFR parts 436 and 442) to include the 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 June 22, 1995. However interested persons may, on or before June 22, 1995, submit written 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 June 22, 1995, a written notice of participation and request for a hearing, and (2) on or before July 24, 1995, 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 a 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 document 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 Parts 436 and 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 436 and 442 are amended as follows:

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

1. The authority citation for 21 CFR part 436 continues to read as follows:

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

2. Section 436.215 is amended by alphabetically adding a new entry to the table in paragraph (b) and by revising paragraph (c)(9) to read as follows:

§ 436.215 Dissolution test.

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(b) * * *