

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 (mephentyoin) 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 | Sadoz, 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 | Tripolidine 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