

or her records or otherwise provide enough information to enable the identification of the individual's record; (3) identify the information that the individual believes is not accurate, relevant, timely or complete; (4) indicate what corrective action is sought; and (5) include supporting justification or documentation for the requested amendment. Verification of identity as described in the Department's Privacy Act regulations may be required. 45 CFR 5b.5.

RECORD SOURCE CATEGORIES:

Information is obtained from individuals and organizations, including third parties conducting business on behalf of a business or organization, that apply for access privileges to the FPLS Child Support Services Portal and its services.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2010-17738 Filed 7-20-10; 8:45 am]

BILLING CODE 4184-42-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Safety and Occupational Health Study Section, Centers for Disease Control and

Prevention, Department of Health and Human Services, has been renewed for a 2-year period through June 30, 2012.

FOR FURTHER INFORMATION CONTACT: Price Connor, PhD, Executive Secretary, Safety and Occupational Health Study Section, Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop E74, Atlanta, Georgia 30333, telephone 404/498-2511 or fax 404/498-2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 13, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-17759 Filed 7-20-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0318]

Novartis Pharmaceuticals Corp. et al.; Withdrawal of Approval of 27 New Drug Applications and 58 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 27 new drug applications (NDAs) and 58 abbreviated new drug applications (ANDAs) from multiple applicants. 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 Date:* August 20, 2010.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 of this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications pursuant to the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1.

Application No.	Drug	Applicant
NDA 6-008	Mesantoin (mephenytoin) Tablets	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936-1080
NDA 9-000	Cafergot (ergotamine tartrate and caffeine) Suppository, 1 milligram (mg)/100 mg and 2 mg/100 mg	Do.
NDA 9-561	Hypaque (diatrizoate sodium)	GE Healthcare, Inc., 101 Carnegie Center, Princeton, NJ 08540
NDA 9-658	Hydrocortisone Tablets	Smith, Miller and Patch, Inc., Division of Cooper Vision, Inc., c/o Cooper Laboratories, Inc., 455 E. Middlefield Rd., Mountain View, CA 94043
NDA 9-942	Deltra (prednisone) Tablets	Merck & Co., Inc., P.O. Box 4, BLA-20, West Point, PA 19486-0004
NDA 10-051	Hydeltra (prednisolone) Tablets	Do.
NDA 10-255	Meticortelone (prednisolone acetate) Injection and Suspension	Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033
NDA 12-885	Winstrol (stanozolol) Tablets, 2 mg	Lundbeck, Inc., Four Parkway North, Deerfield, IL 60015
NDA 13-428	Valpin (anisotropine methylbromide) Tablets	Endo Pharmaceuticals, 100 Endo Blvd., Chadds Ford, PA 19317

TABLE 1.—Continued

Application No.	Drug	Applicant
NDA 16–023	Symmetrel (amantadine hydrochloride (HCl) USP) Syrup	Do.
NDA 16–119	Teslac (testolactone) Injection, 100 mg/milliliter (mL)	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000
NDA 16–403	Hypaque-Cysto (diatrizoate meglumine) and Hypaque (diatrizoate meglumine)	GE Healthcare, Inc.
NDA 16–636	Narcar (naloxone HCl) Injection	Endo Pharmaceuticals
NDA 16–769	Urispas (flavoxate HCl) Tablets, 100 mg	Ortho-McNeil-Janssen Pharmaceutical, Inc., 1000 U.S. Highway 202, P.O. Box 3000, Raritan, NJ 08869–0602
NDA 17–022	Methotrexate Tablets	Lederle Laboratories, A Division of American Cyanamid Co., 401 N. Middletown Rd., Pearl River, NY 10965
NDA 17–118	Symmetrel (amantadine HCl USP) Syrup	Endo Pharmaceuticals
NDA 17–255	MPI DTPA Chelate multidose (kit for the preparation of technetium Tc-99m pentetate injection)	Medi-Physics, Inc., d/b/a GE Healthcare, Inc., 101 Carnegie Center, Princeton, NJ 08540
NDA 17–264	Technetium Tc-99m pentetate kit	Do.
NDA 17–559	Proventil (albuterol USP) Inhalation Aerosol	Schering Corp.
NDA 17–984	Valcaps (diazepam) Capsules	Hoffmann-LaRoche, Inc., Roche Pharmaceuticals, 340 Kingsland St., Nutley, NJ 07110–1199
NDA 18–101	Symmetrel (amantadine HCl USP) Tablets	Endo Pharmaceuticals
NDA 18–445	Dolobid (diflunisal) Tablets, 250 mg and 500 mg	Merck & Co., Inc.
ANDA 18–551	Potassium Iodide Oral Solution USP, 1 gram (g)/mL	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228
NDA 18–706	Hydergine LC (ergoloid mesylates) Capsules	Novartis Pharmaceuticals Corp.
NDA 18–746	Vasocon-A (antazoline phosphate, 0.5% and naphazoline HCl, 0.05%) Ophthalmic Solution	Do.
ANDA 18–750	Furosemide Tablets, 40 mg	Sandoz, Inc., 4700 Sandoz Dr., Wilson, NC 27893
NDA 19–309	Vasotec (enalaprilat) Injection	Biovail Laboratories International SRL, c/o Biovail Technologies Ltd., 700 Route 202/206 North, Bridgewater, NJ 08807
NDA 21–007	Agenerase (amprenavir), 50 mg and 150 mg	GlaxoSmithKline, One Franklin Plaza, 200 North 16th St., Philadelphia, PA 19102
NDA 21–039	Agenerase (amprenavir) Oral Solution, 15 mg/mL	Do.
ANDA 40–149	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/500 mg and 7.5 mg/750 mg	Sandoz, Inc.
ANDA 40–312	Innofem (estradiol tablets USP), 0.5 mg, 1 mg, and 2 mg	Novo Nordisk, Inc., 100 College Rd. West, Princeton, NJ 08540
ANDA 60–568	Urobiotic (oxytetracycline HCl, sulfamethizole, phenazopyridine HCl) Capsules	Pfizer Inc., 235 East 42nd St., New York, NY 10017
ANDA 61–016	Terra-Cortril (hydrocortisone acetate and oxytetracycline HCl)	Do.
ANDA 61–410	Veetids (penicillin V potassium for Oral Solution USP), 125 mg/5 mL and 250 mg/5 mL	Apothecon, c/o Bristol-Myers Squibb, P.O. Box 4000, Princeton, NJ 08543
ANDA 61–471	Tetracycline HCl Capsules, 250 mg	Sandoz, Inc.
ANDA 61–781	Erythromycin Stearate Tablets, 250 mg	Do.
ANDA 61–965	Nystatin Vaginal Tablets, 100,000 Units	Do.
ANDA 62–014	Oxytetracycline Capsules, 250 mg	Do.
ANDA 62–065	Nystatin Tablets, 500,000 Units	Do.

TABLE 1.—Continued

Application No.	Drug	Applicant
ANDA 62–590	Kefurox (cefuroxime for injection USP), 750 mg/vial and 1.5 g/vial	Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285
ANDA 62–592	Kefurox (cefuroxime for injection USP), 750 mg/vial and 1.5 g/vial	Do.
ANDA 64–033	Cefazolin Sodium ADD-Vantage Powder for Injection Solution	GlaxoSmithKline, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101–7929
ANDA 65–210	Clarithromycin Extended-Release Tablets, 1,000 mg	Ranbaxy, Inc., U.S. Agent for Ranbaxy Laboratories Limited, 600 College Rd. East, Princeton, NJ 08540
ANDA 73–696	Nitrofurantoin Capsules USP, 25 mg, 50 mg, and 100 mg	Watson Laboratories, Inc., P.O. Box 450 39 Mt. Ebo Rd. South, Brewster, NY 10509
ANDA 74–648	Lorazepam Oral Solution, 0.5 mg/5 mL	Roxane Laboratories, Inc.
ANDA 74–764	Ranitidine Injection USP	Bedford Laboratories, A division of Ben Venue Laboratories, Inc., 300 Northfield Rd., Bedford, OH 44146
ANDA 75–170	Butorphanol Tartrate Injection USP, 1 mg/mL and 2 mg/mL	Hospira, Inc., 275 N. Field Dr., Dept. 0389, Bldg. H2, Lake Forest, IL 60045–5046
ANDA 76–027	Tamoxifen Citrate Tablets USP, 10 mg and 20 mg	Roxane Laboratories, Inc.
ANDA 76–605	Gabapentin Tablets USP, 600 mg and 800 mg	Do.
ANDA 76–643	Carbidopa and Levodopa Tablets for Oral Suspension, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg	Do.
ANDA 76–663	Carbidopa and Levodopa Extended-Release Tablets, 50 mg/200 mg	KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144
ANDA 77–366	Glimepiride Tablets USP, 3 mg and 6 mg	Ranbaxy Inc.
ANDA 81–096	Acetaminophen, Aspirin, and Codeine Phosphate Capsules, 150 mg/180 mg/30 mg	Mikart, Inc., 1750 Chattahoochee Ave., NW, Atlanta, GA 30318
ANDA 81–097	Acetaminophen, Aspirin, and Codeine Phosphate Capsules, 150 mg/180 mg/60 mg	Do.
ANDA 81–226	Hydrocodone Bitartrate and Acetaminophen Oral Solution, 5 mg/500 mg/15 mL	Do.
ANDA 83–902	Dexedrine (dextroamphetamine sulfate), 5 mg/mL	GlaxoSmithKline, Research Triangle Park, NC 27709–3398
ANDA 84–353	Bethanechol Chloride Tablets, 5 mg	Do.
ANDA 84–378	Bethanechol Chloride Tablets, 10 mg (Blue)	Do.
ANDA 84–379	Bethanechol Chloride Tablets, 10 mg (Pink)	Do.
ANDA 84–383	Bethanechol Chloride Tablets, 25 mg (Yellow)	Do.
ANDA 84–384	Bethanechol Chloride Tablets, 25 mg	Do.
ANDA 84–617	Hydralazine HCl and Reserpine Tablets, 25 mg/0.1 mg	Do.
ANDA 84–773	Prednisolone Tablets, 5 mg	Do.
ANDA 84–774	Prednisone Tablets, 5 mg	Do.
ANDA 84–869	Imipramine HCl Tablets, 25 mg	Do.
ANDA 84–876	Hydrochlorothiazide, Reserpine, and Hydralazine HCl Tablets, 15 mg/0.1 mg/25 mg	Do.
ANDA 84–935	Dexedrine (dextroamphetamine sulfate) Tablets	GlaxoSmithKline, Research Triangle Park, NC 27709–3398
ANDA 84–956	Hydralazine HCl Tablets, 25 mg	Sandoz, Inc.

TABLE 1.—Continued

Application No.	Drug	Applicant
ANDA 85–088	Hydralazine HCl Tablets, 50 mg	Do.
ANDA 85–146	Promethazine HCl Tablets, 25 mg and 50 mg	Do.
ANDA 85–934	Butabarbital Sodium Tablets, 30 mg	Do.
ANDA 85–938	Butabarbital Sodium Tablets, 15 mg	Do.
ANDA 86–171	Trichlormethiazide Tablets, 4 mg	Do.
ANDA 86–505	Hypaque-76 (diatrizoate meglumine and diatrizoate sodium injection USP)	GE Healthcare, Inc.
ANDA 87–118	Chlorthalidone Tablets, 50 mg	Sandoz, Inc.
ANDA 87–282	Methocarbamol Tablets, 750 mg	Do.
ANDA 87–283	Methocarbamol Tablets, 500 mg	Do.
ANDA 87–449	Theophylline Oral Solution, 80 mg/15 mL	Roxane Laboratories, Inc.
ANDA 87–462	Theophylline Extended-Release Capsules, 260 mg	Sandoz, Inc.
ANDA 88–157	Chlorpromazine HCl Intensol (chlorpromazine HCl oral concentrate USP), 30 mg/mL	Roxane Laboratories, Inc.
ANDA 88–158	Chlorpromazine HCl Intensol (chlorpromazine HCl oral concentrate USP), 100 mg/mL	Do.
ANDA 88–193	Triprolidine HCl and Pseudoephedrine HCl Tablets, 2.5 mg/60 mg	Sandoz, Inc.
ANDA 88–587	Hydrochlorothiazide Oral Solution	Roxane Laboratories, Inc.
ANDA 89–127	Mepro-Aspirin (aspirin and meprobamate) Tablets, 325 mg/200 mg	Sandoz, Inc.
ANDA 89–508	Fluorouracil Injection USP, 50 mg/mL	Bedford Laboratories

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the 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 table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective August 20, 2010. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 in this document that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 15, 2010.

Douglas C. Throckmorton,
Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 2010–17785 Filed 7–20–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1907–DR; Docket ID FEMA–2010–0002]

North Dakota; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of North Dakota (FEMA–1907–DR), dated April 30, 2010, and related determinations.

DATES: *Effective Date:* July 15, 2010.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective July 15, 2010.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance