

lecture, demonstrations, and student participation. The foreign article is a relatively simple, medium resolution electron microscope designed for confident use by beginning students with a minimum of detailed programing. The most closely comparable domestic instrument available at the time the foreign article was ordered was the Model EMU-4C electron microscope manufactured by Forgflo. The Model EMU-4C is a relatively complex instrument designed for research, which requires a skilled electron microscopist for its operation. Forgflo comments, " * * * The EMU-4C can be easily adapted and set up for teaching applications * * * " As to this, HEW advises that, "Forgflo comments fail to show that the EMU-4B/C [i.e., the EMU-4B or 4C] is not the more complex instrument. The applicant is not in instrument development therefore suggestions for modification are not appropriate." HEW cites as a precedent its prior recommendation relating to Docket No. 71-00245-33-46040 which conforms in certain particulars to the captioned application. We, therefore, find that the Model EMU-4C electron microscope was 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 was being manufactured in the United States at the time the foreign article was ordered.

SETH M. BODNER,
Director, Office of Import Programs.
[FR Doc.72-8297 Filed 6-13-72;8:48 am]

TEXAS TECH 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 (37 F.R. 3892 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. 72-00255-33-46040. Applicant: Texas Tech University School of Medicine, Department of Anatomy, Post Office Box 4569, Lubbock, TX 79409. Article: Electron microscope, EM 9S-2. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used in studies of steroid producing organs, their structure function and developmental aspects and studies of bone structure, bone healing, fluid movement in bone and vascular-lymphatic aspects of bone biodynamics. The article will also be used to train medical students, residents, and other

medical personnel in the basic aspects of the clinical applications of electron microscopy.

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 8, 1971).

Reasons: The applicant requires an electron microscope which is suitable for instruction in the basic principles of electron microscopy. The foreign article is a relatively simple, medium resolution electron microscope designed for confident use by beginning students with a minimum of detailed programing. The most closely comparable domestic instrument available at the time the foreign article was ordered was the Model EMU-4C electron microscope manufactured by the Forgflo Corp. The Model EMU-4C electron microscope is a relatively complex instrument designed for research, which requires a skilled electron microscopist for its operation. We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated May 19, 1972, that the relative simplicity of design and ease of operation of the foreign article is pertinent to the applicant's educational purposes. We, therefore, find that the Model EMU-4C electron microscope 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 was being manufactured in the United States at the time the foreign article was ordered.

SETH M. BODNER,
Director, Office of Import Programs.
[FR Doc.72-8928 Filed 6-13-72;8:48 am]

UNIVERSITY OF SOUTHERN CALIFORNIA

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 (37 F.R. 3892 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. 72-00267-33-46040. Applicant: University of Southern California, School of Medicine, 2025 Zonal Avenue, Los Angeles, CA 90033. Article: Electron microscope, Model HU-12. Manufac-

turer: Hitachi Perkin-Elmer, Japan. Intended use of article: The article is intended to be used for electron microscopy screening of breast milk for B- and C-types particles from lactating mothers whose mothers have a history of breast or other cancer.

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 has a specified resolving capability of 3 angstroms. The most closely comparable domestic instrument is the Model EMU-4C electron microscope manufactured by the Forgflo Corp. The Model EMU-4C has a specified resolving capability of 5 angstroms. (The lower the numerical rating in terms of angstrom units, the better the resolving capability.) We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated May 19, 1972, that the additional resolving capability of the foreign article is pertinent to the purposes for which the foreign article is intended to be used. We, therefore, find that the Model EMU-4C is not of equivalent scientific value to the foreign article for such purposes as the 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.72-8929 Filed 6-13-72;8:48 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 12339; Docket No. FDC-D-457; NDA No. 13-415]

MERCK SHARP & DOHME

Certain combination Drugs for Inhalation; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New-Drug Application

In an announcement (DESI 12339) published in the FEDERAL REGISTER of November 3, 1970 (35 F.R. 16951), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following drugs:

1. Bronkometer Aerosol containing isoetharine methanesulfonate, phenylephrine hydrochloride, and thenyldiamine hydrochloride; marketed by Breon

Laboratories, Inc., subsidiary of Sterling Drug, Inc., 90 Park Avenue, New York, N.Y. 10016 (NDA 12-339).

2. Bronkospray Solution containing isoetharine hydrochloride, phenylephrine hydrochloride, and thenyldiamine hydrochloride; marketed by Breon Laboratories, Inc. (NDA 12-339).

3. ProDecadron Respihaler containing dexamethasone sodium phosphate and isoproterenol sulfate; marketed by Merck Sharp & Dohme, division of Merck & Co., West Point, Pa. 19846 (NDA 13-415).

The announcement stated that there is a lack of substantial evidence that these drugs are effective as fixed combinations for their labeled claims relating to bronchopulmonary disorders, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new-drug applications for the drugs. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. Merck Sharp & Dohme, holder of NDA 13-415 for ProDecadron Respihaler, has not submitted data pursuant to the announcement. Breon Laboratories, Inc., holder of NDA 12-339 for Bronkometer Aerosol and Bronkospray Solution has submitted a supplemental new-drug application concerning these preparations. The supplement is under review.

Therefore, notice is given to Merck Sharp & Dohme, holder of NDA 13-415 for ProDecadron Respihaler, and to any interested person who may be adversely affected; that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of said application and all amendments and supplements thereto on the grounds that new information before him with respect to the drug, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the applicant, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new-drug application should not be withdrawn. Any related drug for human use, not the subject of an approved new-drug application, may be affected by this action.

Within 30 days after publication hereof in the FEDERAL REGISTER, such persons are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or
2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the new-drug application. Failure of such persons to file a written appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

If such persons elect to avail themselves of the opportunity for a hearing, they must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new-drug application should not be withdrawn, together with a well organized and full factual analysis of the clinical and other investigation data they are prepared to prove in support of their opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing. When it clearly appears from the data in the application and from the reasons and factual analysis in the request for a hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, the Commissioner will enter an order on these data, making findings and conclusions on such data.

If a hearing is requested and justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence. (35 F.R. 7250, May 8, 1970; 35 F.R. 16631, October 7, 1970.)

Received requests for a hearing, and/or elections not to request a hearing, may be seen in the office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355) and under the authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 5, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-8895 Filed 6-13-72;8:45 am]

[DESI 12451; Docket No. FDC-D-447; NDA 12-451]

USV PHARMACEUTICAL CORP.

Ethamivan for Oral Use; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

In an announcement (DESI 12451) published in the FEDERAL REGISTER of April 10, 1970 (35 F.R. 5972), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on Emivan Tablets (NDA 12-451) containing ethamivan. The announcement stated that, for the oral form of the drug, there is a lack of substantial evidence that the drug is effective for its labeled indications and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug application for the drug. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. No data have been received. The holder of the application has stated that the preparation is no longer marketed.

Therefore, notice is given to USV Pharmaceutical Corp., 800 Second Avenue, New York, N.Y. 10017, holder of NDA 12-451 for Emivan Tablets, and to any interested person who may be adversely affected, that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of said application and all amendments and supplements thereto on the grounds that new information before him with respect to the drug, evaluated together with the evidence available to him when the application was approved, shows there is 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.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the applicant, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new drug application should not be withdrawn. Any related drug for human use, not the subject of an approved new drug application, may be affected by this action.

Within 30 days after publication hereof in the FEDERAL REGISTER, such persons are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Maryland 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or