

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withdrawing such approval, an opportunity for a hearing to show why approval of the new-drug application should not be withdrawn.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

DEPARTMENT OF TRANSPORTATION

COAST GUARD

[CGD 72-101N]

Equipment, Construction, and Materials

Approval Notice

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 investigational 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 of Food and Drugs (21 CFR 2.120).

Dated June 5, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-8894 Filed 6-13-72; 8:45 am]

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manufactured by Marine Safety Equipment Corp., Foot of Wycoff Road, Farmingdale, N.J. 07727, effective April 6, 1972. (It reinstates and supersedes Approval No. 160.035/229/0 terminated April 1, 1970.)

Approval No. 160.035/300/5, 24.0' x 8.0' x 3.5' aluminum, motor-propelled lifeboat, without radio cabin or searchlight (Class 1), 37-person capacity, identified by general arrangement dwg. No. 24-9H, Rev. H dated February 14, 1972, 46 CFR 160.035-13(c) Marking, Weights: Condition "A"—3,100 pounds; Condition "B"—10,252 pounds, manufactured by Marine Safety Equipment Corp., Foot of Wycoff Road, Farmingdale, N.J. 07727, effective April 5, 1972. (It supersedes Approval No. 160.035/300/4 dated March 23, 1967, to show change in construction and address.)

BACKFIRE FLAME CONTROL, GASOLINE ENGINES; FLAME ARRESTERS; FOR MERCHANT VESSELS AND MOTORBOATS

Approval No. 162.041/139/0, Barbron backfire flame arrester, part No. 57157, brass element, base and cover, alternate material for base and cover is anodized aluminum, base is 0.25 inches high, opening in base is 3.06 inches in diameter, identical with Barbron Model No. 5727B (162.041/126) except for element height of 1½ inches instead of 2 inches on No. 5727B, manufactured by Barbron Corp., 14580 Lesure Avenue, Detroit, MI 48227, effective April 11, 1972.

BACKFIRE FLAME CONTROL, GASOLINE ENGINES; ENGINE AIR AND FUEL INDUCTION SYSTEMS; FOR MERCHANT VESSELS AND MOTORBOATS

Approval No. 162.042/3/0, OMC 6 horsepower power head, OMC Model 3993057210-6R72D, fuel induction arrangement provides backfire flame protection equivalent to that of an effective backfire flame arrester, uses Reed valve air induction, manufactured by Outboard Marine Corp., 300 Pershing Road, Waukegan, IL 60086, effective April 11, 1972. (It is an extension of Approval No. 162.042/3/0 dated June 12, 1967, and change of Model No.)

INCOMBUSTIBLE MATERIALS FOR MERCHANT VESSELS

Approval No. 164.009/104/0, "FOAM-GLAS" cellulated glass type incombustible material identical to that described in National Bureau of Standards letter file 10.2/10.2, FP 2628 dated August 25, 1948, Pittsburgh Corning letter dated June 5, 1967, and USCG letter 5946/164.009/104 dated June 9, 1967, approved in a 7 through 10 pounds per cubic foot density, manufactured by Pittsburgh Corning Corp., 3 Gateway Center, Pittsburgh, Pa. 15222, Plant: Port Allegany, Pa., and Sedalia, Mo., effective April 3, 1972. (It is an extension of Approval No. 164.009/104/0 dated June 9, 1967, and change of address of manufacturer.)

1. Certain laws and regulations (46 CFR Chapter I) require that various items of lifesaving, firefighting, and miscellaneous equipment, construction, and materials used on board vessels subject to Coast Guard inspection, on certain motorboats and other recreational vessels, and on the artificial islands and fixed structures on the Outer Continental Shelf be of types approved by the Commandant, U.S. Coast Guard. The purpose of this document is to notify all interested persons that certain approvals have been granted as herein described during the period from April 3, 1972 to April 11, 1972 (List No. 11-72). These actions were taken in accordance with the procedures set forth in 46 CFR 2.75-1 to 2.75-50.

2. The statutory authority for equipment, construction, and material approvals is generally set forth in sections 367, 375, 390b, 416, 481, 489, 526p, and 1333 of title 46, United States Code, section 1333 of title 43, United States Code, and section 198 of title 50, United States Code. The Secretary of Transportation has delegated authority to the Commandant, U.S. Coast Guard with respect to these approvals (49 CFR 1.46(b)). The specifications prescribed by the Commandant, U.S. Coast Guard for certain types of equipment, construction, and materials are set forth in 46 CFR Parts 160 to 164.

3. The approvals listed in this document shall be in effect for a period of 5 years from the date of issuance, unless sooner canceled or suspended by proper authority.

LIFEFLOATS FOR MERCHANT VESSELS

Approval No. 160.027/48/2, 6.17' x 4.17' (11" x 10¼" body section), rectangular lifeboat, fibrous glass reinforced plastic shell with unicellular plastic core, 15-person capacity, identified by dwg. No. M-99-15, Rev. E dated April 6, 1972, and fabrication specification dated April 6, 1972, manufactured by Marine Safety Equipment Corp., Foot of Wycoff Road, Farmingdale, N.J. 07727, effective April 11, 1972. (It supersedes Approval No. 160.027/48/1 dated March 25, 1969, to show change in construction.)

LIFEBOATS

Approval No. 160.035/229/1, 28.0' x 9.0' x 3.96' steel, oar-propelled lifeboat, 59-person capacity, identified by general arrangement dwg. No. 28-1B dated February 16, 1972, 46 CFR 160.035-13(c) Marking, Weights: Condition "A"—5,100 pounds; Condition "B"—16,019 pounds,