DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0336]

Schering Corp. et al.; Withdrawal of Approval of 51 New Drug Applications and 25 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 51 new drug applications (NDAs) and 25 abbreviated new drug applications (ANDAs). 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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 17, 2001.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, 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 requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 3–158	Oreton Methyl (methyltestosterone) Tablets, 10 milligrams (mg) and 25 mg.	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 5–963	Sodium Sulamyd (sulfacetamide sodium) Ophthalmic Solution and Ointment.	Do.
NDA 6–325	Tubocurarine Chloride Injection.	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 6–632	Metubine Iodide (metocurine iodide) Injection.	Do.
NDA 6–772	Vasoxyl (methoxamine hydrochloride (HCl)) Injection.	GlaxoSmithKline (GSK), P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709.
NDA 6–925	Nisentil (alphaprodine HCl) Injection.	Hoffman-LaRoche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 7–600	Surital (thiamylal sodium).	Parkdale Pharmaceuticals, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 8–200	Sodium Iodide I-131 Capsules, Solution, and Injection.	Syncor International Corp., 6464 Canoga Ave., Woodland Hills, CA 91367.
NDA 8–592	Ravocaine HCl (propoxycaine HCl and procaine HCl, with nordefrin or norepinephrine bitartrate).	Eastman Kodak Co., Health Imaging, 343 State St., Rochester, NY 14612–1122.
NDA 9–127	Cortril (hydrocortisone) Tablets.	Pfizer, Inc., 235 East 42d St., New York, NY 10017.
NDA 9–130	Cortril (hydrocortisone acetate) Ophthalmic Ointment.	Do.
NDA 9–238	Progesterone Injection.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 9–458	Cortisone Acetate Tablets, 25 mg.	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
NDA 9–996	Sterane (prednisolone) Tablets.	Pfizer, Inc.
NDA 10–423	Lorfan (levallorphan tartrate) Injection.	Hoffman-LaRoche, Inc.
NDA 10–554	Magnacort (hydrocortamate HCl) Topical Ointment.	Pfizer Pharmaceuticals, 235 East 42d St., New York, NY 10017.
NDA 11–539	Ultra-Feminine (Topical Liquid).	Coscelebre, Inc., 415 Madison Ave., New York, NY 10017.
NDA 11–557	Trilafon (perphenazine) Concentrate, 16 mg/5 mL (milliliters).	Schering Corp.
NDA 11–679	Pentothal Sodium (thiopental sodium) Suspension.	Abbott Laboratories, D–389, Bldg. AP30, 200 Abbott Park Rd., Abbott Park, IL 60064–6157.
NDA 12–148	Oreticyl Tablets and Oreticyle Forte (hydrochlorothiazide and deserpidine) Tablets.	Do.
NDA 12–715	Gantanol (sulfamethoxazole) Tablets.	Hoffman-LaRoche, Inc.

Application No.	Drug	Applicant
NDA 13–056	Penthrane (methoxyflurane) Inhalation Liquid.	Abbott Laboratories.
NDA 13–934	Stoxil (idoxuridine) Ophthalmic Solution, 0.1%.	SmithKline Beecham Pharmaceuticals, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101.
NDA 14–083	Apodol (anileridine HCl) Tablets.	Bristol-Myers Squibb, P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 14–087	Apodol (anileridine) Injection.	Do.
NDA 15–868	Stoxil (idoxuridine) Ophthalmic Ointment, 0.5%.	SmithKline Beecham Pharmaceuticals.
NDA 17–255	DTPA (chelate) Multidose (kit for the preparation of Tc-99m pentetate injection).	Nycomed Amersham Imaging, 101 Carnegie Center, Princeton, NJ 08540.
NDA 17–256	Xenon Xe-133.	Do.
NDA 17–257	Selenomethionine Se-75 Injection.	Do.
NDA 17–266	Technetium Tc-99m Sulfur Colloid Injection.	Do.
NDA 17–267	Sodium Pertechnetate Tc-99m Injection.	Do.
NDA 17–383	Methosarb (calusterone) Tablets.	The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001.
NDA 17–456	Technetium Tc–99m Sulfur Colloid.	Do.
NDA 17–483	Methadone HCl Bulk (methadone HCl).	Penick Corp., 158 Mount Olivet Ave., Newark, NJ 07114.
NDA 17–562	Technetium Tc-99m Diphosphonate Injection (Tin Kit).	Nycomed Amersham Imaging.
NDA 17–664	Sodium Polyphosphate Injection (Tin Kit).	Do.
NDA 17–667	Stannous Diphosphonate Injection.	Do.
NDA 18–228	Hypnomidate (etomidate) Injection.	Janssen Research Foundation, 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560.
NDA 18–289	Iodohippurate Sodium I-123.	Nycomed Amersham Imaging.
NDA 18–871	Protostat (metronidazole) Tablets.	R. W. Johnson Pharmaceutical Research Institute, Route 202 South, P.O. Box 300, Raritan, NJ 08869–0602.
NDA 19–450	Velosulin BR Human (semisynthetic purified human insulin) Injection.	Novo Nordisk Pharmaceuticals, Inc., 100 College Rd. West, Princeton, NJ 08540.
NDA 20–420	GenESA (arbutamine HCl) Injection.	Gensia Automedics, Inc., 9360 Towne Centre Dr., San Diego, CA 92121.
NDA 20–689	Posicor (miobefradil dihydrochloride) Oral Tablets, 50 mg and 100 mg.	Hoffmann-LaRoche, Inc.
ANDA 40–059	Fluocinolone Acetonide Topical Solution USP, 0.01%.	Bausch & Lomb Pharmaceuticals, Inc., 8500 Hidden River Pkwy., Tampa, FL 33637.
NDA 50–311	Rondomycin (methacycline HCl) Capsules.	Pfizer, Inc.
NDA 50–448	Grifulvin (griseofulvin) Oral Suspension.	Johnson & Johnson Consumer Products Co., 199 Grandview Rd., Skillman, NJ 8558–9418.
NDA 50–637	Zefazone (cefmetazole sodium) Sterile Powder.	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001.
NDA 50–683	Zefazone (cefmetazole sodium) Intraveous Solution.	Do.
ANDA 60–760	Oxytetracycline HCl Capsules, 250 mg.	Impax Laboratories, Inc.
ANDA 62–223	Totacillin (Ampicillin Trihydrate for Oral Suspension USP).	SmithKline Beecham Pharmaceuticals.
ANDA 62–736	Bactocill (oxacillin sodium) Injection.	GlaxoSmithKline (GSK).
ANDA 64–055	Neomycin Sulfate and Dexamethosone Sodium Phosphate Ophthalmic Solution	Bausch & Lomb Pharmaceuticals, Inc.

Application No.	Drug	Applicant
ANDA 74–813	Etoposide Injection 20 mg/mL.	Pierre Fabre Medicament, c/o Guidelines Integrated Service, 10320 USA Today Way, Miramar, FL 33062.
ANDA 80–079	Trisulfapyrimidines Tablets USP.	Impax Laboratories, Inc.
ANDA 80–151	Thyroglobulin Tablets USP.	Do.
ANDA 80–153	Isoniazid Tablets USP.	Do.
ANDA 80–281	Oreton Methyl Buccal Tablets (Methyltestosterone Tablets USP).	Schering Corp.
ANDA 80–780	Prednisolone Tablets USP, 5 mg.	Impax Laboratories, Inc.
ANDA 80–807	Diphenhydramine HCl Capsules USP, 25 mg and 50 mg.	Do.
ANDA 80–951	Ergocalciferol Capsules USP.	Do.
ANDA 80–952	Vitamin A Capsules USP.	Do.
ANDA 80–953	Vitamin A Capsules USP.	Do.
ANDA 80–955	Vitamin A Capsules USP.	Do.
ANDA 83–011	Hydrocortisone Cream USP, 1%.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
ANDA 83–347	Quinidine Sulfate Tablets USP, 200 mg.	Impax Laboratories, Inc.
ANDA 84–214	Promethazine HCl Tablets USP, 25 mg.	Do.
ANDA 84–340	Triamcinolone Tablets USP, 4 mg.	Do.
ANDA 84–575	Aminophylline Tablets USP, 200 mg.	Do.
ANDA 84–577	Aminophylline Tablets USP, 100 mg.	Do.
ANDA 85–098	Hydrocholorothiazide Tablets USP, 100 mg.	Do.
ANDA 85–563	Glycopyrrolate Tablets, 2 mg.	Circa, 130 Lincoln St., Copiague, NY 11726.
ANDA 86–639	Levsin PB (hyoscyamine sulfate and phenobarbital) Oral Solution.	Schwarz Pharma, Inc., P.O. Box 2038, Milwaukee, WI 53201.

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 17, 2001.

Dated: August 1, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–20605 Filed 8–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Biomedical Research Technology.

Date: October 22–23, 2001.

Time: October 22, 2001, 8:00 am to adjournment.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott, Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Mohan Viswanathan, Phd, Scientific Review Administrator, National Center for Research Resources, National Institutes of Health, Office of Review, 6705 Rockledge Drive, MSC 7965, One Rockledge Centre, Room 6018, Bethesda, MD 20892, (301) 435–0829, viswanathanm@ncrr.nih.gov

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)