

of the procedures and format, the importance of this review requires that it begin immediately. Accordingly, notice is hereby given that all data and information regarding the safety and effectiveness of bacterial vaccines and bacterial antigens whose labels are required by 21 CFR 273.601(r) to state "No U.S. standard of potency," which is the first category of licensed products to be reviewed, are requested to be submitted. To be considered, eight copies of the data and information must be submitted in the prescribed format within 60 days from the date of this publication to:

Safety and Efficacy Review (BI-5), Bureau of Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852.

Pursuant to the prior notice published in the FEDERAL REGISTER for March 15, 1972 (37 F.R. 5404), licenses of two manufacturers for these products have already been revoked (37 F.R. 13360). The product licenses for products for which no submissions are made pursuant to this notice will similarly be revoked. The prior notice of March 15, 1972, has now been superseded by the notice of proposed rule making governing the safety, efficacy, and label review published in this issue of the FEDERAL REGISTER (21 CFR Part 273). Data and information pertinent to this category of biological products is also requested from any other interested person, including the companies whose licenses have already been revoked.

Dated: August 14, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-13997 Filed 8-17-72; 8:47 am]

[Docket No. FDC-D491; NDA 4-690, etc.]

G. D. SEARLE AND CO. ET AL.

New Drug Applications; Notice of Withdrawal of Approval

The holders of the new drug applications listed herein have not submitted annual reports of experience with the drugs as required and have advised the Food and Drug Administration that the new drugs involved were never marketed or marketing has been discontinued and have requested withdrawal of approval of the new drug applications, thereby waiving opportunity for a hearing.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053 as amended; 21 U.S.C. 355(e), and under authority delegated to the Commissioner (21 CFR 2.120)), approval of the following new drug applications, and supplements thereto, is hereby withdrawn on the grounds that the applicants have failed to make reports under section 505(j) of the Act (21 U.S.C. 355(j)) and § 130.13 or § 130.35 (e) and (f) of the new drug regulations (21 CFR 130.13 and 130.35).

NDA No.	Drug name	Applicant's name and address
4-690	Pavatrine Tablets (diethylaminoethyl fluorene 9 carboxylate hydrochloride).	G. D. Searle and Co., Post Office Box 5110, Chicago, IL 60680. Do.
5-415	Pavatrine with phenobarbital tablets (diethylaminoethyl fluorene 9 carboxylate hydrochloride, phenobarbital).	
5-419	Protein Hydrolysate Injection (protein, free amino acids, polypeptides).	Travenol Laboratories, 6301 Lincoln Ave., Morton Grove, IL 60053.
5-466	Analgesic Balm Ointment (menthol, methyl salicylate).	The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49001.
6-428	Parestrol EC Tablets (dienestrol).	The Central Pharmaceutical Co., 116-128 East Third St., Seymour, IN 47274.
7-060	Vitral Injection (Vitamin B-12).	Cooper Laboratories, Inc., 2900 North 17th St., Philadelphia, PA 19132.
8-049	Diolandrone Tablets (methylandrostenediol).	Carnrick Laboratories, 65 Horse Hill Rd., Cedar Knolls, NJ 07927.
16-542	Pen-Nitrate Tablets (pentaerythritol tetranitrate).	Cooper Laboratories, Inc., 2900 North 17th St., Philadelphia, PA 19132.

This order shall become effective on its date of publication in the FEDERAL REGISTER (8-18-72).

Dated: August 8, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-13003 Filed 8-17-72; 8:45 am]

Withdrawn

DEPARTMENT OF TRANSPORTATION

[CGD 72-79]

Coast Guard

CERTAIN STATE AND LOCAL BOAT SAFETY LAWS OF TEXAS

Notice of Exemption

The purpose of this rule is to exempt certain Texas laws from the Federal preemption clause of the Federal Boat Safety Act of 1971. The effective date of the Act (46 U.S.C. 1451, et seq.; Public Law 92-75; 85 Stat. 213) was August 10, 1971. On August 11, 1971, the Secretary of Transportation, by his authority in section 9 of the Act, 46 U.S.C. 1458, exempted laws then in effect of the States, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the District of Columbia and subdivisions thereof from section 10 of the Act, 46 U.S.C. 1459, which provides that the Act preempts State law in certain matters covered by the Act. 36 F.R. 15764 (August 18, 1971).

That exemption applied only to laws in effect on August 10, 1971. On August 10, 1971, the Texas Legislature had enacted the "Water Safety Act" (title

19, Article 1722a, Texas Penal Code, as amended by Acts 1971, 62d Legislature, p. 2929, Chapter 971) with requirements for carrying and using approved lifesaving devices, ventilation equipment, lighting equipment, sounding equipment, mufflers, backfire flame arrestors, and fire extinguishers with an effective date of September 1, 1971.

The State of Texas has requested that these provisions of its law be exempt from section 10 of the Federal Boat Safety Act of 1971. Boating safety will not be adversely affected by continuing in effect those laws of the State of Texas until new boating safety regulations are issued under the Federal Boat Safety Act of 1971.

Accordingly, under the authority vested in me by section 9 of the Federal Boat Safety Act of 1971, 46 U.S.C. 1458 and 49 CFR 1.46(o), delegating to the Commandant, U.S. Coast Guard authority vested in the Secretary by the Federal Boat Safety Act of 1971, I hereby exempt the State of Texas and political subdivisions thereof from the provision of section 10 of the Federal Boat Safety Act of 1971 to the extent that they may continue in effect and enforce the following laws: title 19, Article 1722a, Texas Penal Code amended by Acts 1971, 62nd Legislature, p. 2929, Chapter 971, effective September 1, 1971, containing requirements for carrying and using approved lifesaving devices, ventilation equipment, lighting equipment, sounding equipment, mufflers, backfire flame arrestors, and fire extinguishers.

This exemption becomes effective on publication (8-18-72), and continues in effect until superseded, rescinded or otherwise terminated.

Issued in Washington, D.C., August 11, 1972.

T. R. SARGENT,
Vice Admiral, U.S. Coast Guard,
Acting Commandant.

[FR Doc.72-13994 Filed 8-17-72; 8:46 am]

[CGD 72-79]

CERTAIN STATE AND LOCAL BOAT SAFETY LAWS OF MINNESOTA

Notice of Exemption

The purpose of this rule is to exempt certain Minnesota laws from the Federal preemption clause of the Federal Boat Safety Act of 1971. The effective date of the Act (46 U.S.C. 1451, et seq.; Public Law 92-75; 85 Stat. 213) was August 10, 1971. On August 11, 1971, the Secretary of Transportation, by his authority in section 9 of the Act, 46 U.S.C. 1458, exempted laws then in effect of the States, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the District of Columbia and subdivisions thereof from section 10 of the Act, 46 U.S.C. 1459, which provides that the Act preempts State law in certain matters covered by the Act. 36 F.R. 15764 (August 18, 1971).

That exemption applies only to laws in effect on August 10, 1971. On August 10, 1971, the Minnesota Legislature