

Special Import Programs Division,
Department of Commerce, Washington,
D.C.

Docket No. 72-00602-00-46040. Applicant: St. Joseph's Hospital, Research Laboratory, 3001 West Buffalo Avenue, Tampa, FL 33607. Article: Electrical exposure shutter with equipment for exposure measurement. Manufacturer: Siemens AG, West Germany. Intended use of article: The article is an accessory for an existing electron microscope which is being used in the study of the ultrastructure of various types of cancer cells and tumor viruses and in the training of medical students in this field of research. Application received by Commissioner of Customs: June 1, 1972.

Docket No. 72-00603-33-46070. Applicant: State University of New York at Buffalo, 3435 Main Street, Buffalo, NY 14214. Article: Scanning electron microscope, Model JSM-U3. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used to carry out sophisticated and detailed studies of metallic, nonmetallic and biological materials. Specific projects will include:

1. Large strain rate deformation of materials.
2. Surface integrity studies of high strength alloys.
3. Stress corrosion sensitivity of engineering surfaces of commercial alloys.
4. Friction and wear behavior of cast irons.
5. Studies in Process Metallurgy: Gas-liquid reactions and solidification of two component alloys.
6. Effect of topography and heterogeneity on wetting of solids by liquids.
7. Calcified tissue research.
8. Drug release rates of spansules.

The article will also be used for educational purposes in graduate and undergraduate level courses, including nontechnical people in health services. Application received by Commissioner of Customs: June 1, 1972.

Docket No. 72-00604-01-68495. Applicant: Yale University, Purchasing Department, 260 Whitney Avenue, New Haven, CT 06520. Article: He⁺ pumping package. Manufacturer: Alcatel Vacuum Technics, France. Intended use of article: The article is intended to be used to facilitate operation of a polarized proton target in an experiment to be performed at Brookhaven National Laboratory. In this experiment the resultant asymmetries in the scattering of K⁺, K⁻ mesons and antiprotons will be measured when the direction of polarization is reversed. Application received by Commissioner of Customs: June 1, 1972.

Docket No. 72-00605-00-77040. Applicant: University of Illinois at Urbana, Champaign, Purchasing Division, 223 Administration Building, Urbana, Ill. 61801. Article: Ion probe and scan control unit. Manufacturer: A.E.I. Scientific Equipment, Ltd., United Kingdom. Intended use of article: The article is intended to be used as an accessory to an existing mass spectrometer being used in support of graduate research.

This research includes crystal structure, diffusion of atoms and ions, superconductivity, properties of liquid helium, semiconductors, high pressure phenomena, crystal defects and radiation damage, magnetic properties including electron and nuclear magnetic resonance, optical properties including infrared, far ultraviolet absorption and Raman scattering, mechanical properties, phase transformations, properties of thin films, and recrystallization of glasses. Application received by Commissioner of Customs: June 1, 1972.

Docket No. 72-00609-00-46040. Applicant: University of Chicago, Department of Biophysics, 1160 East 55th Street, Chicago, IL 60615. Article: 70 mm. rollfilm camera. Manufacturer: Siemens AG, West Germany. Intended use of article: The article is an accessory to an existing electron microscope which will enable more precise recording of high resolution micrographs of terrestrial and extraterrestrial materials, as well as a wide variety of biological specimens. Application received by Commissioner of Customs: June 5, 1972.

Docket No. 72-00610-33-46040. Applicant: University of Florida, College of Medicine, Department of Ophthalmology, Gainesville, Fla. 32601. Article: Electron microscope, Model EM 9S-2. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used in ultrastructural studies of human cornea to resolve the corneal lamellae and viruses associated with human disease and ultrastructural studies of the Canal of Schlemm and trabecular meshwork in human eyes from both autopsy and biopsy samples to correlate ultrastructure with physiology or diseased states. The article will also be used for training purposes in the courses: Topics in Ophthalmology Research MED 600 series and Special Topics in Pathology MED 646. The students will become familiar with the operation of the instrument along with other techniques and procedures such as tissue culture, microsurgical techniques, immunological techniques, research virology, techniques in genetics, perfusion techniques and general research design. Application received by Commissioner of Customs: June 5, 1972.

Docket No. 72-00612-00-61800. Applicant: Columbia Museum of Art Commission, 1519 Senate Street, Columbia, SC 29201. Article: Planetarium projector, Model MS-10. Manufacturer: Minolta Camera Co., Japan. Intended use of article: The article is intended to be used together with the control console to demonstrate astronomical phenomena (related to astronomical and for navigational sciences as the course subject may require) and also allow student participation and involvement. The curriculum oriented program and teacher training will include: Astronomy III, Astronomy 112, Physical Science 22, planetarium classes grades 1 through 12, enrichment classes for junior and senior high school students, and astronomy workshops for teachers. In addition, the article will be used in the implementation of regular scheduled public demonstrations and

community astronomy classes. Application received by Commissioner of Customs: June 6, 1972.

SETH M. BODNER,
Director, Office of Import Programs.
[FR Doc.72-10473 Filed 7-7-72;8:46 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
[DESI 12462]

CERTAIN ANTIDIARRHEAL PREPARATIONS CONTAINING DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Lomotil Tablets (NDA 12-462) and Lomotil Liquid (NDA 12-699), both containing diphenoxylate hydrochloride and atropine sulfate; marketed by G. D. Searle & Co., Post Office Box 5110, Chicago, Illinois 60680.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drug without approval.

A. Effectiveness classification. The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that diphenoxylate hydrochloride with atropine sulfate preparations are effective for use as adjunctive therapy in the management of diarrhea.

B. Conditions for approval and marketing. The Food and Drug Administration is prepared to approve abbreviated new-drug applications and abbreviated supplements to previously approved new-drug applications under conditions described herein.

1. *Form of drug.* Diphenoxylate hydrochloride with atropine sulfate preparations are in tablet or liquid form suitable for oral administration.

2. *Labeling conditions.* a. The labels bear the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drugs are labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The "Indications" section is as follows:

INDICATIONS

As adjunctive therapy in the management of diarrhea.

3. *Marketing status.* Marketing of such drugs may be continued under the con-

ditions described in the notice entitled "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study" published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), as follows:

a. For holders of "deemed approved" new-drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling, an abbreviated supplement for updating information, and adequate data to show the biologic availability of the drug in the formulation which is marketed as described in paragraphs (a) (1) (i), (ii), and (iii) of the notice of July 14, 1970. Clinical trials which have established effectiveness of the drug may also serve to establish the bioavailability of the drug if such trials were conducted on the currently marketed formulation.

b. For any person who does not hold an approved or effective new-drug application, the submission of an abbreviated new-drug application to include biologic availability of the drug in the formulation which is or is intended to be marketed, as described in paragraph (a) (3) (ii) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12462, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (Identify with NDA number):
Office of Scientific Evaluation (BD-100),
Bureau of Drugs.
Original abbreviated new-drug applications
(Identify as such); Drug Efficacy Study
Implementation Project Office (BD-60),
Bureau of Drugs.
Requests for the Academy's report: Drug
Efficacy Study Information Control (BD-
67), Bureau of Drugs.
All other communications regarding this
announcement: Drug Efficacy Study Im-
plementation Project Office (BD-60),
Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 27, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10457 Filed 7-7-72; 8:48 am]

[DESI 10598]

ANTIEMETIC COMBINATION PREPARATION

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Bendectin Tablets containing dicyclomine hydrochloride, doxylamine succinate, and pyridoxine hydrochloride; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, Ohio 45215 (NDA 10-598).

This drug is regarded as a new drug (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that this preparation is possibly effective for nausea and vomiting of pregnancy.

B. *Marketing status.* Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as possibly effective may be continued for six months as described in paragraphs (d), (e), and (f) of the notice Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273).

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 10598, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (Identify with NDA number):
Office of Scientific Evaluation (BD-100),
Bureau of Drugs.
Original new-drug applications: Office of
Scientific Evaluation (BD-100), Bureau of
Drugs.
Requests for the Academy's report: Drug
Efficacy Study Information Control (BD-
67), Bureau of Drugs.
All other communications regarding this an-
nouncement: Drug Efficacy Study Imple-
mentation Project Office (BD-60), Bureau
of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 27, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-10455 Filed 7-7-72; 8:48 am]

[DESI 12152]

CERTAIN ANTIHISTAMINE-CON- TAINING DRUG CONTAINING CHLORPHENIRAMINE MALEATE, PHENYLPROPANOLAMINE HYDRO- CHLORIDE, AND ISOPROPAMIDE IODIDE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug for oral use:

Ornade Spansules (sustained release capsules) containing chlorpheniramine maleate, phenylpropanolamine hydrochloride, and isopropamide iodide; Smith, Kline & French Laboratories, 1500 Spring Garden Street, Philadelphia, Pa. 19101 (NDA 12-152).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that:

1. This drug is possibly effective for relief of upper respiratory tract congestion and hypersecretion associated with vasomotor rhinitis and allergic rhinitis, and for prolonged effect.

2. The drug lacks substantial evidence of effectiveness for relief of nasal congestion and hypersecretion associated with: the common cold; sinusitis (acute, subacute and chronic); influenza; and postnasal drip.

B. *Marketing status.* 1. Within 60 days of the date of publication of this announcement in the FEDERAL REGISTER, the holder of any approved new drug application for which a drug is classified in paragraph A. 2. above as lacking substantial evidence of effectiveness is requested to submit a supplement to his application, as needed, to provide for revised labeling which deletes those indications for which substantial evidence of effectiveness is lacking. Such a supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new drug regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time, and the revised labeling should be put into use within the 60-day period. Failure to do so may result in a proposal to withdraw approval of the new drug application.

2. If any such preparation is on the market without an approved new drug application, its labeling should be revised if it includes those claims for which substantial evidence of effectiveness is lacking as described in paragraph A. 2. above. Failure to delete such indications and put the revised labeling into use within 60