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Certifier	Michael W. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1833]

SoloPak Laboratories, Inc.; Withdrawal of Approval of 1 New Drug Application and 38 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 1 new drug application (NDA) and 38 abbreviated new drug applications (ANDA's). SoloPak Laboratories, Inc., notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: (Insert date 30 days after date of publication in the FEDERAL REGISTER.)

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: SoloPak Laboratories, Inc., 1845 Tonne Rd., Elk Grove Village, IL 60007-5125, has informed FDA that the drug products listed in the following table are no
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longer marketed and has requested that FDA withdraw approval of the applications. SoloPak Laboratories, Inc., has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
NDA 19-961	Ganite (gallium nitrate)
ANDA 62-507	Gentamicin Sulfate Injection USP, 10 and 40 milligrams (mg)/milliliter (mL)
ANDA 62-605	Kanamycin Sulfate Injection USP, 500 mg/2 mL and 75 mg/2 mL and 1 gram/3 mL
ANDA 62-819	Clindamycin Phosphate Injection USP, 150 mg/mL
ANDA 62-852	Clindamycin Phosphate Injection USP, 150 mg/mL
ANDA 70-046	Dopamine Hydrochloride Injection USP, 40 mg/mL
ANDA 70-047	Dopamine Hydrochloride Injection USP, 80 mg/mL
ANDA 70-078	Furosemide Injection USP, 10 mg/mL
ANDA 70-137	Propranolol Hydrochloride Injection USP, 1 mg/mL
ANDA 70-623	Metoclopramide Injection USP, 5 mg/mL
ANDA 70-633	Nitroglycerin Injection USP, 5 mg/mL
ANDA 70-696	Verapamil Hydrochloride Injection USP, 2.5 mg/mL
ANDA 70-801	Haloperidol Lactate Injection USP, 5 mg/mL
ANDA 70-841	Methyldopate Hydrochloride Injection USP, 50 mg/mL
ANDA 70-864	Haloperidol Injection USP, 5 mg/mL
ANDA 71-671	Naloxone Hydrochloride Injection USP, 0.02 mg/mL
ANDA 71-681	Naloxone Hydrochloride Injection USP, 0.4 mg/mL

Application No.	Drug
ANDA 71-682	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
ANDA 71-754	Droperidol Injection USP, 2.5 mg/mL
ANDA 71-755	Droperidol Injection USP, 2.5 mg/mL
ANDA 87-591	Hydroxyzine Hydrochloride Injection USP, 25 mg/mL
ANDA 87-593	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL
ANDA 87-595	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL
ANDA 88-239	Heparin Sodium Injection USP, 1,000 Units/mL
ANDA 88-457	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88-458	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88-459	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88-460	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88-517	Hydralazine Hydrochloride Injection USP, 20 mg/mL
ANDA 88-519	Phenytoin Sodium Injection USP, 50 mg/mL
ANDA 88-530	Procainamide Hydrochloride Injection USP, 100 mg/mL
ANDA 88-531	Procainamide Hydrochloride Injection USP, 500 mg/mL
ANDA 88-580	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88-581	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88-749	Aminophylline Injection USP, 25 mg/mL
ANDA 88-767	Fluorouracil Injection USP, 50 mg/mL
ANDA 88-960	Trimethobenzamide Hydrochloride Injection USP, 100 mg/mL

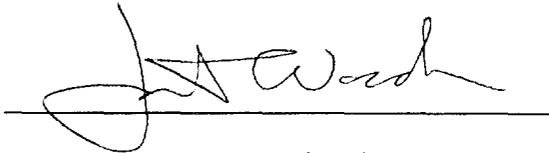
Application No.	Drug
ANDA 89-251	Prochlorperazine Edisylate Injection USP, 5mg/mL
ANDA 89-434	Flourouracil Injection USP, 50 mg/mL

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this

document, and all amendments and supplements thereto, is hereby withdrawn, effective (insert date 30 days after date of publication in the FEDERAL REGISTER).

Dated: 6/7/99

June 7, 1999



Janet Woodcock
Director
Center for Drug Evaluation and Research

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

