(ix) The premises of Tom Friend, 10602 Bolsa Avenue, Garden Grove, Orange County.

* * * * *

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, from the quarantined area, and, therefore, must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 9th day of March 1979.

NOTE: This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by M. A. Mixson, Acting Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the possibility of the spread of exotic Newcastle disease into other States or Territories of the United States from the quarantined area is severe enough to constitute an emergency which warrants the publication of this quarantine without waiting for public comment. This amendment, as well as the complete regulations, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, 301-436-8695.

E. A. SCHILF,
Acting Deputy Administrator,
Veterinary Services.

[FR Doc. 7954 Filed 3-15-79; 8:45 am]

[3410-34-M]

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to quarantine an additional portion of Orange County in California because of the existence of exotic Newcastle disease. Exotic Newcastle disease was confirmed in Orange County, California, on March 3, 1979. Therefore, in order to prevent the dissemination of exotic Newcastle disease it is necessary to quarantine an additional portion of such county.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. M. A. Mixson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, Maryland 20782, 301-436-8073.

SUPPLEMENTARY INFORMATION: This amendment quarantines an additional portion of Orange County, California, because of the existence of exotic Newcastle disease in such area. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah, and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles, from quarantined areas, as contained in 9 CFR Part 82, as amended, will apply to the quarantined area.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respect:

In § 82.3(a)(1), relating to the State of California, a new paragraph (viii) relating to Orange County is added to read:

§ 82.3 Areas Quarantined

(a) * * *

* * * * *

(1) *California.*

* * * * *

(viii) The premises of Thomas Johnston, 2273 Columbia Street, Costa Mesa, Orange County.

* * * * *

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28277; 38 FR 19141.)

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, from the quarantined area, and, therefore, must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 9th day of March 1979.

NOTE: This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by M. A. Mixson, Acting Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the possibility of the spread of exotic Newcastle disease into other States or Territories of the United States from the quarantined area is severe enough to constitute an emergency which warrants the publication of this quarantine without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, 301-436-8695.

E. A. SCHILF,
Acting Deputy Administrator,
Veterinary Services.

[FR Doc. 79-7953 Filed 3-15-79; 8:45 am]

[7590-01-M]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 9—PUBLIC RECORDS

Waiver or Reduction of Fees for Searching and Reproduction of Records

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: This rule amends the Commission's regulations "Public Records" by adding a new section "Waiver or Reduction of Fees." These amendments reflect the requirements of the Freedom of Information Act that documents shall be furnished without charge or at a reduced charge where an agency determines that waiver or reduction of the fee for searching and reproduction of records is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

EFFECTIVE DATE: This rule becomes effective on April 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. J. M. Felton, Director, Division of Rules and Records, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (telephone 301-492-7211).

SUPPLEMENTARY INFORMATION: On March 31, 1977 the Commission published in the FEDERAL REGISTER (42 FR 17131) proposed amendments to its regulation "Public Records," 10 CFR Part 9, which would add a new § 9.14a, "Waiver or Reduction of Fees." At the request of the Union of Concerned Scientists, the comment period was extended to May 23, 1977.

Comments on the proposed rule were received from the Union of Concerned Scientists (UCS) and the Rochester Gas and Electric Corporation (RG&E).

DISCUSSION OF COMMENTS

1. *Adequacy of Standards for Making Determinations to Waive or Reduce Fees.* Section 9.14a(c) of the proposed rule required a person who requests the NRC to waive or reduce fees to provide information concerning such matters as the intended use of the records, how the information would be disseminated to the public, the size of the public to be benefited, and any financial benefit the requester may receive from the use of the records. The rule repeated the Congressional mandate contained in the FOIA that records shall be furnished without charge or at a reduced charge where the agency determines "that 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 making this determination, the proposed rule provided that the NRC would, based upon the information submitted by the requester, balance whether the benefit to the public outweighs the cost to the public.

In their comments, UCS stated that the governing criteria were vague and subject to arbitrary agency determinations, and that the NRC should develop criteria to be applied in specific cases. In response to the comments, paragraph (c) of § 9.14a has been revised to require the requester to show how the intended use of the records is reasonably likely to:

(i) Result in actions to maintain or enhance the public's health, safety, or the quality of the environment;

(ii) Result in improved regulatory processes;

(iii) Reduce the cost of providing a government service;

(iv) Contribute substantially to public debate on an important policy issue; or

(v) Contribute substantially to matters of historical importance. In addition, a new paragraph (d) has been added to § 9.14a which specifies those situations in which a public benefit would not normally result. Finally, a new paragraph (e) has been added which provides that based upon the criteria in paragraph (d) and the information furnished by the requester in response to paragraph (c), 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.

2. *Automatic Waiver of Fees for Public Interest Groups.* UCS proposed that non-profit organizations whose mission is to protect or enhance the public health, safety, and welfare, are automatically entitled to a waiver or reduction of fees. The Commission does not agree, and believes the proper statutory criterion is whether production of the records would primarily benefit the general public; that is, the focus of the decision to waive or reduce fees should be on the intended use of the records, and not the requester's organization affiliation, the organization's tax exempt status, or the purpose of the organization. It is recognized, however, that many non-profit organizations, whose mission is to protect or enhance the public health and safety, would qualify for a waiver or reduction of fees. In hearings before the Senate Subcommittee on Administrative Practice and Procedure in October, 1977, the head of the Freedom of Information Committee and other Department of Justice witnesses indicated in response to questions by Senator Abourezk that, although the decision would have to be made on a case-by-case basis, there would be a presumption that fees should be waived for public interest groups and media representatives. In light of these considerations, a new provision has been added to the proposed effective rule as § 9.14a(f) which provides that the NRC, in absence of a specific request for a waiver or reduction of fees, may waive or reduce the fees if it determines, based upon information furnished by the requester in his request for access to records, that production of the records would primarily benefit the general public. This provision allows the agency to waive or reduce fees where the information provided in the request letter indicates that the requester is likely to use the records in a manner which primarily benefits the general public. It is designed to alleviate the formal showing by requester organizations that they meet the requirements of § 9.14a where it is obvious a fee waiver or fee reduction is justified under the circumstances.

3. *General Waiver Provisions.* With respect to the general waiver provisions set forth in § 9.14a(b) of the proposed rule, the Rochester Gas and Electric Corporation challenges the right of the NRC to waive fees for searches which do not exceed four hours or for reproduction costs which do not exceed $10.00. The basis for the company's claim are that there has been no showing that the general waiver provisions are in the public interest and that it is unfair to assess taxpayers for work done by a public employee for the benefit of a private party. The purpose of the general waiver provisions was to eliminate the costs of billing and processing payments and responding to requests for a waiver of fees when these costs to the government were relatively small in relation to the amount of staff time that would be required to process a fee waiver request or to collect reproduction costs. In view of the NRC's practice of granting access to records by placing copies of the records in NRC Public Document Room or a Local Public Document Room, the provision granting waiver of reproduction costs not in excess of $10.00 has been eliminated from the effective rule. The Commission believes, however, that it is in the public interest to waive the minimal costs encompassed by the search fee waiver provisions, and the effective rule continues to contain this provision. The Rochester Gas and Electric Corporation also challenges the propriety of automatically waiving search fees as provided in § 9.14a(b)(4) of the proposed rule when no documents subject to the request are located or when no documents are located which can be disclosed to the requester. The Commission believes that this situation is now adequately addressed by the revised fee waiver criteria set forth in § 9.14a, and this provision has been eliminated from the effective rule.

4. *Relevancy of Information Required To Be Submitted by a Requester for Waiver or Reduction of Fees.* UCS questions the right of the NRC to require organizations to submit information in order to qualify for a waiver of fees stating that "it is the responsibility of the agency to initially decide whether a primarily public benefit will ensue from the release of the information" and the request "need only raise a substantial question as to whether the release of the information will 'primarily benefit the general public' ". As noted above in item 2, § 9.14a(f) provides that the NRC may waive fees on its own initiative, and the information required by § 9.14a(b) would only have to be submitted when the agency has concluded that the request, on its face, does not automatically warrant waiver or reduction of

fees. Under these circumstances, the Commission believes that the burden of proof properly shifts to the requester to provide NRC with sufficient information to justify that production of the records will primarily benefit the general public. UCS also questions the ability of the requester to comply with certain information requirements § 9.14a(c) of the proposed rule and challenges the relevancy of others. These are discussed as follows:

A. UCS questions the ability of the requester to respond to the requirements in § 9.14a(c)(1) of the proposed rule regarding the "intended use of the records", and states that the exact use cannot be determined until the requested documents are reviewed. The information required by this provision is *intended* use of the records, not *exact* use. Failure of a requester to have some idea in mind as to how the records requested will be used would be persuasive evidence that the requester is on a fishing expedition and that providing the records would not primarily benefit the general public. This provision has been retained in the effective rule.

B. UCS also questions the ability of a requester to respond to the requirement "why all the requested documents are necessary to accomplish the requester's intended use" (§ 9.14a(c)(2) of the proposed rule). UCS points out that in most FOIA cases, "all" the requested documents are never necessary. The Commission agrees with this comment and feels that this information is not necessary. Where an issue is raised regarding the scope of a request, it has been the experience of the Commission that a negotiated resolution can be reached with the requester.

C. UCS questions the requirement to provide information concerning how the documents will be reviewed or analyzed and the results thereof disseminated to the public (§ 9.14a(c)(3) of the proposed rule), and argues that a specific use cannot be meaningfully presented until the documents are read. As stated in item 3.A above, the Commission believes there should be an intended use of the documents at the time a request for waiver is made. Further, the requirement for review and analysis of the documents reinforces that belief, as provided in § 9.14a(d)(5) of the effective rule, that the intent to distribute copies of the records to the public does not, by itself, constitute public benefit.

D. UCS, while questioning the relevancy of the requirement to provide information regarding what financial benefit, if any, the requester will receive from use of the requested records (§ 9.14a(c)(6) of the proposed rule), acknowledges the relevancy of the requirement if direct financial benefit is the only motivating factor in making the request. The ability of the requester to pay for the records also was acknowledged by Congress as being relevant to a determination of whether to waive or reduce fees. The Senate Report on the 1974 Amendments to the FOIA indicated that if a requester was indigent, a waiver or reduction of fee would be in the public interest. The Commission has, however, deleted the requirement regarding the requesters "willingness to pay" for the requested documents.

It should be noted that the specific items of information required to be furnished by requesters is based upon the guidelines contained in the Attorney General's Memorandum on the 1974 Amendments. In the Justice Department's recent testimony before the Abourezk Subcommittee, it was stated that these guidelines were coordinated with both the House and Senate committees responsible for the FOIA legislation.

The Commission believes that in the absence of clear Congressional guidance as to what was the intent of the term "primarily benefiting the general public", and in light of the diversity of requesters and type of records requested, the standards and criteria set forth in § 9.14a of the effective rule are sufficient to assure that the agency makes a fair and equitable determination with respect to any request for a waiver or reduction of fees.

5. *Adequacy of Procedures for Processing Requests for Waiver or Reduction of Fees.* UCS alleges that the proposed rule did not set forth an adequate administrative structure to assure fair and efficient processing of FOIA requests and requests for waiver or reduction of fees. UCS questions whether NRC has the right, if a request for records does not qualify for a waiver of fees, to deem the request not received, for purposes of complying with the ten-day FOIA response deadline, until a deposit equal to the estimated costs is received or the requester has agreed to bear the anticipated costs. UCS also states that requesters should be allowed to initiate fee waiver requests on appeal.

In response to UCS's comments, a new § 9.14b has been added to the effective rule which specifies the procedures which will be followed in processing an FOIA request for a waiver or reduction of fees. The procedures provide that if the request involves more than four hours of search time, and the requester does not qualify for a waiver of fees under § 9.14a(f), the NRC will notify the requester within 10 working days of the estimated costs of complying with the request. Thereafter, the requester may agree to pay for the records or request a waiver or reduction of fees. If the NRC refuses to waive or reduce the fees, it will provide a statement to the requester as to why the request does not meet the requirements of § 9.14a, and this determination may be appealed to the EDO or to the Commission, as appropriate. Where the request does qualify for waiver or reduction of fees, § 9.14b provides that records will be promptly provided.

The Commission believes that the new procedures for processing requests are responsive to UCS's concerns and provide a reasonable balance between the rights of the requester, the resources available to the NRC, and the rights of the general public. The Commission further believes that the NRC has an obligation not to expend public funds to search for records requested under the FOIA when the request does not either qualify for an automatic waiver of fees or the requester does not agree to pay the costs of the search. Congress, in permitting agencies to charge fees to cover costs of searching for records, implied that where production of the records would not primarily benefit the general public, search costs should be assessed. It would be a misuse of public funds to divert the staff from other important activities to conduct a search for records which a requester may never agree to pay for or may never make the showing that waiver of the fees is justified under the circumstances. In view of these considerations, the Commission continues to believe that a request for access to records should not be deemed to have been received until the fee issue is resolved by the requester either agreeing to pay for the records or by qualifying for a waiver or reduction of fees. In addition, the Commission does not agree with UCS's recommendation that documents be made available to the requester at the initial stage and that a requester then be permitted to request a fee waiver on appeal "even though no such initial request was made." The Commission has, however, agreed on a trial basis to provide in § 9.14b(d) that, in those cases where a waiver of fees was requested and denied and the requester 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 the documents has materially changed the information originally furnished by the requester.

With respect to the waiver or reduction of fees for reproduction costs, the majority of NRC requesters, as a matter of practice, accept access to requested records at the NRC Public Document Room in Washington, D.C. or at a Local Public Document Room in cases where the requested documents pertain to a specific facility.

The requester may then examine the records which have been made available, and make copies of just those records in which he is interested. The Commission believes this procedure is in the public interest and represents a reasonable balance between the rights of the public and the rights of the individual requester. The Commission also believes that this procedure is in accord with the broad purpose of the FOIA by providing general public access to agency records. Under the circumstances when access to records can be provided to a requester at a PDR or LPDR, to also waive reproduction costs would result in a private benefit only to the requester. This practice has now been incorporated into the regulations by adding a sentence to § 9.10(a) of the effective rule that provides that copies of documents disclosed in response to FOIA requests will normally be placed in the NRC PDR or local PDR, and by providing in § 9.14a(g) that the NRC will not waive reproduction costs for documents located in the PDR or LPDR in the absence of a compelling reason to do so. A "compelling reason" could be, for example, if the requester were both indigent and required the documents for intervention in an NRC licensing proceeding.

6. *Charging Professional and Clerical Rates for Searching.* UCS states that the present rule does not adequately indicate when clerical rates or when professional rates for search will be applied, and recommends that professional search charges should only be applied in those instances where it is absolutely essential for professionals to search for documents due to the nature and content of the requested document. The Commission believes that the proposed rule, as published, is adequate, and that this matter is properly left to the discretion of the responsible operating official. Decisions regarding who will conduct the search are dependent upon subject matter of the request, familiarization of staff with subject matter, and the necessity to assure an adequate and timely search within the FOIA statutory deadlines. FOIA requests received by the NRC are normally related to specific technical issues and, in many cases, only a member of the professional staff is capable of assuring that all records within the scope of the request are identified. The diversity of the subject matter of FOIA requests received by NRC would make it virtually impossible to establish general criteria applicable to all requests. It is expected, however, that the responsible operating official will use clerical staff to conduct the search where it is feasible to do so in order not to unnecessarily divert the technical staff from their regulatory functions or to increase costs to the requester.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9 are published as a document subject to codification:

1. Paragraph (b) of § 9.8 is revised to read as follows:

§ 9.8 Requests for records.

* * * * *

(b) All requests for copies of records must reasonably describe the record sought in sufficient detail to permit the identification of the requested record. Where possible, specific information regarding dates, titles, docket numbers, file designations, and other information which may help identify the records should be supplied by the requester. If a request does not reasonably describe the record sought in sufficient detail to permit its identification, the requester will be so informed by the Director, Office of Administration, or his designee, within 10 working days after receipt of the request and requested to submit additional information regarding the request or to meet with appropriate NRC personnel in order to clarify the request. Requests for Waiver or reduction of fees shall be made in accordance with § 9.14a, waiver or reduction of fees, and shall be processed in accordance with § 9.14b, Processing of requests for a waiver or reduction of fees.

2. Sections 9.10, 9.11, and 9.14 are revised to read as follows:

§ 9.10 Form and content of responses.

(a) When a requested record has been identified and is available, the head of the office of which a request has been referred or the Director, Office or Administration, will promptly furnish the record or notify the requester as to where and when the record will be available for inspection and copying. Copies of records disclosed in response to Freedom of Information Act requests will normally be placed in the NRC Public Document Room and, in the case of records relating to nuclear power facility, in the Local Public Document Room established for that facility. The notification will also advise the requester of any applicable fees under § 9.14.

(b) A reply denying a request for a record or denying a request for waiver or reduction of fees filed pursuant to § 9.14a will be in writing signed by the Director, Office of Administration, or his designee, and will include as appropriate:

(1) The reason for the denial;

(2) A reference to the specific exemption under the Freedom of Information Act and the Commission's regulations authorizing the withholding of the record;

(3) The name and title or position of each person responsible for the denial of the request, including the head of the office recommending denial of the request;

(4) A statement as to why the request does not meet the requirements of § 9.14a if the request is for a waiver or reduction of fees; and

(5) A statment that the denial may be appealed within 30 days from the receipt thereof to the Executive Director for Operations.

(c) A copy of each letter granting or denying requested records or denying a request for waiver or reduction of fees will be maintained by or furnished to the Director, Office of Administration, or his designee.

§ 9.11 Appeal from initial determination.

(a) Except as provided in § 9.15, a requester may within 30 days of receipt of a notice of denial of the request for records or denial of a request for waiver or reduction of fees pursuant to this subpart, appeal such denial to the Executive Director for Operations. The appeal shall be in writing, addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should clearly state on the envelope and in the letter, that it is an "Appeal from Initial FOIA Decision." An appeal that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Executive Director for Operations.

(b) Except as provided in § 9.13, the Executive Director for Operations will make a determination with respect to any appeal pursuant to this section within 20 working days after the receipt of such appeal.

(c)(1) If on appeal the denial of the request for records is upheld in whole or in part, the Executive Director for Operations will notify the person making such request of the denial, including the exemption relied upon, an explanation of how the exemption applies to the records withheld, and the reasons for asserting the exemption.

(2) If on appeal the denial of a request for waiver or reduction of fees for locating and reproducing records is upheld in whole or in part, the Executive Director for Operations will notify the person making such request of the denial, including a statement as to why the request does not meet the requirements of § 9.14a.

(3) The requester shall be informed that the denial is a final agency action and that judicial review is available in

a district court of the United States in the district in which the requester resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia.

(d) Copies of all appeals and written determinations on appeal will be furnished by the Executive Director for Operations, or his designee, to the Director, Office of Administration, or his designee.

* * * * *

§ 9.14 Charges for production of records.

(a) Requests for the reproduction of records at the NRC Public Document Room, located in Washington, D.C. will be honored upon payment of the following charges:

(1) Sizes up to 8½ x 14 inches made on office copying machines—$0.08 per page copy. Larger sizes—$0.08 for each 8½ x 14 inch unit or fraction thereof per page copy. Microfiche—8½ x 11 inches—$0.15 per page copy.

(2) The charge for reproducing records other than those specified above will be computed on the basis of NRC's direct costs.

(3) The charges for requests made through the mails will be the same as paragraph (a) (1) and (2) of this section except that shipping or mailing costs shall be added. If the amount of any mailed in order is less than $2.00, excluding the shipping or mailing costs, the customer shall be charged a minimum of $2.00 plus costs of shipping or mailing.

(b) Requests for copies of records to be reproduced and furnished by the NRC at locations other than the NRC Public Document Room located in Washington, D.C., will be honored at the following charges:

(1) Sizes up to 8½ x 14 inches made on office copying machines—$0.10 per page copy. Larger sizes—$0.10 for each 8½ x 14 inch unit or fraction thereof per page copy.

(2) The charge for reproducing records other than those specified above will be computed on the basis of NRC's direct costs.

(3) If a request is for records at locations other than the NRC Public Document Room, a charge of $5.00 per hour will be made for searching for the requested records by clerical or administrative employees and a charge of $12.00 per hour for searching by professional or supervisory employees.

(4) When a computer search is necessary in order to fulfill a request, the computer search charge will be the actual direct cost of the computer search.

(5) Except as otherwise provided in § 9.14a, unless the request specifically states that whatever cost is involved will be acceptable, or acceptable up to a specified limit, the NRC will, for requests involving anticipated costs in excess of the minimum specified in § 9.14a(a), so advise the requester as provided in § 9.14(b), and the request will not be deemed to have been received until a deposit equal to the estimated costs is received, or the requester has agreed to bear the anticipated costs, or a determination has been made on a request for waiver or reduction of fees. Fees may be required to be paid in full prior to the issuance of the requested records.

(6) Refunds of unused deposits or additional billings will be made to adjust to the anticipated cost to the actual cost.

(c) In compliance with the Federal Advisory Committee Act, transcripts of testimony in NRC proceedings, which are transcribed by a reporting firm under contract with the NRC, may be purchased directly from the reporting firm at the cost of reproduction as provided for in the contract with the reporting firm, or may be purchased from the NRC at the cost of reproduction as provided in paragraphs (a) and (b) of this section.

(d) Copyrighted material will not be reproduced in violation of the copyright laws.

(e) The Director, Office of Administration, or his designee, or the Executive Director for Operations, on appeals, in accordance with the provisions of § 9.14a, will waive or reduce any fee required by this section upon a determination that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

3. New sections 9.14a and 9.14b are added to read as follows:

§ 9.14a Waiver or reduction of fees.*

(a) Fees for searching and reproduction of records at locations other than the NRC Public Document Room shall be waived:

(1) for search fees when the time for the search does not exceed four hours, in the aggregate, for a request or series of related requests;

(2) where the records are requested by and made available to a Federal, State, or local government, to an intergovernmental agency, or to a foreign government or international agency, and furnishing the records without charge is an appropriate courtesy.

(b) Except as provided in paragraph (a) and (f) of this section, fees for searching and reproduction of records may be waived only upon request. A person requesting the NRC to waive or reduce search or reproduction fees under this subpart shall, as set forth in 9.14b(b) provide sufficient factual information to permit NRC to make the determination whether waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(c) In making a request for waiver or reduction of fees, the requester shall provide a statement setting forth the following information to the extent possible:

(1) How the information obtained from the records, or how the conclusions or results from any review or analyses of the records, will be published or otherwise disseminated to the general public;

(2) The size of the public that will be benefited by the disclosure;

(3) The nature, significance and likelihood of any tangible benefit that the public may receive from dissemination of the information;

(4) The financial benefit, if any, the requester will receive from the use of the requested materials;

(5) The ability of the requester to pay for any of the anticipated costs;

(6) How the intended use of the various types of records requested is reasonably likely to:

(i) Result in actions to maintain or enhance the public's health, safety, or the quality of the environment;

(ii) Result in improved regulatory processes;

(iii) Reduce the cost of providing a government service;

(iv) Contribute substantially to public debate on an important policy issue; or

(v) Contribute substantially to matters of historical importance.

(d) Public benefit will not normally result:

(1) When the requested records will be used primarily for the personal benefit of an individual or group rather than the general public;

(2) When the requested records will be used primarily for a commercial purpose or financial benefit;

(3) When the requested records have already been made available, or are being made available in response to the request, for inspection and copying in the NRC Public Document Room or a Local Public Document Room;

(4) When the requested records will not add appreciably to the information already available to the public in the NRC Public Document Room or a Local Public Document Room;

(5) When the requested records consist primarily of technical data which will only be distributed or made available to the public by the requester without further analyses or comment;

* 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).

(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.