(6) When the costs to the public outweigh any benefit which may accrue to the public.

(e) Based upon the information furnished by the requester in response to paragraph (c) and the criteria set forth in paragraph (d) of this section, and the NRC will determine if waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public. In determining whether to waive fees in whole or in part, the NRC will consider the total estimated search and reproduction costs necessary to comply with the request and the extent to which the requester has carried the burden of making the necessary public interest showing under paragraph (c) of this section.

(f) In the absence of a specific request for waiver or reduction of fees, if the information furnished by the requester is sufficient to meet the requirements of this section for waiver or reduction of fees, NRC may determine that production or disclosure of the requested records can be considered as primarily benefiting the general public.

(g) The NRC will not waive the reproduction costs for documents located or made available in the NRC Public Document Room or a local public document room in the absence of a compelling reason to do so.

§ 9.14b Processing of requests for a waiver or reduction of fees*

(a) Within 10 working days after receipt of a request for access to records which does not involve more than four hours of search time, or in which the NRC agrees to waive fees pursuant to § 9.14a(f), the NRC will respond to the request as provided in § 9.9. If the request is expected to require more than four hours of search time to locate the requested records and the NRC has not waived fees under § 9.14a(f), the NRC will notify the requester that fees will be assessed. The notification shall include the estimated cost of search fees and the nature of the search required. Requesters are encouraged to discuss with the NRC the possibility of narrowing the scope of the request while retaining the requester's original objective. The requester will be advised that he may agree to bear the estimated costs, submit a deposit equal to the estimated cost of complying with the request, or submit a request for waiver or reduction of fees pursuant to § 9.14a.

(b) Within 10 working days of the receipt of NRC's notice that fees will be assessed, the requester shall notify NRC in writing that he agrees to bear the estimated costs, submit a deposit equal to the estimated cost of responding to the request or submit a request for waiver or reduction of fees pursuant to § 9.14a. In making a request for waiver or reduction of fees, a requester must provide the information required by § 9.14a(c).

(c) Within 10 working days after receipt of a request for the waiver or reduction of fees made in accordance with § 9.14a, the NRC will waive or reduce the fees and notify the requester of the NRC's intent to promptly provide the records or will deny the request and provide a statement to the requester as to why the request does not meet the requirements of § 9.14a(e).

(d) In those cases where a waiver of fees was requested and denied and the requester has agreed to bear the estimated cost, the requester may within 30 days of receipt of the requested documents resubmit a request for a waiver or reduction of fees if the receipt of documents has materially changed the information originally furnished by the requester pursuant to 9.14a(c). This paragraph (d) will become ineffective after December 17, 1979 such that no requests for reconsideration submitted after this date will be reviewed unless the Commission takes action to extend or make permanent this provision.

(e) As provided in §§ 9.11 and 9.15, a denial of a request to waive or reduce fees may be appealed within 30 days to the Executive Director for Operations or to the Commission, as appropriate.

4. Section 9.15 is revised to read as follows:

§ 9.15 Committees, boards, panels, and offices reporting to the Commission.

(a) For boards, panels, and offices reporting directly to the Commission, and the Office of the Executive Legal Director, the initial determination on a request for records or request for waiver or reduction of fees for locating and reproducing such records, required by § 9.9 shall be made by the head of such board, panel, or office, or his designee, instead of the Director, Office of Administration, and an appeal of an adverse determination shall be made to the Commission instead of the Executive Director for Operations.

(b) The Advisory Committee Management Officer shall make the initial determination required by § 9.9 on requests for records of advisory committees established pursuant to Part 7 of this chapter, including the Advisory Committee on Reactor Safeguards, or requests for waiver or reduction of fees for locating and reproducing such records, and an appeal of an adverse determination shall be to the Commission.

(c) The head of boards, panels, and offices reporting directly to the Commission, and the Advisory Committee Management Officer for advisory committees established pursuant to Part 7 of this chapter, will make the initial determination required by paragraph (a) and (b) of this section only after consultation with the Office of the General Counsel.

Effective date. These amendments become effective on April 16, 1979.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841); 5 U.S.C. 552).

Dated at Washington, D.C. this ninth day of March, 1979.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 79-7913 Filed 3-15-79; 8:45 am]

[3510-24-M]

Title 13—Business Credit and Assistance

CHAPTER III—ECONOMIC DEVELOPMENT ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 309—GENERAL RULES FOR FINANCIAL ASSISTANCE

Interim Regulation

AGENCY: Economic Development Administration (EDA), Department of Commerce.

ACTION: Interim rule.

SUMMARY: This amendment is intended to clarify regulations interpreting a statutory prohibition on the use of EDA assistance to relocate jobs from one labor area to another. As modified, EDA's nonrelocation regulations would allow, in certain limited situations, retail establishments to participate indirectly in EDA-assisted projects without regard to their relocation actions. The intended effect of this amendment is to bring EDA's nonrelocation regulations into closer conformance with their statutory authority.

DATES: Effective date: March 12, 1979. Comments by: May 15, 1979.

ADDRESSES: Send comments to: Assistant Secretary for Economic Development, U.S. Department of Commerce, Room 7800B, Washington, D.C. 20230.

FOR FURTHER INFORMATION ON THIS INTERIM RULE CONTACT:

James F. Marten, U.S. Department of Commerce, Room 7009, Washington, D.C. 20230, (202) 377-5441.

*The application requirements contained in sections 9.14a(c) and 9.14b(d) have been approved by the U.S. General Accounting Office under number B-180225 (R0582).

SUPPLEMENTARY INFORMATION:

The amendment to EDA's nonrelocation regulations adds an exception to the prohibition of 13 CFR 309.3(g). Subsection (g) presently denies financial assistance to any applicant or establishment which has relocated within 24 months of applying for EDA assistance or which is relocating or will relocate with EDA assistance. New paragraphs (g) (1) through (4) provide an exemption for retail stores which have multiple outlets, which are not directly aided by EDA financial assistance, which are not engaging in a pattern of operations to transfer operations from one region to another, and which will not experience a significant reduction in employment in its entire operations by participating indirectly in the EDA project. As drafted, the amendment affects only indirect beneficiaries of EDA assistance. It does not apply to applicants for or direct recipients of EDA assistance.

This amendment distinguishes between retail stores and manufacturing firms with respect to EDA's requirement of an assurance on past and future non-relocation. The reason for so distinguishing is the nature of retail stores and their essential difference from manufacturing firms in terms of relocation activities. The principal difference is that the area served by a retail store is governed by the market area for its goods. This market area is normally local and within a labor area. Such relocations would not normally involve a loss in the number of job opportunities in the area; therefore, they would not fall within the scope of activities prohibited for EDA assistance. On the other hand, industrial firms are most frequently regional, national or international in their operations. Such firms can, and do, relocate from one labor area to another for purposes such as reducing costs of production. These relocations reduce available job opportunities in a labor area and, thus, would act as a bar to EDA assistance.

Section 202(b)(1) of PWEDA, the statutory basis for the nonrelocation regulations, supports such a distinction. Following its prohibition of assistance which would aid establishments relocating from one area to another, section 202(b)(1) states:

Provided, however, That such limitations shall not be construed to prohibit assistance for the expansion of an existing business entity through the establishment of a new branch, affiliate, or subsidiary of such entity if the Secretary finds that the establishment of such branch, affiliate, or subsidiary will not result in an increase in unemployment of the area of original location or in any other area where such entity conducts business operations. * * * (42 USC 3142)

EDA feels that the amendment to 13 CFR 309.3 would further the expressed intent of Congress with respect to the relationship of EDA assistance and relocation of business establishments.

In accordance with the criteria of Department of Commerce Administrative Order 218-7, EDA has determined that this amendment does not constitute a significant regulation subject to the requirements of Executive Order 12044. In furtherance of the policies of that executive order and DAO 218-7 for all regulations, EDA will accept written comments on this amendment for 60 days after its publication in the FEDERAL REGISTER. After all comments are received, EDA will evaluate the suggestions and may revise the interim regulation, if appropriate, before publishing it as a final rule.

Accordingly, EDA amends 13 CFR 309.3(g) as follows:

§ 309.3 Nonrelocation.

* * * * *

(g) EDA financial assistance is not available to any establishment or applicant which has relocated within 24 months of applying for EDA assistance or which is relocating or will relocate in the future with EDA assistance. Retail stores are exempt from this requirement provided:

(1) The retail store has multiple outlets;

(2) The retail store is not a direct recipient of EDA financial assistance;

(3) The retail store is not engaged in a pattern of operations which would result in relocating a substantial portion of its operations from one region to another; and

(4) The indirect participation by the retail store will not result in a significant reduction of employment in the retail store's entire operation.

* * * * *

AUTHORITY: Sec. 701, Pub. L. 89-136, 79 Stat. 570 (42 U.S.C. 3211); Department of Commerce Organization Order 10-4, as amended (40 FR 56702, as amended).

Dated: March 12, 1979.

ROBERT HALL,
Assistant Secretary for Economic Development.

[FR Doc. 79-8016 Filed 3-15-79; 8:45 am]

[1505-01-M]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

SUBCHAPTER B—GUIDES

PART 23—GUIDES FOR THE JEWELRY INDUSTRY

PART 24—GUIDES FOR THE LUGGAGE AND RELATED PRODUCTS INDUSTRY

Recodification of Parts and Removal of Obsolete Sections In Those parts

Correction

In FR Doc. 79-5798 appearing on page 11176 in the issue of Tuesday, February 27, 1979, make the following corrections:

(1) In the first column of page 11187, in the first line of the NOTE to § 23.5(c)(1), "When the 'Gold,'" should have read "When the term 'Gold,'".

(2) In the third column of page 11191, in the tenth line of paragraph (i) of § 24.2(b)(7), "G21" should have been a reference to the footnote "1".

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 77C-0208]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Ferric Ferrocyanide (Iron Blue); Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of the December 22, 1978, of a regulation which "permanently" lists ferric ferrocyanide (iron blue) as a color additive for use in externally applied drugs and cosmetics, including those intended for use in the

area of the eye, exempts the color from certification, and removes ferric ferrocyanide (iron blue) from the provisional listing.

DATE: Effective date confirmed: December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of November 21, 1978 (43 FR 54235) added new §§ 73.1299 and 73.2299 (21 CFR 73.1299 and 73.2299) to provide for the safe use of ferric ferrocyanide (iron blue) as a color additive for use in externally applied drugs and cosmetics, including those intended for use in the area of the eye. The regulation also amended § 81.1 *Provisional listing of color additives* (21 CFR 81.1) by deleting the entry in paragraph (g) for ferric ferrocyanide (iron blue) and amended § 81.27 *Conditions of provisional listing of additives* (21 CFR 81.27) by deleting from paragraph (c) the requirements for ferric ferrocyanide (iron blue).

Under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376 (b), (c), and (d)) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of November 21, 1978. Accordingly, the amendments promulgated thereby became effective on December 22, 1978.

Dated: March 8, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7642 Filed 3-15-79; 8:45 am]

[4110-03-M]

[Docket No. 75N-0107]

FOODS FOR SPECIAL DIETARY USE

Vitamin and Mineral Products; Revocation of Regulations

AGENCY: Food and Drug Administration.

ACTION: Final Order.

SUMMARY: The Food and Drug Administration (FDA) revokes regulations that the United States Court of Appeals for the Second Circuit has ruled are invalid. The regulations had established definitions and a standard of identity and labeling requirements for dietary supplements of vitamins and minerals.

EFFECTIVE DATE: March 16, 1979.

FOR FURTHER INFORMATION CONTACT:

L. Robert Lake, Bureau of Foods (HFF-302), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1254.

SUPPLEMENTARY INFORMATION: Regulations establishing definitions and a standard of identity and labeling requirements for dietary supplements of vitamins and minerals were first issued in 1973 after a lengthy administrative hearing. The regulations defined five types of preparations and prescribed maximum and minimum potencies for ingredients. These potencies were stated in terms of a new unit of measurement, the U.S. Recommended Daily Allowances (U.S. RDA) that were derived from the Recommended Dietary Allowances published by the Food and Nutrition Board of the National Academy of Sciences/National Research Council. In general, the minimum potency for a nutrient in a dietary supplement was established at 50 percent of the U.S. RDA for that nutrient; the maximum potency, at 150 percent of the U.S. RDA. The 1973 regulations were challenged by fifteen petitioners. In a lengthy opinion, the United States Court of Appeals for the Second Circuit "broadly sustain[ed] the regulations" but remanded them to the agency for further action. *National Nutritional Foods Ass'n* v. *FDA*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975).

While FDA was in the process of implementing the Court's remand directions, Congress enacted new legislation (Pub. L. 94-278, Title V, sections 501-502, 90 Stat. 410-413; April 22, 1976) restricting FDA's authority to limit the maximum potency of vitamins and minerals and ingredient composition in dietary supplements offered for use by adults (other than pregnant or lactating women) and recognized as safe. Codified in part, these amendments became section 411 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350).

In the FEDERAL REGISTER of October 19, 1976 (41 FR 46156), FDA promulgated regulations (21 CFR 125.1, 125.2, 125.3, and 80.1 (recodified as 21 CFR 105.3, 105.60, 105.77, and 105.85, respectively, in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302))) to comply with both the Court's remand directions and the 1976 vitamin and mineral amendments. In effect, the agency retained the standard of identity promulgated in 1973, amended it in accordance with the Court's instructions, and incorporated an exemption from the limitations on maximum potency and ingredient composition in dietary supplements offered for use by most adults to comply with the 1976 legislation.

Subsequently, a petition was submitted by National Nutritional Foods Association (NNFA) asking the agency to reconsider the procedural propriety of amending the regulations to comply with 1976 amendments without notice and comment. In the FEDERAL REGISTER of April 19, 1977 (42 FR 20292), FDA denied the petition, noting that the 1976 amendments contained a provision that the dietary supplement regulations be revised in accordance with 5 U.S.C. 553 to conform to the legislation; that 5 U.S.C. 553 contains a good cause exemption from notice and public procedures; and that the changes in the dietary supplement regulations to conform them to requirements of the 1976 amendments satisfied the good cause exemption.

On appeal, the Second Circuit held that the good cause exemption in 5 U.S.C. 553 is to be narrowly construed, and that the dietary supplement regulations do not qualify for the exemption and must be republished for comment. In addition, the court held, *inter alia*, that vitamins and minerals that are not generally recognized as safe are food additives under the act, and that the agency has authority to retain the minimum potency requirements for dietary supplements. *National Nutritional Foods Ass'n* v. *Kennedy*, 572 F. 2d 377 (2d Cir. 1978).

Copies of the judicial decisions cited above have been placed on file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and are available for public inspection between 9 a.m. and 4 p.m., Monday through Friday.

Under the decision by the Court of Appeals, the Commissioner of Food and Drugs hereby orders that 21 CFR 105.3, 105.60, and 105.85 be revoked or revised. Those portions of the regulations which were to have been superseded by amendment of Part 105 are hereby reinstated. Accordingly, Parts 101, 105, and 201 are amended as follows:

PART 101—FOOD LABELING

1. In part 101:

a. By revising § 101.2(c)(1)(iii)(*a*), (2)(iii)(*a*), and (3)(ii)(*a*) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(c) * * *
(1) * * *
(iii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

(2) * * *

(iii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

(3) * * *

(ii) * * *

(a) Nutrition labeling in accordance with § 101.9.

* * * * *

b. Section 101.9 is amended by revising paragraphs (a)(2) and (h)(1)(i) and (2) to read as follows:

§ 101.9 Nutrition labeling of food.

(a) * * *

(2) If any vitamin and/or mineral is added to a food so that a single serving provides 50 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age, as specified in paragraph (c)(7)(iv) of this section, of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this section.

* * * * *

(h) * * *

(1)(i) Except where expressly covered by § 105.65 of this chapter, infant, baby, and junior-type food promoted for infants and children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section.

* * * * *

(2) Dietary supplements are exempted, except that the labeling of a dietary supplement in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section.

PARTS 105—FOODS FOR SPECIAL DIETARY USE

2. In Part 105:

a. Section 105.3 is amended by revising paragraph (a)(1), by deleting paragraphs (b) and (c), by revising paragraphs (d) and (e), and by deleting paragraphs (f) and (g) as follows:

§ 105.3 Definitions and interpretations.

* * * * *

(a)(1) The term "special dietary uses", as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

* * * * *

(b) and (c) [Reserved]

(d) If a food purports to be or is represented for special dietary use by man by reason of the presence of any constituent which is not utilized in normal metabolism, the label shall bear a statement of the percent by weight of such constituent, and, in juxtaposition with the name of such constituent, the word "nonnutritive". If such constituent is fibrous plant matter, it shall be considered to be crude fiber and its percent expressed as such. But if such constituent is saccharin or a saccharin salt, the label shall bear, in lieu of such statement and word, the statement "Contains saccharin (or saccharin salt, as the case may be), a nonnutritive, artifical sweetener which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the percent by weight of saccharin or saccharin salt in such food. The provisions of this section shall not be construed as authorizing the use of saccharin or its salts in any food other than one for use by persons who must restrict their intake of carbohydrates, or as relieving any food from compliance with any requirement of section 402(b) or (d), 403(g), or other provisions of the act.

(e) For the purposes of the regulations in this part, the terms "infant," "child," and "adult" mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

§§ 105.60, 105.77, and 105.85 [Revoked]

b. By revoking § 105.60 *Restrictions, placement, false or misleading respresentations,* § 105.77 *Vitamins and minerals,* and § 105.85 *Dietary supplements of vitamins and minerals.*

PART 201—LABELING

§ 201.19 [Amended]

3. In Part 201, § 201.19 is amended by changing "§ 105.3(d)" to read "§ 105.3(e)."

Because this order is a ministerial act revoking regulations already ruled by the Court of Appeals to be invalid, and because it relieves a restriction and there is no useful purpose in postponing the effective date, the Commissioner concludes, under the Administrative Procedure Act (5 U.S.C. 553(b)(B) and (d)(1) and (3)), that notice and public procedure and delayed effective date are unnecessary.

Executive Order 12044 on improving government regulations requires the agency to consider economic impacts in the development of regulations. Because this action is being taken to revoke regulations which the Court of Appeals has already invalidated, no assessment of its economic impact is being made at this time. No economic impacts are expected to occur from the revocation since no new requirements are imposed at this time. The economic impact of vitamin and mineral supplement standards and labeling regulations will be evaluated in the course of reissuing these regulations through the normal rulemaking procedure.

Effective date. This order is effective March 15, 1979.

Dated: March 12, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7982 Filed 3-15-79; 8:45 am]

[4110-03-M]

Subchapter D—Drugs for Human Use

[Docket No. 78N-0341]

PART 448—PEPTIDE ANTIBIOTIC DRUGS

Combination Otic Solutions and Suspensions; Postponement of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document postpones the effective date of a final rule that revises provisions for certification or release of certain combination otic products. The effective date is postponed to allow time for completion of review of the requests for a hearing.

DATE: Postponement is effective March 12, 1979.

FOR FURTHER INFORMATION CONTACT:

Nathan J. Treinish, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of January 30, 1979 (44 FR 5879), the Director of the Bureau of Drugs promulgated a final rule to be effective on March 12, 1979, amending Part 448 of the antibiotic regulations (21 CFR Part 448) by revising § 448.430 (21 CFR 448.430) which provides for certification of polymyxin-B sulfate otic solution.

Hearing requests were received from two firms. In response to the January 30, 1979 final rule, Lemmon Pharmacal Co. filed a hearing request concerning Otocort (NDA 60-730). Kleinfeld, Kaplan and Becker, as attorneys for Burroughs Wellcome Co., filed a hearing request concerning Aerosporin Otic Solution (NDA 60-756, DESI 8426) and Lidosporin Otic Solution (NDA 50-171, DESI 50171).

Any data, information, and analyses on which the firms rely to justify a hearing must be submitted by April 2, 1979. The hearing requests will be reviewed, and when the review is completed the Commissioner of Food and Drugs will announce in the FEDERAL REGISTER whether or not Lemmon or Burroughs Wellcome has demonstrated the existence of a genuine and substantial issue of fact requiring a hearing.

A certification regulation exists for Aerosporin but not for Lidosporin or Otocort. Lidosporin and Otocort have been released pending a final determination as to their effectiveness.

Therefore, the effective date of the January 30, 1979 regulation as it pertains to the revision of § 448.430 is hereby postponed to allow time for completion of review of the hearing request for the product covered by this monograph, Aerosporin Otic Solution. In regard to the other two products, which are released, the date for ceasing to release the products is hereby postponed to allow time for completion of review of the hearing requests. If the result at the completion of this proceeding so indicates, monographs will be prepared to cover these released products.

The January 30, 1979 notice also amended 21 CFR Parts 444, 449, and 455. Because no person filed objections or a request for hearing concerning those parts, they are not affected by this notice, and the March 12, 1979 effective date is hereby confirmed.

This action is taken under the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-1051 as amended, 59 Stat. 463 as amended (21 U.S.C. 352, 357)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director, Bureau of Drugs (21 CFR 5.78).

Effective date. This postponement is effective March 12, 1979.

(Secs. 502, 507, 52 Stat. 1050-1051 as amended, 59 Stat. 463 as amended (21 U.S.C. 352, 357))

Dated: March 9, 1979.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 79-7970 Filed 3-15-79; 8:45 am]

[4110-03-M]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 77N-0164]

PART 514—NEW ANIMAL DRUG APPLICATIONS

Criteria for Adequate and Well-Controlled Investigations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document updates the new animal drug regulations to provide for the use of untreated and individual controls as an alternate basis to establish the effectiveness of new animal drugs. As amended, the regulations more closely conform to those for human drugs.

EFFECTIVE DATE: April 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Myron C. Rosenberg, Bureau of Veterinary Medicine (HFV-100), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of September 20, 1977 (42 FR 47218) the Food and Drug Administration proposed to update the new animal drug regulations to provide for the use of untreated controls as an alternate basis to establish the effectiveness of new animal drugs. The proposed amendment to the regulations would make § 514.111 (21 CFR 514.111) more equivalent to the corresponding § 314.111 (21 CFR 314.111) covering drugs for human use. Interested persons were given 60 days to comment.

Two responses to the proposal were received. Comments were received from the Animal Health Institute (a national association representing producers of animal health and nutrition products) and a manufacturer of drug products intended for veterinary use. Both responses concurred with the proposed amendment to § 514.111, and both suggested a further modification to § 514.111(a)(4) to add a fifth method for comparing the results of treatment or diagnosis with a control so as to permit quantitative evaluation. The suggested fifth method was individual control. The responses maintained that in some cases an animal may serve as its own control and the results obtained before or during treatment may be used for comparison with those obtained in the same animal at the completion of therapy or necropsy. Examples were given of the importance of individual control, e.g., evaluating anthelmintics.

The Commissioner of Food and Drugs has evaluated the comments received and available information regarding "individual control" and concludes that a change in the regulation suggested in the comments received should be adopted but does not agree that this is a fifth method of control. The Commissioner concludes, rather, that it is an established principle that with an appropriate design the same animal can be used for both the test drug and control using three of the four types of proposed controls. This clarification has been added to the statement of principles of adequate and well-controlled clinical (field) investigations and is being finalized as proposed with the revised statement.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 514 is amended in § 514.111 by revising paragraph (a) (3), (4), and (5) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(3) The methods used in and the facilities and controls used for the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions. In making this determination the Commissioner shall consider, among other relevant factors:

(i) The probable consumption of such drug and of any substance formed in or on food because of the use of such drug;