(1) The resources requested are reasonable and adequate to accomplish the project.

(2) Total costs are reasonable and consistent with anticipated results.

2. Review and Selection Process

Initial OCS Screening

Each application submitted to OCS will be screened to determine whether it was received by the closing date and time.

Applications received by the closing date and time will be screened for completeness and conformity with the following requirements. Only complete applications that meet the requirements listed below will be reviewed and evaluated competitively. Other applications will be returned to the applicants with a notation that they were unacceptable and will not be reviewed.

All applications must comply with the following requirements except as noted:

OCS Evaluation of Applications

Applications that pass the initial OCS screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this program announcement. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application. The review panel awards points only to applications that are responsive to the program elements and relevant review criteria within the context of this program announcement.

The OCS Director and program staff use the reviewer scores when considering competing applications. Reviewer scores will weigh heavily in funding decisions, but will not be the only factors considered.

Applications generally will be considered in order of the average scores assigned by the review panel. Because other important factors are taken into consideration, highly ranked applications are not guaranteed funding. These other considerations include, for example: The timely and proper completion by the applicant of projects funded with OCS funds granted in the last five (5) years; comments of reviewers and government officials; staff evaluation and input; amount and duration of the grant requested and the proposed project's consistency and harmony with OCS goals and policy; geographic distribution of applications; previous program performance of applicants; compliance with grant terms under previous HHS grants, including the actual dedication to program of mobilized resources as set forth in project applications; audit reports; investigative reports; and applicant's progress in resolving any final audit disallowance on previous OCS or other Federal agency grants.

VI. Award Administration Information

1. Award Notices

Following approval of the application selected for funding, ACF will mail a written notice of project approval and authority to draw down project funds. The official award document is the Financial Assistance Award that specifies the amount of Federal funds approved for use in the project, the project and budget period for which support is provided and the terms and conditions of the award. The Financial Assistance Award is signed and issued via postal mail by an authorized Grants Officer.

ACF will notify unsuccessful applicants after the award is issued to the successful applicant.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental).

3. Reporting

All grantees are required to submit semi-annual program reports and semi-annual expenditure reports (SF–269) with final reports due 90 days after the project end date. A suggested format for the program report will be sent to all grantees after the awards are made.

VII. Agency Contacts

Program Office Contact

Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-mail: *OCS@lcgnet.com*, Phone: 1–800–281–9519.

Grants Management Office Contact

Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-mail: *OCS@lcgnet.com*, Phone: 1–800–281–9519.

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: *http://www.acf.hhs.gov/programs/ocs.*

Dated: April 28, 2004.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 04–10086 Filed 5–4–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0159]

Schering Corp. et al.; Withdrawal of Approval of 92 New Drug Applications and 49 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 92 new drug applications (NDAs) and 49 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: June 4, 2004

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 5–292	Estinyl (ethinyl estradiol) Tablets	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 5–795	Furacin (nitrofurazone)	Shire Pharmaceutical Development, Inc., 1801 Research Blvd., suite 600, Rockville, MD 20850
NDA 6–110	Dienestrol (dienestrol) Cream	Ortho-McNeil Pharmaceutical, Inc., c/o Johnson & Johnson Research & Development, L.L.C., 920 Highway 202, P.O. Box 300, Raritan, NJ 08869#ndash;0602
NDA 6–800	Paradione (paramethadione)	Abbott Laboratories, D-491/AP30–1E, 200 Abbott Park Rd., Abbott Park, IL 60064–6157
NDA 7–110	Cortone Acetate (cortisone acetate injectable suspension USP) Injectable Suspension	Merck & Co., Inc., Sumneytown Pike, BLA–20, P.O. Box 4, West Point, PA 19486
NDA 7–707	Phenurone (phenacemide) Tablets	Abbott Laboratories
NDA 7–750	Cortone Acetate (cortisone acetate tablet USP) Tablets	Merck & Co., Inc.
NDA 8–328	Spectrocin	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000
NDA 8–604	Phenergan VC Syrup (promethazine hydrochloride (HCl) and phenylephrine HCl) and Phenergan Expectorant (promethazine HCl, ipecac, and potassium guaiacolsulfonate)	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 8–857	Phenergan Injection (promethazine HCl)	Do.
NDA 9–298	Amm-I-Dent (sodium lauroyl sarcosinate/urea/ammonium phosphate) Toothpaste and Tooth Powder	Block Drug Co., Inc., 257 Cornelison Ave., Jersey City, NJ 07302
NDA 10–039	Avlosulfon (dapsone) Tablets	Wyeth Pharmaceuticals
NDA 10–727	Peri-Colace Capsules (30 milligrams (mg) casanthranol/100 mg docusate sodium) and Syrup (30 mg casanthranol/60 mg docusate sodium per 15 milliliters (mL))	Shire Pharmaceutical Development, Inc.
NDA 10–775	Trilafon (perphenazine) Tablets	Schering Corp.
NDA 10–858	Enzactin (triacetin) Cream	Wyeth Consumer Healthcare, Five Giralda Farms, Madison, NJ 07940–0871
NDA 10–971	PMB (conjugated estrogens USP with meprobamate) Tablets	Wyeth Pharmaceuticals
NDA 11–140	Enzactin (triacetin) Powder	Wyeth Consumer Healthcare
NDA 11–460	Lanesta (chlorindanol) Vaginal Gel	Sanofi-Synphelabo, Inc., 90 Park Ave., New York, NY 10016
NDA 11–860	Humorsol (demecarium bromide) Ophthalmic Solution	Merck & Co., Inc.
NDA 11–977	Decadron Ophthalmic Ointment (dexamethasone sodium phosphate ophthalmic ointment)	Do.
NDA 12–052	Hydrocortone (hydrocortisone sodium phosphate injection USP) Injection, 50 mg/mL	Do.
NDA 12–071	Decadron (dexamethasone sodium phosphate injection USP) Injection, 4 mg/mL and 24 mg/mL	Do.
NDA 12–095	Orinase (sterile tolbutamide sodium) Diagnostic Sterile Powder for Injection	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199

Application No.	Drug	Applicant
NDA 12–283	Hygroton (chlorthalidone) Tablets, 25 mg, 50 mg, and 100 mg	Aventis Pharmaceuticals, Inc., Mail Stop BX2 - 209G, 200 Crossing Blvd., Bridgewater, NJ 08807–0890
NDA 12–359	Salutensin and Salutensin-DEMI (hydroflumethiazide and reserpine) Tablets	Shire Laboratories, Inc., c/o Shire Pharmaceutical Development, Inc., 1801 Research Blvd., suite 600, Rockville, MD 20850
NDA 12–376	Decadron (dexamethasone) Elixir, 0.5 mg/5 mL	Merck & Co. Inc.
NDA 12–594	Metahydrin (trichlormethiazide) Tablets, 2 mg and 4 mg	Aventis Pharmaceuticals, Inc.
NDA 12–657	Celestone (betamethasone tablets USP) Tablets	Schering Corp.
NDA 12–972	Metatensin (trichlormethiazide and reserpine) Tablets, 2 mg/0.1 mg and 4 mg/0.1 mg	Aventis Pharmaceuticals, Inc.
NDA 14–116	Johnson #Johnson First Aid Spray (dequainium acetate and cetylpyridinium chloride)	Johnson & Johnson Consumer Products Co., 199 Grandview Rd., Sillman, NJ 08558
NDA 14–122	Protopam (pralidoxime chloride) Tablets	Wyeth Pharmaceuticals
NDA 14–127	Xylocaine (lidocaine) 5% Solution	AstraZeneca LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355
NDA 14–713	Etrafon (perphenazine and amitriptyline HCl) and Etrafon Forte Tablets	Schering Corp.
NDA 15–103	Regroton (chlorthalidone, 50 mg and reserpine, 0.25 mg) and Demi-Regroton (chlorthalidone, 25 mg and reserpine, 0.125 mg) Tablets	Aventis Pharmaceuticals, Inc.
NDA 16–034	Vontrol (diphenidol HCl) Injection	GlaxoSmithKline, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101–7929
NDA 16–035	Vontrol (diphenidol pamoate) Suspension	Do.
NDA 16–036	Vontrol (diphenidol) Suppositories	Do.
NDA 16–087	Valium (diazepam) Injection	Roche Laboratories, Inc., 340 Kingsland St., Nutley, NJ 07110–1199
NDA 16–110	Prolixin (fluphenazine enanthate) Injection, 25 mg/mL	Apothecon, c/o Bristol-Myers Co., P.O. Box 4500, Princeton, NJ 08543–4500
NDA 16–618	Pondimin (fenfluramine HCl) Tablets and Ponderex (fenfluramine HCl) Capsules	A.H. Robins Co., c/o Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 16–647	Quinaglute (quinidine gluconate) Dura-Tabs	Berlex Laboratories, Inc., 340 Changebridge Rd., P.O. Box 1000, Montville, NJ 07045–1000
NDA 16–786	Ovral 28 (norgestrel/ethinyl estradiol) and Ferrous Fumarate Tablets	Wyeth Pharmaceuticals
NDA 16–803	Bronkaid (epinephrine inhalation aerosol) Mist	Bayer Consumer Care Division, 36 Columbia Rd., P.O. Box 1910, Morristown, NJ 07962–1910
NDA 16–849	Selsun Blue Shampoo	Ross Laboratories, 625 Cleveland Ave., Columbus, OH 43215–1754
NDA 16–883	Antiminth (pyrantel pamoate) Oral Suspension	Pfizer Consumer Healthcare, 201 Tabor Rd., Morris Plains, NJ 07950
NDA 16–912	Larodopa (levadopa) Tablets and Capsules	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199

Application No.	Drug	Applicant
NDA 16–985	Gleem (sodium fluoride) Dentrifice	Proctor & Gamble Pharmaceuticals, Inc., Oral Care Products Division, 8700 Mason-Montgomery Rd., Mason, OH 45040
NDA 17–020	Panwarfin (warfarin sodium tablets USP) Tablets, 2 mg, 2.5 mg, 5 mg, 7.5 mg, 10 mg, and 25 mg	Abbott Laboratories
NDA 17–389	Dial 2 (pyrithione zinc) Dandruff Shampoo	Armour-Dial, Inc., 15101 N. Scottsdale Rd., Scottsdale, AZ 85260
NDA 17–535	Lorelco (probucol) Tablets	Aventis Pharmaceuticals, Inc.
NDA 17–536	Diprosone (betamethasone dipropionate) Cream, 0.05%	Schering Corp.
NDA 17–684	Pyrolite (technetium Tc-99m pyro- and trimeta-phosphates kit)	CIS-US, Inc., 10 De Angelo Dr., Bedford, MA 01730
NDA 17–710	Nalfon (fenoprofen calcium) Tablets	Dista Products Ltd., c/o Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 17–736	Paxipam (halazepam) Tablets, 20 mg and 40 mg	Schering Corp.
NDA 17–853	Proventil (albuterol sulfate) Tablets, 2 mg and 4 mg	Do.
NDA 17–895	Janimine (imipramine HCl) Tablets	Abbott Laboratories
NDA 17–952	Trimpex (trimethoprim) Tablets	Hoffman-La Roche, Inc.
NDA 18–306	NasalCrom (cromolyn sodium) Nasal Solution	Pharmacia Consumer Healthcare, 100 Route 206 North, Peapack, NJ 07977
NDA 18–521	Vancenase (beclomethasone dipropionate) Nasal Inhaler	Schering Corp.
NDA 18–584	Beconase (beclomethasone dipropionate) Inhalation Aerosol	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709
NDA 18–587	Wytensin (guanabenz acetate) Tablets, 4 mg, 8 mg, and 16 mg	Wyeth Pharmaceuticals
NDA 18–592	Monistat 5 (miconazole nitrate) Tampons, 100 mg	Personal Products Co., 199 Grandview Rd., Skillman, NJ 08558
NDA 19–059	Inderide LA (propranolol HCl and hydrochlorothiazide) Capsules, 80 mg/50 mg, 120 mg/50 mg, and 160 mg/50 mg	Ayerst Pharmaceuticals, c/o Wyeth Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 19–279	Dimetane DX (brompheniramine maleate/ pseudoephedrine HCl/dextromethorphan HBr) Cough Syrup	A.H. Robins Co., c/o Wyeth Pharmaceuticals
NDA 19–428	Pseudoephedrine HCl and Chlorpheniramine Maleate Extended-Release Capsules	Central Pharmaceuticals, c/o Schwarz Pharma, Inc., P.O. Box 2038, Milwaukee, WI 53201
NDA 19–757	Chibroxin (norfloxacin) Sterile Ophthalmic Solution, 0.3%	Merck &Co., Inc.
NDA 19–858	Cipro (ciprofloxacin) in Sodium Chloride	Bayer Corp.
NDA 20–055	Glyburide (micronized) Tablets	Aventis Pharmaceuticals, Inc.
NDA 20–058	Thioplex (thiotepa) For Injection)	Immunex Corp., 51 University St., Seattle, WA 98101–2936
NDA 20–135	Motrin (ibuprofen) Chewable Tablets	McNeil Consumer & Specialty Pharmaceuticals, 7050 Camp Hill Rd., Fort Washington, PA 19034–2299

Application No.	Drug	Applicant
NDA 20–233	Rhinocort (budesomide) Nasal Inhaler	AstraZeneca LP
NDA 20–240	Renormax (spirapril HCl) Tablets, 3 mg, 6 mg, 12 mg, and 24 mg	Schering Corp.
NDA 20–418	Motrin (ibuprofen) Caplets	McNeil Consumer & Specialty Pharmaceuticals
NDA 20–469	Vancenase AQ (beclomethasone dipropionate monohydrate) Nasal Spray	Schering Corp.
NDA 20–476	Motrin (ibuprofen) Oral Drops	McNeil Consumer &Specialty Pharmaceuticals
NDA 20–874	Lunelle (estradiol cypionate and medroxyprogesterone acetate) Injection	Pharmacia Corp., c/o Pfizer Pharmaceuticals Group, 235 E. 42d St., New York, NY 10017–5755
NDA 20–951	Tagamet HB (cimetidine) Suspension	GlaxoSmithKline Consumer Healthcare LP, 1500 Littleton Rd., Parsippany, NJ 07054–3884
NDA 50–012	Garamycin (gentamicin sulfate injection USP) Injectable	Schering Corp.
NDA 50–051	Grisactin (griseofulvin, microcrystalline) Capsules	Wyeth Pharmaceuticals
NDA 50–092	Pathocil (dicloxacillin sodium) for Suspension	Do.
NDA 50–094	Erythrocin (erythromycin) Suppositories	Abbott Laboratories
NDA 50–111	Unipen (nafcillin sodium) Capsules	Wyeth Pharmaceuticals
NDA 50–262	Declomycin (demeclocycline HCl) Capsules	Lederle Laboratories, c/o Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 50–273	Achromycin (tetracycline HCl) Intravenous Injection	Do.
NDA 50–276	Achromycin (tetracyclilne HCl and procaine HCl) Sterile Intramuscular Injection	Do.
NDA 50–296	Erythrocin Suspension	Abbott Laboratories
NDA 50–324	Neodecadron (neomycin sulfate and dexamethasone sodium phosphate) Ophthalmic Ointment	Merck Research Laboratories, Sumneytown Pike, P.O. Box 4, BLA-20, West Point, PA 19486–0004
NDA 50–341	Fungizone (amphotericin B) Oral Suspension	Bristol-Myers Squibb Co.
NDA 50–425	Garamycin (gentamicin sulfate) Ophthalmic Ointment	Schering Corp.
NDA 50–439	Erythrocin (erythromycin stearate)	Abbott Laboratories
NDA 50–482	Keflin (cephalothin sodium) for Injection	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285
NDA 50–744	Periostat (doxycycline hyclate USP) Capsules, 20 mg	CollaGenex Pharmaceuticals, Inc., 301 South State St., Newtown, PA 18940
ANDA 60–006	Pen-Vee K (penicillin V potassium) Tablets, 125 mg, 250 mg, and 500 mg (base)	Wyeth Pharmaceuticals
ANDA 60–611	Neomycin Sulfate and Methylprednisolone Acetate Topical Cream	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001
ANDA 60–624	Omnipen (ampicillin) Capsules, 250 mg and 500 mg	Wyeth Pharmaceuticals
ANDA 62–178	Grisactin Ultra (griseofulvin, ultramicro crystalline) Tablets, 125 mg and 250 mg	Do.

Application No.	Drug	Applicant
ANDA 62–438	Grisactin Ultra (griseofulvin, ultramicro crystalline) Tablets, 165 mg and 330 mg	Do.
ANDA 62–549	Keflin (cephalothin sodium for injection USP), 1 g and 2 g	Lilly Research Laboratories
ANDA 62–690	Ticar (ticarcillin disodium) Injection, 3 g	GlaxoSmithKline
ANDA 62–905	Clindamycin Phosphate Injection USP, 150 mg/mL	Loch Pharmaceuticals, c/o Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146
ANDA 63–087	Lincomycin HCl USP	Abbott Laboratories
ANDA 63–321	Vancoled (vancomycin HCl for oral solution USP)	Lederle Laboratories, c/o Wyeth Pharmaceuticals
ANDA 70–188	Naloxone HCl Injection USP, 0.02 mg/mL	Wyeth Pharmaceuticals
ANDA 70–189	Naloxone HCl Injection USP, 0.02 mg/mL	Do.
ANDA 70–190	Naloxone HCl Injection USP, 0.4 mg/mL	Do.
ANDA 70–191	Naloxone HCl Injection USP, 0.4 mg/mL	Do.
ANDA 70–480	Leucovorin Calcium for Injection, 50 mg	Elkins Sinn, c/o Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
ANDA 70–917	Nalbuphine HCl Injection, 20 mg/mL	Abbott Laboratories
ANDA 72–639	Metoclopramide HCl Tablets USP, 10 mg	Clonmel Healthcare Ltd., c/o STADA Pharmaceuticals Inc., U.S. Agent, 5 Cedar Brook Dr., Cranbury, NJ 08512
ANDA 74–051	Diltiazem HCl Tablets USP, 30 mg, 60 mg, 90 mg, and 120 mg	Apothecon, c/o Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
ANDA 74–211	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216
ANDA 74–257	Naproxen Sodium Tablets USP	Do.
ANDA 80–454	Meperidine HCl Tablets USP, 50 mg	Do.
ANDA 80–553	Thiamine HCl Injection USP, 100 mg/mL	Do.
ANDA 80–554	Cyanocobalamin Injection USP	Do.
ANDA 80–577	Diphenhydramine HCl Injection USP, 50 mg/mL	Do.
ANDA 81–224	Leucovorin Calcium for Injection, 100 mg	Elkins Sinn, c/o Wyeth Pharmaceuticals
ANDA 81–239	Cycrin (medroxyprogesterone acetate) Tablets USP, 2.5 mg	Do.
ANDA 81–240	Cycrin (medroxyprogesterone) Tablets USP, 5 mg	Do.
ANDA 83–159	Calcium Gluceptate Injection	Abbott Laboratories
ANDA 83–262	Secobarbital Sodium Injection USP, 50 mg/mL	Wyeth Pharmaceuticals
ANDA 83–640	Quinidine Sulfate Tablets USP, 200 mg	Roxane Laboratories, Inc.
ANDA 84–316	Dimenhydrinate Injection USP, 50 mg	Wyeth Pharmaceuticals
ANDA 84–386	Digoxin Injection USP, 500 micrograms/2 mL	Do.
ANDA 84–445	Phenaphen with Codeine (acetaminophen and codeine phosphate capsules USP) No. 3 Capsules	A. H. Robins Co.

Application No.	Drug	Applicant
ANDA 84–446	Phenaphen with Codeine (acetaminophen and codeine phosphate capsules USP) No. 4 Capsules	Do.
ANDA 85–328	Theo-Dur (theophylline) Extended-Release Tablets, 100 mg and 300 mg	Schering Corp.
ANDA 85–632	Quinidine Sulfate Tablets USP, 300 mg	Roxane Laboratories, Inc.
ANDA 86–134	Nitro-Bid Ointment (nitroglycerin ointment USP, 2%)	Altana Inc., 60 Baylis Rd., Melville, NY 11747
ANDA 86–348	Prochlorperazine Edisylate Injection USP, 5 mg (base)/mL	Wyeth Pharmaceuticals
ANDA 86–998	Theo-Dur (theophylline) Extended-Release Tablets, 200 mg	Schering Corp.
ANDA 88–584	DHCplus (dihydrocodeine bitartrate, acetaminophen, and caffeine) Capsules, 356.4 mg	Purdue Frederick Co., One Stamford Forum, Stamford, CT 06901–3431
ANDA 89–116	Brompheril (dexbrompheniramine maleate/pseudoephedrine sulfate) Extended-Release Tablets, 6 mg/120 mg	Copley Pharmaceuticals, Inc., c/o Teva Pharmaceuticals, 1090 Horsham Rd., North Wales, PA 19454
ANDA 89–131	Theo-Dur (theophylline) Extended-Release Tablets, 450 mg	Schering Corp.
ANDA 89–386	Cycrin (medroxyprogesterone acetate) Tablets, 10 mg	Wyeth Pharmaceuticals
ANDA 89–573	Methylprednisolone Sodium Succinate for Injection USP, 40 mg	Abbott Laboratories
ANDA 89–574	Methylprednisolone Sodium Succinate for Injection USP, 125 mg	Do.
ANDA 89–575	Methylprednisolone Sodium Succinate for Injection USP, 500 mg	Do.
ANDA 89–576	Methylprednisolone Sodium Succinate for Injection USP, 1000 mg	Do.
ANDA 89–822	Uni-Dur (theophylline) Extended-Release Tablets, 400 mg	Schering Corp.
ANDA 89–823	Uni-Dur (theophylline) Extended-Release Tablets, 600 mg	Do.

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 by the Commissioner, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 4, 2004.

Dated: March 22, 2004.

Steven K. Galson,

Acting Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 04–10194 Filed 5–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004D–0187, 2004D–0188, and 2004D–0189]

Draft Guidances for Industry on Premarketing Risk Assessment; Development and Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three draft guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' All are dated May 2004. These draft guidances provide guidance to industry on risk management activities for drug products, including biological drug products, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The draft guidances address, respectively, premarket risk assessment; the development, implementation, and evaluation of risk minimization action plans for drug products; and good pharmacovigilance practices and pharmacoepidemiologic assessment of observational data.