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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1498]

Lilly Research Laboratories et al.; Withdrawal of Approval of 28 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 28 new drug applications (NDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective September 30, 2000.

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: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

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Application No.	Drug	Applicant
NDA 4-038	Diethylstilbestrol (DES) Injection.	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 4-039	DES Tablets.	Do.
NDA 4-040	DES Suppository.	Do.
NDA 4-041	DES Tablets.	Do.
NDA 4-056	Stilbetin Tablets (Diethylstilbestrol Tablets USP).	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000.
NDA 6-327	Isuprel (Isoproterenol Hydrochloride) Inhalation Solution.	Sanofi-Synthelabo, Inc., 90 Park Ave., New York, NY 10016-1389.
NDA 7-371	Mecostrin Injection (Dimethyl Tubocurarine Chloride).	Bristol-Myers Squibb Co.
NDA 8-392	Nydrazid (Isoniazid USP) Tablets, Syrup, Capsules.	Do.
NDA 9-052	Rezipas (Aminosalicylic Acid Resin Powder).	Do.
NDA 9-273	Rauwolfia Serpentina, 50-milligram (mg) and 100-mg Tablets, 35-mg Capsule.	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
NDA 9-627	Reserpine, 0.1-mg, 0.25-mg, 0.5-mg, and 1-mg Tablets.	Do.
NDA 10-010	Stilphostrol (Diethylstilbestrol Diphosphate) Injection and Tablets.	Bayer Corp., 400 Morgan Lane, West Haven, CT 06516-4175.
NDA 10-347	Delalutin (Hydroxyprogesterone Caproate Injection USP).	Bristol-Myers Squibb Co.
NDA 11-359	Ora-testryl (Fluoxymesterone Tablets USP).	Do.
NDA 11-642	Cardioquin (Quinidine Polygalacturonate) 275-mg Tablets.	Purdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06850-3590.
NDA 11-745	Konakion (Phytonadione) Injection.	Hoffman-La Roche, Inc., 340 Kingsland St.,

		Nutley, NJ 07110.
NDA 12-248	Plegine (Phendimetrazine Tartate) Tablets.	Wyeth Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 12-339	Bronkometer (Isoetharine Mesylate Inhalation Aerosol) and Bronkosol (Isoetharine Hydrochloride Inhalation Solution).	Sanofi-Synthelabo, Inc.
NDA 16-911	Delalutin (Hydroxyprogesterone Caproate Injection USP).	Bristol-Myers Squibb Co.
NDA 17-424	Septisol Foam (Hexachlorophene).	Steris Corp., P.O. Box 147, St. Louis, MO 63166-0147.
NDA 18-672	Nitro IV 5 mg/milliliters (mL) Injection and Nitronal Injection.	G. Pohl-Boskamp GmbH & Co., Kieler Strasse 11, D-25551 Hohenlockstedt, Germany.
NDA 18-762	Brethaire (Terbutaline Sulfate) Inhalation Aerosol.	Novartis Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936-1080.
NDA 19-069	Mycelex (Clotrimazole) Vaginal Tablets.	Bayer Corp.
NDA 19-082	Dalgan (Dezocine) Injection, 5, 10, and 15 mg/mL.	AstraZeneca LP, 725 Chesterbrook Blvd., Wayne, PA 19087-5677.
NDA 19-174	Trandate HCT (Labetalol Hydrochloride/ Hydrochlorothiazide) Tablets.	Glaxo Wellcome, Inc., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 19-287	DIZAC (Diazepam Injectable Emulsion).	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001-0199.
NDA 20-559	Tritec (Ranitidine Bismuth Citrate) Tablets.	Glaxo Wellcome, Inc.
NDA 21-048	17-Estradiol Transdermal System.	R. W. Johnson Pharmaceutical Research Institute, 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869-0602.

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 September 30, 2000.

Dated: September 5, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00-23477-Filed 9-12-00; 8:45 am]
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