VETERANS' ADMINISTRATION HOSPITAL, SAN FRANCISCO, CALIF.

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (34 F.R. 15787 et seq.).

Copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 71-00454-33-46500. Applicant: Veterans' Administration Hospital, 4150 Clement Street, San Francisco, CA 94121. Article: Ultramicrotome, Model OmU2. Manufacturer: C. Reichert Optische Werke A.G., Austria.

Intended use of article: The article will be utilized for the preparation of thin and thick sections of osmium tetroxide and glutaraldehyde fixed and epoxy resin embedded material. These sections, which are examined by electron and light microscopy, are a part of research in the area of liver and gut, lipid, cholesterol, drug and steroid metabolism.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: Examination of the applicant's thin sections under the electron microscope will provide optimal information when such sections are uniform in thickness and have smoothly cut surfaces. Conditions for obtaining high quality sections depend to a large extent on the properties of the specimen being sectioned (e.g., hardness, consistency, toughness, etc.), the properties of the embedding media and the geometry of the block. In connection with a prior case (Docket No. 69-00118-33-46500) which relates to the duty-free entry of an identical foreign article, the Department of Health, Education, and Welfare (HEW) advised that "Smooth cuts are obtained when the speed of cutting, (among such [other] factors as knife edge condition and angle), is adjusted to the characteristics of the material being sectioned." In connection with another prior case (Docket No. 69-00665-33-46500) relating to the duty-free entry of a similar foreign article, HEW advised that "The range of cutting speeds and a capability for the higher cutting speeds is a pertinent characteristic of the ultramicrotome to be used for sectioning materials that experience has shown difficult to section."

In connection with another prior case (Docket No. 70-00077-33-46500) relating to the duty-free entry of an identical foreign article, HEW advised that "ultrathin sectioning of a variety of tissues having a wide range in density, hardness etc." requires a maximum range in cutting speed and, further, that "The production of ultrathin serial sections of specimens that have great variation in physical properties is very difficult." The foreign article has a cutting speed range of 0.1 to 20 millimeters/second (mm./sec.). The most closely comparable domestic instrument is the Model MT-2B ultramicrotome manufactured by Ivan Sorvall, Inc. (Sorvall). The Sorvall Model MT-2B ultramicrotome has a cutting speed range of 0.09 to 3.2 mm./sec.

We are advised by HEW in its memorandum of July 16, 1971, that the extended range of cutting speeds of the foreign article is pertinent to the production of blemish-free sections of uniform thickness with maximum precision which is required in the applicant's studies involving quantitative electron microscopy of various tissues including very limited biopsy material. HEW cites as a precedent its prior recommendations relating to Dockets Nos. 70-00680-33-46500 and 70-00729-33-46500 which conform in many particulars to the captioned application.

We, therefore, find that the Model MT-2B ultramicrotome is not of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc.71-13436 Filed 9-10-71;8:51 am]

WOODS HOLE OCEANOGRAPHIC INSTITUTION

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (34 F.R. 15787 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 71-00286-58-46070. Applicant: Woods Hole Oceanographic Institution, Water Street, Woods Hole, MA 02543. Article: Scanning electron microscope, Model JSM-U3. Manufacturer: Japan Electron Optics Laboratory Co., Ltd., Japan. Intended use of article: The article will be used for research concerning the morphology of small planktonic crustaceans called copepods, collected from widely different areas. Other investigations involve formainifera, radiolarians, bottom sediments and suspended materials in sea water.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, was being manufactured in the United States at the time the foreign article was ordered (November 13, 1969).

Reasons: The foreign article is equipped with a rapid TV scan attachment which provides a picture having a continuous motion instead of the interrupted motion provided by the conventional mode of presentation. We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated March 10, 1971, that the characteristic of the article described above is pertinent to the purposes for which the article is intended to be used. HEW further advises that it knows of no comparable domestic instrument which provided this pertinent capability at the time the foreign article was ordered.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States at the time the foreign article was ordered.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc.71-13437 Filed 9-10-71;8:51 am]

YALE UNIVERSITY

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (34 F.R. 15787 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 71-00398-33-07730. Applicant: Yale University, Purchasing Department, 260 Whitney Avenue, New Haven, CT 06520. Article: X-ray diffraction camera. Manufacturer: Baird & Tatlock, United Kingdom.

Intended use of article: The article will be used for research on the molecular arrangements present in biological membranes and the structure of atherosclerotic deposits in deceased human arterial tissue. X-ray diffraction theory and technique will be taught in courses on Molecular Biophysics and Biochemistry for undergraduate and graduate students.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for

such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides focussed X-rays of high intensity which minimizes the exposure time required to obtain an X-ray diffraction pattern. We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated May 7, 1971, that the characteristics of the article described above are pertinent to the applicant's intended purposes. HEW further advises that it knows of no domestic X-ray camera which provides the pertinent characteristics of the article.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc.71-13438 Filed 9-10-71;8:51 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

FD&C RED NO. 2

Color Additives; Notice Concerning the Filing of Data About Specific Uses

Preliminary data on reproduction studies with FD&C Red No. 2, one of the color additives provisionally listed, have recently come to the attention of the Food and Drug Administration. These data indicate that the aggregate use of this color may need to be lowered from the level at which it has been heretofore used. Section 706(b)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376(b)(8)) concerns those cases where it may be necessary to allocate the aggregate allowable safe tolerance of a color additive among uses.

Pursuant to § 8.11 of the color additive regulations (21 CFR 8.11), all persons interested in the use of FD&C Red No. 2 after December 31, 1971, are hereby notified to present their data as to all specific uses showing the amounts of this color proposed for continued use in foods, ingested drugs, and ingested cosmetics not later than October 31, 1971. The required data should be sent to the Food and Drug Administration, Bureau of Foods, Office of Compliance, Division of Petitions Processing, 200 C Street SW., Washington, D.C. 20204.

Dated: September 7, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-13367 Filed 9-10-71;8:46 am]

PROVISIONALLY LISTED COLOR ADDITIVES

Notice Concerning Certain Scientific Investigations

Section 8.501 of the color additive regulations (21 CFR 8.501), designates those color additives that are provisionally listed pursuant to section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), Public Law 86-618, 74 Stat. 405; 21 U.S.C. 376, note). Section 203 provided for provisionally listing certain color additives on an interim basis pending completion of scientific investigations needed as a basis for making determinations as to whether they should or should not be listed under section 706 of the Federal Food, Drug, and Cosmetic Act (sec. 706, 74 Stat. 399-403; 21 U.S.C. 376).

It has been determined that, for those uses of color additives listed in paragraphs (a) and (b) of § 8.501 of the color additive regulations which involve ingestion because of use in products such as food, drugs for internal use, and cosmetic lipsticks, petitions for regulations under section 706 of the act shall include reports of studies for teratological potential and reports of multigeneration reproduction studies in animals adequate to show whether the color additive produces any adverse effects on reproduction. There being information at hand showing that such studies can be commenced promptly, it is reasonable to require that the final reports on teratological potential for color additives now provisionally listed in § 8.501 be filed with the Food and Drug Administration not later than October 1, 1972, and that the final reports on multigeneration reproduction studies be filed with FDA not later than July 1, 1973.

Any questions concerning teratogenic studies or reproduction studies may be taken up with the Food and Drug Administration pursuant to § 8.35(c) of the color additive procedural regulations (21 CFR 8.35(c)).

For a further extension of provisional listing beyond December 31, 1971, any person having the prescribed animal studies underway may file a request for a further extension with FDA. Such request shall be supported (1) by progress reports on the animal studies, and (2) by a statement estimating the date when a petition can be filed seeking a regulation under section 706 of the act. Current usage data showing the levels of use in specific foods or in classes of foods, the levels of use in specific drugs for internal use or in classes of internal drugs, and the levels of use in cosmetics subject to ingestion shall be submitted in support of such petition at the time it is filed.

The Commissioner may give consideration to the termination of a provisional listing of the color additives listed in paragraphs (a) and (b) of § 8.501 if (1) no request for an extension of the provisional listing is received prior to the date the provisional listing expires; (2) the request for extension is not adequately supported by the information requested; or (3) any report, be it a progress report or a final report, shows that the color additive is unsafe under its proposed conditions of use. The Commissioner may also give consideration, where the scientific data so indicate, to reducing the aggregate use of a color in a provisional listing by eliminating or restricting certain uses in accordance with the procedure in § 8.11 (21 CFR 8.11).

Data in response to this notice should be addressed to the Food and Drug Administration, Bureau of Foods, Office of Compliance, Division of Petitions Processing, 200 C Street SW., Washington, DC 20204.

Dated: September 7, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-13366 Filed 9-10-71;8:46 am]

[DESI 8530; Docket No. FDC-D-141; NDA Nos. 10-613 and 8-530]

WINTHROP PRODUCTS, INC., AND WINTHROP LABORATORIES

Alevaire; Notice of Withdrawal of Approval of New-Drug Applications

In an announcement published in the FEDERAL REGISTER of July 17, 1968 (33 F.R. 10227), Winthrop Products, Inc., holder of new-drug application No. 10-613 for Alevaire (tyloxapol 0.125 percent) and Winthrop Laboratories, Division of Sterling Drug, holder of new-drug application No. 8-530 for Alevaire (tyloxapol 0.125 percent), were notified of the National Academy of Sciences-National Research Council, Drug Efficacy Study Group's evaluation of the article as ineffective, and of the Food and Drug Administration's concurrence with the evaluation and its conclusions that there is a lack of substantial evidence that Alevaire will have the effect it purports and is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling. Accordingly, the Commissioner of Food and Drugs noted his intent to initiate action to withdraw approval of the new-drug applications for Alevaire, and invited holders of the NDA's to submit any pertinent data.

After the announcement, Winthrop met with representatives of the Food and Drug Administration on August 13, 1968, to present arguments and additional evidence in support of the claimed effectiveness of Alevaire. The arguments and data were evaluated, but failed to provide any evidence of effectiveness derived from adequate and well controlled clinical investigations. On December 6, 1969, there was, therefore, published in the FEDERAL REGISTER (34 F.R. 19389), a notice of opportunity for hearing in which the Commissioner of Food and Drugs proposed to issue an order under the provisions

of section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (e)) withdrawing approval of new-drug application Nos. 10–613 and 8–530 for Alevaire, and all amendments and supplements thereto, on the ground that there was a lack of substantial evidence to support the claims of effectiveness for the drug for the conditions for which it is prescribed, recommended, or suggested in the labeling.

Winthrop Products, Inc., holder of NDA No. 10–613; Winthrop Laboratories, Division of Sterling Drug Inc., holder of NDA No. 8–530; and Breon Laboratories, Inc., a firm marketing Alevaire in the United States, filed a written appearance and request for hearing on January 20, 1970.

Submitted with the request was a statement of grounds, including the medical documentation relied upon, arguments which contended that there was an unqualified right to a hearing, and the affidavits of six physicians and scientists attesting to the drug's effectiveness. Additional medical documentation was submitted by a letter dated May 7, 1970.

On June 5, 1970, in response to the May 8, 1970 FEDERAL REGISTER publication of procedural and interpretative regulations, a supplemental election for hearing was submitted, included in which, was further medical documentation and a reiteration of the argument and reasons for a hearing as stated in the initial request for hearing. On August 13, 1970, one final medical document was submitted as a supplement to the January 20, and June 5 filings, and on March 1, 1971, the affidavit of the Medical Director of Breon Laboratories was received.

This presentation, as well as the medical documentation reviewed by the NAS-NRC panel and the medical documentation contained in both NDA's have been considered. The Commissioner of Food and Drugs concludes that there is no genuine and substantial issue of fact requiring a hearing and that the legal arguments are insubstantial.

Reasons for withdrawal of approval—1. *The Drug.* Alevaire is a fixed combination aqueous solution of 0.125 percent tyloxapol, 2 percent sodium bicarbonate, and 5 percent glycerin.

It is recommended in the treatment of patients "with diseases and disorders of the lungs accompanied, or complicated, by excessive or thickened bronchopulmonary secretions," and is indicated also for persons having pulmonary diseases where "* * * the normal mechanism for elimination of secretions is diminished or absent * * * or depressed."

The rationale for Alevaire has been variously described. At the time of initial NDA approval, it was offered as a "mucolytic" detergent aerosol which exerted a liquefying effect on excessive or thickened mucus secretions, thereby aiding the patient in their expulsion. The rationale, as reflected in the labeling submitted for review by the NAS–NRC panel, is that the drug acts as a detergent aerosol facilitating the removal of the pulmonary secretions allowing for excretion by normal processes by lowering or reducing the surface and interfacial tensions and reducing their viscosity.

Alevaire is recommended for administration in an undiluted form by an aerosol nebulizer delivering a fine mist to the patient in an open tent, croup tent or incubator. Where short periods of therapy are indicated, 10 to 20 ml. are recommended to be administered by a face mask, positive pressure breathing machines, or oral or nasal spray apparatus.

2. *Clinical Evidence to Support the Claims of Effectiveness.* Petitioners have presented summaries of 19 published and unpublished reports, and have cited nine additional articles, described as establishing that Alevaire is effective for use, and, that contrary to the "clinical impression" of the NAS-NRC panel, clinical and other evidence establishes Alevaire to be more effective than water.

Of the 19 reports summarized, none may be classified as an adequate and well-controlled clinical investigation. Twelve of these reports involve nothing more than discussions of clinical impressions and observations concerning the use of Alevaire, in vitro experiments, or articles mainly devoted to a discussion of medical problems. These 12 reports are as follows: One consisted of a collection of case reports on 17 adults treated by several doctors, in which the authors state that "* * * this does not pretend to be a controlled study." Another was a report of an in vitro study of the viscosity of saliva, bronchiatic pus and amniotic fluid, together with statements of the author as to Alevaire's effectiveness based upon his clinical use of the drug. Another evaluated resuscitation of infants born by Cesarean section, and contained undocumented statements as to the usefulness of Alevaire in such treatment. Two additional reports were based or clinical impressions from use of the drug in a number of individual cases, and were testimonial in nature. Three reports consisted of discussions of the treatment of laryngitis in children, general pulmonary problems, and bronchopulmonary disorder, in which Alevaire was employed in treatment and is discussed only incidentally. Two of the articles were devoted to discussions and clinical impressions of aerosol therapy agents in general, and references to Alevaire again was generalized and consisted of undocumented clinical impressions. One report was of an in vitro experiment of the effect of the drug as a surface-active agent, and another, a study of Alevaire conducted on cats, an animal whose respiratory tract differs from that of man.

The seven remaining articles were reports of studies conducted with Alevaire. These, however, provide no substantial evidence of efficacy. These seven consisted of five completed and two preliminary studies, and each was deficient to varying degrees in meeting the criteria for adequate and well controlled clinical trials, as follows. In one, an unpublished preliminary study, the investigations saturated the incubators of newborn infants with Alevaire. The conclusion that the therapy was of value, however, was based on general clinical observations rather than documented results. In another incomplete and unpublished study, a crossover comparison between Alevaire and isotonic saline, the "Interim report" of the investigator was that it was his "impression" on the basis of "preliminary information" that Alevaire is more effective than saline in increasing volume of sputum.

In one published study, Alevaire was administered to 300 patients with varying pulmonary conditions, and the therapeutic response was measured by general physical condition after treatment, characteristics of the sputum, and changes in respiratory effect. There were no controls and the study yielded no meaningful data on therapeutic response. Similarly, another study of children with acute bronchitis is lacking in the criteria necessary for a controlled study by failing to indicate diagnostic criteria or patient selection, methods of observation, measurement of variables, quantitation of results, and information as to the substance which may have been used as a control. Of the three remaining studies, one is an unpublished single blind crossover comparison of the effectiveness of Alevaire with water which appeared to indicate that Alevaire significantly increased both sputum volume and weight. The study, however, failed to state the method of patient selection, and the diagnostic criteria for bronchial asthma and chronic bronchitis was not stated. Further, no assessment of subjective response, nor steps taken to minimize bias were included in the study, nor was there documentation of the levels and methods of blinding. Another study, an unpublished crossover study in which Alevaire was reported as more effective than saline or water, lacked the necessary criteria for an adequate and well-controlled clinical trial, as reflected in the report itself. The protocol for this study showed that unsuitable patient selection reflected variable disease conditions and as a consequence, the variability of sputum volume and retention qualities precluded uniform measurement of effectiveness. No assessment of the subjective response of the patients was stated, nor was there an assurance in the protocol or results of the comparability of the different test groups of pertinent variables. In addition, the levels and methods of blinding were not documented. Although the statistical evaluation purported to show that Alevaire is more effective than either water or saline, its validity is highly questionable since Alevaire was administered to only half the number of patients who received normal saline and water, and the use of Bronkometer aerosol which in itself has mucoevacuant properties, unduly complicates the spirometric test. Nor does

the data obtained contain adequate detail to permit trend analysis. Another published single blind study to evaluate the comparative efficacy of Alevaire and another mucoevacuant, ascumist, was conducted among 75 patients undergoing thoracic surgery. The results showed that there was no significant reduction in the viscosity of sputum with Alevaire, but that Alevaire did produce an increase of sputum volume. The investigator's statement that "both ascumist and Alevaire can increase 24-hour sputum volume" is not warranted and cannot be translated into evidence of Alevaire's effectiveness, since the study failed to provide meaningful controls in the form of water or of the drug's vehicle consisting of water, sodium bicarbonate and glycerin. Numerous other deficiencies in the design of the study cause it to fail to meet the criteria which constitute an adequate and well-controlled clinical study.

In addition to these 19 published and unpublished reports commented upon above, the citations to nine other articles were provided as evidence favorable to claims of the drug's effectiveness. No adequate and well-controlled studies, clinical or otherwise, were present. Of the nine articles, four consisted of clinical discussions of pulmonary conditions generally, two involved the concurrent use of Alevaire and other drugs, one was a study of inhalation therapy in dogs, one a preliminary report of an uncontrolled study, and one a testimonial article based on clinical impressions of Alevaire.

The Commissioner also has considered the medical documentation submitted by the petitioners and reviewed by the NAS-NRC panel, and to the materials contained in the NDA's. Again, no adequate and well-controlled clinical studies were found. Of the 21 articles reviewed and evaluated by the NAS-NRC panel, 10 were resubmitted and summarized in the Request for Hearing materials. They have been already discussed. Nine of the remaining 11 are discussions of techniques of aerosol therapy, clinical impressions or preliminary reports on Alevaire's use, or of pulmonary surface activity. In two of the articles, however, the author (Palmer) reported on two controlled clinical investigations in which the drug was compared in one with its vehicle (sodium bicarbonate, water, and glycerine), and in the other with a control solution, normal saline solution, and water. The results showed use of Alevaire to be of no advantage over the use of any of the control or comparison solution, including water.

The NDA's for Alevaire contain 33 studies or articles from the medical literature. These, too, consist only of methods and techniques of aerosol therapy, reports of animal studies, uses of the drug for conditions other than its recommended ones, clinical impressions of the drug, or in which Alevaire is mentioned only incidentally. A number were concerned with drugs other than Alevaire.

3. *Affidavits to Support the Claims of Effectiveness.* The affidavits of six physicians were submitted with the Request for Hearing. In each of them, the affiant argues that clinical experience has shown Alevaire to be both safe and effective for its recommended uses, and each raises the argument that the criteria for adequate and well-controlled clinical studies prescribed by the regulations is impossible to meet with respect to any study of Alevaire. Neither of these two arguments raises a substantial question.

Despite the expressed opinions that the drug is both safe and effective, in only three of the affidavits (Cohen, Miller, Beck) is anything more than general clinical experience relied upon to justify such a conclusion. And in the affidavits of Cohen, Miller, and Beck, their conclusions are based on general clinical impressions and upon uncontrolled studies each has conducted on Alevaire. These studies were among those submitted in support of the Request for Hearing, and inasmuch as none meet the criteria for an adequate and well-controlled clinical study, do not constitute a valid basis for their final conclusions. And, although the conduct of an adequate and well-controlled clinical investigation of the drug may be made more difficult by conditions peculiar to its recommended use and method of administration, no valid reasons for alteration of any of the criteria has been raised.

4. *Legal Arguments.* The petitioners have urged several legal arguments in connection with the issuance of the Notice of Opportunity for Hearing. Those objections directed to the validity of the regulations clarifying the nature of the evidence to be submitted, has been resolved in "Upjohn Co. v. Finch," 422 F. 2d 944 (C.A. 6, 1970); "Pharmaceutical Manufacturers Assn. v. Richardson," 318 F. Supp. 301 (D. Del., 1970); and "Pfizer v. Richardson," 434 F. 2d 536 (C.A. 2, 1970). The contention that this drug is not subject to the efficacy review because it was not covered by an effective NDA on the day preceding the effective date of the 1962 Drug Amendments, is insubstantial. All drugs that were covered by new-drug applications filed at any time between 1938 and 1962 are subject to the efficacy review under the 1962 Drug Amendments. Similarly, the claimed application of different standards of evaluation by the Food and Drug Administration between Alevaire and other drugs, has no merit. The documentation of this argument in the form of an affidavit of the Medical Director of Breon Laboratories, itself points out that the two drugs are of different composition and different modes or mechanisms of action.

Therefore, the Commissioner, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (section 505(e), 52 Stat. 1052, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that, on the basis of new information before him with respect to Alevaire, NDA No. 10-613 and NDA No. 8-530, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

For the foregoing reasons, approval of new-drug applications Nos. 10-613 and 8-530, and all amendments and supplements thereto, is withdrawn effective on the date of the publication of this document.

Dated: August 27, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-13365 Filed 9-10-71;8:45 am]

Office of the Secretary

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part 3 (Health Services and Mental Health Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health, Education, and Welfare (33 F.R. 15953, October 30, 1968 et seq.) is hereby amended with regard to section 3-B, Organization as follows:

Under the center head "National Center for Family Planning Services (3F00)" substitute the following text:

Plans, directs, coordinates, and serves as "lead agency" for the family planning activities of the Health Services and Mental Health Administration. Specifically: (1) Develops HSMHA policy on matters pertaining to family planning activities; (2) develops long-range (5-year) family planning program objectives and plans; (3) formulates guidelines governing the preparation of annual family planning programs and reviews those programs on behalf of the Administrator; (4) administers family planning project grant and contract activities; (5) administers extramural research and training activities, both domestic and abroad (through use of Public Law 83-480 funds), incidental to family planning activities of HSMHA; (6) coordinates through Regional Offices the provision of technical assistance in family planning to State and local health organizations and to interested private organizations and institutions; (7) serves as a national clearinghouse for family planning information and data; (8) coordinates family planning activities of HSMHA with those of other operating agencies of the Department, other departments and agencies, and interested private organizations and institutions; (9) provides support and assistance to the Deputy Assistant Secretary for Population Affairs in the development of overall DHEW family planning policy and priorities, and in preparing reports to the Congress with respect to family planning program objectives, program accomplishments, and future plans; and (10) provides technical assistance and consultation to governments of other countries and public and

private organizations involved in international family planning programs.

Office of the Director (3F01). (1) Plans, directs, administers, coordinates, and evaluates the program and management operations of the Center; (2) stimulates research and development activities; (3) provides national and international leadership in family planning services; (4) assists the Administrator, HSMHA and the Deputy Assistant Secretary of Population Affairs in the development and implementation of national priorities, objectives, and plans in the area of family planning; and (5) provides professional and technical assistance to Regional Office personnel on family planning matters.

Office of Resources Management (3F19). (1) Plans and conducts the administrative management affairs of the Center; (2) develops and implements a comprehensive grants and contracts management program for the Center; (3) recommends allocation or reallocation of grant funds to the Regions; (4) provides program guidance and information to the Office of Financial Management, HSMHA, for use in the operation of a financial management system for the Center, including the interpretation of program policy and budget formulation and execution; (5) participates in the preparation of program planning and budget data; (6) develops, presents, and implements the working budgets for the Center; (7) provides direction to the Center and Regional Office staffs in managing financial, personnel, and facilities resources to accomplish program goals; and (8) coordinates the development of program reports required by law to be submitted to the Congress.

Office of Program Planning and Evaluation (3F31). (1) Develops family planning service goals, priorities, and plans; (2) maintains liaison and coordinates Center program planning and evaluation activities with other HSMHA programs, other DHEW organizations, Regional Offices, and the Office of the Deputy Assistant Secretary for Population Affairs; (4) conducts special studies and analyses of program priorities and objectives; (5) evaluates programs and achievements of the Center in relation to objectives; (6) develops methods, techniques, and standards for and evaluates effectiveness of grantee and contractor operations in relation to objectives; (7) assists in developing criteria for the review and approval of project applications to assure that objectives will be met on a priority basis; and (8) plans, in conjunction with the Office of Resources Management and the HSMHA Assistant Administrator for Management, the use of resources to achieve objectives.

Division of Information and Education (3F33). (1) Serves as a national clearinghouse for family planning information and data; (2) develops and administers a program of public education to inform the general public, and tailored to obtain intelligent support and participation in the obtaining of family planning services by individuals and widely varied social groups comprising the service population; (3) assembles and distributes printed material, films, guides, and resource directories to Regional Offices for use in the education effort; (4) develops new materials (brochures, audiovisual aids, etc.), to meet the needs of special groups with sharply different mores, for use by contractors, grantees, and Regional Offices; (5) plans and supports workshops and conferences to promote the effective use of available materials and the latest information by government, grantee, contractor, and other private or public groups concerned with public information and education in support of the program; (6) keeps informed of and communicates information to participating organizations as to new developments generated by the scientific community with regard to family planning; (7) works with television and radio stations and networks, the press, and other information and education media to obtain support and participation in the education effort; and (8) responds to inquiries from the lay public, provides technical assistance in preparing congressional presentations, and prepares speeches, reports, interpretive documents, press releases, and other materials concerning the NCFPS program.

Division of Services-Delivery Research (3F41). (1) Conducts services-delivery research into key areas related to, and having an impact upon, the delivery of family planning services; (2) conducts and/or supports extensive intra- or extramural studies designed to furnish Central and Regional Office staff with specific definitive answers to such operational problems as: (a) How to increase patient retention rates and (b) how to increase the numbers of patients who utilize family planning grantee clinics; (3) formulates and develops operating methods, techniques, and procedures for incorporating answers into existing and future family planning programs; (4) assists in the development, in conjunction with the Office of the Director, of international services-delivery research projects and evaluates the data generated by these studies; (5) develops methods for analyzing the progress and effectiveness of NCFPS services-delivery research programs with accompanying record keeping and control systems; and (6) interprets and recommends dissemination of services-delivery research results to ensure that current, scientifically factual information is available for use in the planning, operation, and evaluation of family planning programs.

Division of Training (3F51). (1) Serves as the training arm for the National Center for Family Planning Services to assure maximum effectiveness of headquarters, Regional Office, contractor, and grantee staffs in the execution of family planning service programs; (2) identifies training needs, develops training programs directly and through grantee and contractor assistance, and conducts necessary training through its own resources, Regional Offices, and through grantee and contractor facilities to improve competence of staffs of participating organizations; (3) provides guidance in training program development and reviews Regional Office training plans and efforts; and (4) adapts training programs to meet varying needs.

Division of Field Operations (3F61). (1) Provides technical advice and assistance to Regional Offices in the handling of family planning services project grants, including such matters as operating procedures, policies, policy interpretations, guidelines, technical assistance to grantees and prospective grantees on any aspect of grant applications or operations after grants are made; (2) keeps informed on family planning grants activities of the respective regions to identify incipient problems and devise solutions before critical incidents occur; (3) in conjunction with Regional Offices, furthers coordination of joint efforts of participating organizations (including Federal and local government agencies, grantees, contractors, and otherwise involved individuals, groups, associations, and companies), through meetings and conferences to explain the intent, purpose, and philosophy of the program and facilitate cooperative working relationships; (4) recommends allocation or reallocation of grant funds to regions; (5) on request of Regional Offices, assists prospective grantees in development of grant applications to assure inclusion of medical and social features needed and desirable for a particular service population; (6) keeps other elements of NCFPS headquarters informed of the current status of grantee development, progress, and problem areas; and (7) provides a focal point for coordination of communications with and visits to Regional Offices by headquarters NCFPS staff.

Dated: September 6, 1971.

ELLIOT L. RICHARDSON,
Secretary.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. D-71-126]

REGIONAL ADMINISTRATORS, ET AL.

Redelegation of Authority

SECTION A. *Authority redelegated.* Each Regional Administrator, Deputy Regional Administrator, Assistant Regional Administrator for Housing Management, and Insurance Advisor of the Department of Housing and Urban Development is authorized, with respect to the programs listed below, to approve non-Federal insurance contracts and to execute endorsements on behalf of the Department of Housing and Urban Development on insurance checks on which the United States of America, Department of Housing and Urban Development, or any predecessor agency of the Department of Housing and Urban Development, is a joint payee: