tainer, and amount of radioactivity per unit volume or unit mass at a designated referenced time;

(6) The route of administration, if it is for other than oral use;

(7) The net quantity of contents;

(8) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

(9) The name and address of the manufacturer, packer, or distributor;

(10) The expiration date, if any;

(11) If the drug is intended for parenteral use, a statement as to whether the contents are sterile;

(12) If the drug is for other than oral use, the names of all inactive ingredients, except that:

(i) Trace amounts of harmless substances added solely for individual product identification need not be named.

(ii) If the drug is intended for parenteral use, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust pH or to make the drug isotonic may be declared by name and a statement of their effect; if the vehicle is water for injection, it need not be named. *Provided, however,* That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, the information required by paragraph (f) (1) and (12) of this section may be placed on the shielded container only.

Effective date. This regulation shall become effective on July 25, 1975. This date is necessary because of the various effective dates set forth for specific changes relating to the transitional regulation of radioactive new drugs from the Nuclear Regulatory Commission to the Food and Drug Administration, and the need for this regulation to be in force as soon as possible so that there will be regulatory control over the safety and effectiveness of all radioactive drugs.

(Secs. 505, 701(a), 52 Stat. 1052-1053, as amended, 1055 (21 U.S.C. 355, 371(a)); the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262))

Dated: July 18, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-19316 Filed 7-24-75;8:45 am]

[Docket No. 75N-0068]

RADIOACTIVE BIOLOGICAL PRODUCTS

Reassignment of Responsibility

By this regulation, the Commissioner of Food and Drugs is reassigning responsibility within the Food and Drug Administration for regulating radioactive biological products from the Bureau of Biologics to the Bureau of Drugs. As a result of this reassignment, manufacturers of radioactive biological products will be required to comply with the requirements for drugs (including submitting new drug applications and periodic reports) for such products in lieu of the requirements for biological products (including submitting establishment and product license applications). All future correspondence and submissions regarding radioactive biological products shall be directed to the Bureau of Drugs. This order becomes effective August 25, 1975.

The Division of Biologics Standards (DBS) was transferred from the National Institutes of Health to the Food and Drug Administration (FDA) and renamed the Bureau of Biologics (notice of which was published in the FEDERAL REGISTER of June 29, 1972 (37 FR 12865)). As the first step in effecting an orderly transfer, the DBS was appended to the FDA as a Bureau without any realignment of overlapping or related functions that had developed between DBS and FDA based on historical, statutory, and organizational distinctions.

Since the transfer of DBS to FDA, the Commissioner has reviewed those activities that historically have been conducted by DBS and the Bureau of Biologics under section 351 of the Public Health Service Act as well as those conducted by the FDA, principally the Bureau of Drugs, under the Federal Food, Drug, and Cosmetic Act. He concludes that there is a need for some reassignment of activities regarding radioactive drugs between the Bureau of Biologics and the Bureau of Drugs to provide uniformity in processing and a focal point for action within FDA for this category of products.

The Bureau of Biologics currently exercises primary control over those radioactive drugs which contain a biological product in addition to a radionuclide; such products have been subject to licensure under section 351 of the Public Health Service Act. The Bureau of Drugs regulates all other radioactive drugs.

Radioactive biological products, however, in addition to being subject to section 351 of the Public Health Service Act, are also "drugs" and "new drugs" as those terms are defined in section 201 (g) and (p), respectively, of the Federal Food, Drug, and Cosmetic Act and are therefore subject to the drug provisions of the Federal Food, Drug, and Cosmetic Act, including the new drug provisions. Recognizing this dual jurisdiction over biological products, the Department of Health, Education, and Welfare decided many years ago (prior to the transfer of DBS to FDA) that to market a biological product a manufacturer should not be required to submit both a license application under section 351 of the Public Health Service Act and a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act. To require such dual submissions would have resulted in unnecessary duplication of effort, both by the manufacturer and by the Department. Instead, to avoid such duplication, only license applications under section 351 of the Public Health Service Act would be required. The new drug regulations (21 CFR 310.4) were amended to state that a new drug would not be deemed subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act if it is a drug licensed as a biological product under the Public Health Service Act.

The Commissioner now concludes that, since radioactive drugs, including radioactive biological products, are drugs in which the radioactive component is of primary interest, all radioactive drugs should be regulated through only one Bureau to achieve uniformity of treatment through a single contact point. The Commissioner further concludes that the Bureau of Drugs should be responsible for all radioactive drugs because of its existing organizational structure and staffing. The Bureau of Biologics will provide the Bureau of Drugs needed expertise with respect to the biological component of radioactive biological products and will test all samples of such products that are submitted in support of new drug applications.

As a result of this decision to transfer responsibility for radioactive biological products from the Bureau of Biologics to the Bureau of Drugs, all future applications and submissions for radioactive drugs, including radioactive biological products, shall be in the format and follow the procedures prescribed in 21 CFR Part 314. For radioactive biological products, the new drug application prescribed in 21 CFR 314.1 will be deemed to constitute the establishment and product license applications required for biological products; approval of the new drug application shall be in lieu of issuing a product and an establishment license. The requirement to submit new drug applications is not expected to impose any hardship on manufacturers of radioactive biologicals. The evidence required to establish safety and effectiveness are essentially the same for both biological products and new drugs. These are firms now holding biological product licenses for radioactive biological products, and all of them also manufacture other products requiring new drug applications. The impact on the regulated industry should, therefore, not be significant. The Commissioner advises that, if any person is preparing a biological product license application, he should submit it within 30 days in order to have it processed in that form.

In addition, compliance with the provisions of 21 CFR Part 314 shall be deemed to constitute compliance with the provisions of Subchapter F, the biological product regulations, unless the Commissioner makes a determination that a particular regulation in Subchapter F shall be applicable to radioactive drugs containing a biological product. Application of a Subchapter F regulation will only be made when the Commissioner concludes that it is necessary to assure the safety or effectiveness of the product, is not duplicative of the requirements in Part 314, and is to assure the same degree of regulatory control currently exercised over such products. The Commissioner has reviewed the provisions of Subchapter F and concludes at this time that the provisions of § 610.2 Requests for samples and protocols; official release shall remain applicable to radioactive drugs containing

a biological product. Appropriate changes have been made to this section to reflect that the Director of the Bureau of Drugs may use this section for radioactive drugs containing a biological product when it is deemed necessary for the safety, purity, or potency of the product.

To effect the transfer of responsibility, amendments must be made in 21 CFR Parts 310, 312, 314, 600, 601, and 610. In Part 310, § 310.4 provides the exemption, previously discussed, that a licensed biological product need not also be subject to an approved new drug application; that section is amended to exclude radioactive biological products from this exemption. In Part 312, § 312.1(g) currently provides that a "Notice of Claimed Investigational Exemption for a New Drug" (IND) for a biological product be submitted to the Bureau of Biologics; this section is amended to provide that an IND for a radioactive biological product be submitted to the Bureau of Drugs. In Part 314, § 314.110(a)(7) provides that a new drug application will be refused for filing if the drug is subject to licensing under the Public Health Service Act; this section is amended to permit filing of a new drug application for a radioactive biological product. Part 600 is amended in § 600.3 to include a definition of a radioactive biological product, which is defined as a biological product labeled with a radionuclide or a biological product intended solely to be labeled with a radionuclide. (Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is issuing a final regulation on radioactive drugs which includes a definition of "radioactive drug" in Part 310; this definition cross-references the new definition in Part 600.) In Part 601, § 601.2 currently outlines the procedures for filing applications for establishment and product licenses or biologics; this section is amended to provide that radioactive biological products shall be covered by new drug applications and not by biological product licenses. Part 610 is amended as discussed above.

These changes are prospective in nature. Every biological product licensed prior to July 1, 1972, is currently under review for safety, effectiveness, and appropriate labeling, as described in 21 CFR 601.25. The product license for such a radioactive biological product, together with portions of the establishment license relevant to the requirements for a new drug application, now constitutes an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act. Any such products, even through new subject to new drug applications, will remain subject to the biological product review, because they were licensed as biological products before July 1, 1972. Those products which are found to be unsafe, or ineffective, or misbranded will be subject to regulatory action. Those which are determined to be safe, effective and not misbranded may continue to be marketed; in addition, the conditions under which an identical, similar or related product may be introduced to the market (i.e., full new drug application, abbreviated new drug applications, or other conditions) will be determined at that time.

A new drug application does not have to be submitted for any radioactive biological product licensed after July 1, 1972, and before the effective date of this order. The product license for such a radioactive biological product, together with portions of the establishment license relevant to the requirements for a new drug application, now constitutes an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act.

Any radioactive biological product for which a license application is pending on the effective date of this order will be processed and approved or disapproved as submitted. Again, no new drug application need be submitted for these products. If the product is found acceptable for licensure, it will be approved as a new drug application in lieu of issuance of a product license.

Future changes in all approved radioactive biological products will be subject to supplemental new drug applications (21 CFR 314.8) rather than amendments to the license. Likewise, all radioactive biological products are subject to the records and reports requirements of 21 CFR 310.300 after the effective date of this section.

Every current "Notice of Claimed Investigational Exemption for a New Drug" for a radioactive biological product will be transferred to the Bureau of Drugs. Any amendments of or supplements to any such notice, and all progress reports regarding such notice, shall be filed in the future with the Bureau of Drugs. Any new "Notice of Claimed Investigational Exemption for a New Drug" for a radioactive biological product shall be submitted directly to the Bureau of Drugs.

For all radioactive biological products, including any subject to pending application for licensure on the effective date of this order, all correspondence, "Notices of Claimed Investigational Exemption for a New Drugs," and original and supplemental new drug applications shall be submitted to the Division of Oncology and Radiopharmaceutical Drug Products (HFD-150), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. All samples of radioactive biological products submitted in support of a new drug application shall, when notified by the Bureau of Drugs, be sent directly to the Bureau of Biologics, Food and Drug Administration, Bldg. 29A, 8800 Rockville Pike, Bethesda, MD 20014.

The Commissioner notes that the labeling standards under Part 610, Subpart G, of Subchapter F will no longer apply to radioactive biological products; instead, the requirements of 21 CFR Part 201 of Subchapter C will be applicable. In particular, this means that the manufacturer's license number appearing on the container and package labels (21 CFR 610.60(a)(2) and 610.61(b)) is no longer required. To permit an orderly and economical transition regarding labels and labeling of marketed products, the Commissioner will delay the effective date on which marketed radioactive biological products must comply with the requirements of Part 201 until the date on which new labels and/or labeling is printed by the manufacturer of such product, or July 26, 1976, whichever occurs first.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052–1053 as amended, 1055 (21 U.S.C. 355, 371(a)), the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)), and under authority delegated to the Commissioner (21 CFR 2.120), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 310—NEW DRUGS

1. In Subpart A by revising § 310.4 to read as follows:

§ 310.4 Biologics; products subject to license control.

(a) Except for radioactive biological products intended for human use, a new drug shall not be deemed to be subject to section 505 of the act if it is a drug licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 et seq.)) or under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 et seq.)).

(b) A radioactive biological product (as defined in § 600.3(ee) of this chapter) intended for human use is subject to section 505 of the act. Any license for such a radioactive biological product which is issued under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 et seq.)) and which has not been revoked or suspended as of August 25, 1975 shall constitute an approved new drug application in effect under the same terms and conditions as set forth in such license and such portions of the establishment license relating to such product, which include data and information required under Part 314 of this chapter for a new drug application. Any such radioactive biological product for which licensure under the Public Health Service Act is pending on August 25, 1975 shall, upon determination that it is acceptable for licensure, be approved as a new drug application in lieu of issuance of a biological product license.

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

2. In § 312.1 by revising paragraph (g) to read as follows:

§ 312.1 Conditions for exemption for new drugs for investigational use.

* * * * *

(g) A "Notice of Claimed Investigational Exemption for a New Drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 et seq.)) shall

be submitted initially to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014. Radioactive biological products for human use are not deemed to be subject to the licensing provisions of the Public Health Service Act (see § 310.4 of this chapter) and a "Notice of Claimed Investigational Exemption for a New Drug" which pertains to radioactive biological products shall be submitted to the Division of Oncology and Radiopharmaceutical Drug Products, Bureau of Drugs, 5600 Fishers Lane, Rockville, MD 20852. Amendments of or supplements to such notice, and progress reports, consultations, or other communications with regard to the investigation shall be directed to the same office to which the original notice was sent. A sponsor for a "Notice of Claimed Investigational Exemption for a New Drug" submitted to the Bureau of Biologics shall substitute in reading this section "Bureau of Biologics" for "Bureau of Drugs" wherever it appears.

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PART 314—NEW DRUG APPLICATIONS

3. In § 314.110 by revising paragraph (a)(7) to read as follows:

§ 314.110 **Reasons for refusing to file applications.**

(a) * * *

(7) The new drug is a drug, other than a radioactive biological product (as defined in § 600.3(ee) of this chapter) intended for human use, subject to licensing under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 et seq.)).

* * * * *

PART 600—GENERAL PROVISIONS

4. In § 600.3 by adding a new paragraph (ee) to read as follows:

§ 600.3 **Definitions.**

* * * * *

(ee) "Radioactive biological product" means a biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

PART 601—LICENSING

5. In § 601.2 by redesignating the present text as paragraph (a) *General* and adding at the end a new sentence and by adding a new paragraph (b). As revised, § 601.2 reads as follows:

§ 601.2 **Applications for establishment and product licenses; procedures for filing.**

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Bureau of Biologics, on forms prescribed for such purpose, and in the case of an application for a product license, shall submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the labels enclosures and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data shall have been received from the manufacturer by the Bureau of Biologics. In lieu of the procedures described in this paragraph, applications for radioactive biological products shall be handled as set forth in paragraph (b) of this section.

(b) *Radioactive biological products.* In lieu of submitting an establishment and product license for the manufacture of a radioactive biological product, as defined in § 600.3(ee) of this chapter, the manufacturer of such a product shall submit a new drug application to the Director, Division of Oncology and Radiopharmaceutical Drug Products, Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, on form FD-356(H) as set forth in § 314.1(c)(2) of this chapter. For such products, the approval of the new drug application will be in lieu of issuing a product and an establishment license. Compliance with the provisions of Part 314 of this chapter shall be deemed to constitute compliance with the provisions of Subchapter 4 of this chapter unless the Commissioner makes a determination that a particular regulation from Subchapter F shall be applicable to radioactive drugs containing a biological product, e.g., § 610.2 of this chapter.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

6. In § 610.2 by redesignating the present text as paragraph (a) *General* and revising it, and by adding a new paragraph (b). As revised, § 610.2 reads as follows:

§ 610.2 **Request for samples and protocols; official release.**

(a) *General.* Samples of any lot of any licensed product, except for radioactive biological products, together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Bureau of Biologics. Upon notification by the Director, Bureau of Biologics, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Bureau of Biologics: *Provided*, That the Director, Bureau of Biologics, shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

(b) *Radioactive biological products.* Samples of any lot of a radioactive biological product, as defined in § 600.3(ee) of this chapter, together with the protocols showing results of applicable tests, may at any time be required to be sent to the Food and Drug Administration for official release. Upon notification by the Director, Bureau of Drugs, a manufacturer shall not distribute a lot of a radioactive biological product until the lot is released by the Director, Bureau of Drugs: *Provided*, That the Director, Bureau of Drugs shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

Since these changes concern internal reassignment of activities and will promote uniform handling of all radioactive drug products, the Commissioner finds that the changes covered by this order are such that, under 5 U.S.C. 553, the notice and comment procedure for rule making are unnecessary and are not prerequisites to this promulgation. In reaching this decision, the Commissioner has considered the facts that less than ten firms currently hold biological product licenses for radioactive biological products, and that all of these firms also hold approved new drug applications. The Commissioner also advises that any person currently preparing a biological product license for a radioactive biological product may submit it within 30 days and thereafter will not be required to resubmit a new drug application for the product.

Interested persons may, however, on or before September 23, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments in quintuplicate on any portion of the order. Comments received will be available for public inspection at the office noted above during working hours, Monday through Friday. Any changes in this order justified by such comments will be the subject of a further order amending the specific regulations involved.

Effective date. This regulation shall be effective August 25, 1975, except for the requirements for labels and labeling of radioactive biological products. The labels and labeling of any marketed radioactive biological product must comply with the requirements of 21 CFR Part 201 on the date on which such labels and labeling are next printed or July 26, 1975, whichever occurs first.

(Secs. 505, 701(a) 52 Stat. 1052-1053 as amended, 1055 (21 U.S.C. 355, 371(a)); sec. 351, 58 Stat. 702 as amended (42 U.S.C 262))

Dated: July 18, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 75N-0069]

RADIOACTIVE DRUGS, INCLUDING BIOLOGICAL PRODUCTS

Notice to Nuclear Pharmacies Regarding the Development of Proposed Regulations and Interim Enforcement Policy

This notice states the interim enforcement policy of the Commissioner of Food and Drugs regarding nuclear pharmacies until definitive regulations on this matter are issued by the Food and Drug Administration. Under the conditions set forth in this notice, the agency will not take regulatory action for the failure of a nuclear pharmacy to comply with the requirements of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, except where such regulatory action is necessary to safeguard the public health.

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is issuing a final regulation terminating the exemption from new drug requirements for radioactive drugs, including radioactive biological products. As a result, manufacturers and distributors of these products must comply with the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and the regulations thereunder, including registration, drug listing, compliance with current good manufacturing practices, marketing under an approved new drug application or biological product license, research under the requirements for investigational drugs, and labeling and advertising requirements. In commenting on the proposal published in the FEDERAL REGISTER of July 29, 1974 (39 FR 27538), which preceded this final regulation, several persons inquired about the legal obligations of "nuclear pharmacies" under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act upon the effective date of the final regulation, especially insofar as these "nuclear pharmacies" may be deemed to be manufacturing or distributing these products other than as part of the compounding and dispensing of drugs in the ordinary practice of pharmacy.

Many radioactive drugs, including biological products, because of their short half-lives, must be prepared in the final dosage form shortly before they are to be used for diagnosis or treatment of disease in man. In addition, the preparation of radioactive drugs requires a special knowledge of radioactive materials, involves the use of special equipment and facilities, and, where reactor-produced radionuclides are involved, requires licensing by the Nuclear Regulatory Commission or an Agreement State. Certain pharmacies, referred to as "nuclear pharmacies," conduct operations which vary from repackaging or preparing radioactive drugs for administration to more extensive and complex manufacturing and compounding procedures. In most cases these nuclear pharmacies are affiliated with, or operated by, hospitals, medical groups, clinics, universities, medical schools, and public health agencies. Some of these pharmacies are not so affiliated, are privately owned, or are operated by several institutions on a cooperative basis. The radioactive drugs prepared by a nuclear pharmacy may be intended solely for use within the institution in which the pharmacy is located, or they may be prepared for distribution to other institutions. For example, a nuclear pharmacy in a university hospital may prepare radioactive drugs for distribution to other hospitals and clinics.

At present, pharmacies are subject to the misbranding and adulteration sections of the Federal Food, Drug, and Cosmetic Act and to the provisions of the Public Health Service Act regarding the licensing of biological products. If they engage in the manufacture of new drugs, they may also be subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act. Pharmacies are generally exempted under sections 510(g) and 704 (a) of the Federal Food, Drug, and Cosmetic Act from regulations regarding registration, drug listing, inspection, and compliance with current good manufacturing practices where their operations are in compliance with applicable local pharmacy laws and do not involve manufacturing procedures other than in the regular course of their business of dispensing or selling drugs at retail. Application of these rules and exemptions to nuclear pharmacies, which would be an immediate result of the final regulation referred to below, raises numerous complex issues or problems because of the unique nature of operations in nuclear pharmacies.

To clarify the obligations of nuclear pharmacies under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, the Food and Drug Administration is drafting regulations which will define those operations connected with the preparation of radioactive drugs and biological products which will be regarded as manufacturing procedures and not part of the practice of pharmacy. Nuclear pharmacies engaged in such operations will then be subject to regulations regarding registration, drug listing, inspection, new drug applications or biological product licenses, compliance with current good manufacturing practices, and related requirements. Operations not deemed to be manufacturing procedures will also be identified and will thereafter be treated as part of the practice of pharmacy. It is anticipated that these regulations will be proposed in the FEDERAL REGISTER in the near future. Interested persons will be given 60 days to comment on the proposed regulations and all such comments will be considered in the preparation and promulgation of the final regulation.

The Commissioner advises that, until the regulations outlined above are proposed and made final, the Food and Drug Administration will not take regulatory action for the failure of a nuclear pharmacy to comply with the requirements of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, so long as the pharmacy (1) complies with applicable local laws regulating the practice of pharmacy and (2) is licensed, where applicable, by the Nuclear Regulatory Commission or an Agreement State to possess, use, or transfer radioactive drugs, except where the Commissioner determines that such regulatory action is necessary to safeguard the public health. The Food and Drug Administration is adopting this policy as an interim measure to avoid any disruption in the practice of nuclear pharmacy and nuclear medicine throughout the United States.

Dated: July 18, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-19314 Filed 7-24-75;8:45 am]