and resultant under-utilization; *Form Number:* CMS–R–52 (OMB#: 0938–0386); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profit and Federal government; *Number of Respondents:* 4,757; *Total Annual Responses:* 4,757; *Total Annual Hours:* 160,702.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: June 9, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–9479 Filed 6–15–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0222]

Merck & Co., Inc., et al.; Withdrawal of Approval of 65 New Drug Applications and 52 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 65 new drug applications (NDAs) and 52 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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 June 16, 2006.

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 1–645	Vitamin B6 (pyridoxine hydrochloride (HCl))	Merck & Co., Inc., 770 Sumneytown Pike, P.O. Box 4, BLA–20, West Point, PA 19486–0004
NDA 5–521	Heparin Sodium Injection USP	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 5–657	Tubocurarine Chloride Injection USP	Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
NDA 5–794	Sultrin Triple Sulfa Cream and Triple Sulfa Tablets	Ortho-McNeil Pharmaceutical, Inc., 1000 U.S. Highway 202, P.O. Box 300, Raritan, NJ 08869–0602
NDA 6–012	Folvron (folic acid and iron)	Lederle Laboratories, 401 North Middleton Rd., Pearl River, NY 10965
NDA 7–149	Rubramin (cyanocobalamin) Tablets and Capsules	Bristol-Myers Squibb Co.
NDA 7–504	Acthar (corticotropin for injection)	Aventis Pharmaceuticals, Inc., 200 Crossing Blvd., BX 2–309E, Bridgewater, NJ 08807
NDA 7–794	Neothylline (dyphylline)	Teva Pharmaceuticals USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454
NDA 9–176	Cortril (hydrocortisone) Topical Ointment	Pfizer Global Pharmaceuticals, 235 East 42nd St., New York, NY 10017
NDA 10–028	Equanil (meprobamate) Tablets	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 10–093	Biphetamine (dextroamphetamine and amphetamine) Capsules	Celltech Pharmaceuticals, Inc., 755 Jefferson Rd., P.O. Box 31710, Rochester, NY 14603
NDA 10–513	Ketonil (amino acids and electrolytes)	Merck & Co., Inc.
NDA 10–787	Iron Dextran Injection	Aventis Pharmaceuticals, Inc.
NDA 10–799	Dimetane (brompheniramine maleate) Tablets and Extendtabs	Wyeth Consumer Healthcare, 5 Giralda Farms, Madison, NJ 07940
NDA 11–340	Cerumenex (triethanolamine polypeptide oleate-condensate), 10%	The Purdue Frederick Co., 1 Stamford Forum, Stamford, CT 06901–3431

Application No.	Drug	Applicant
NDA 11–960	Aristocort (triamcinolone diacetate) Syrup	Astellas Pharma US, Inc., 3 Parkway North, Deerfield, IL 60015–2548
NDA 11–984	Decadron Phosphate (dexamethasone sodium phosphate) Sterile Ophthalmic Solution	Merck & Co., Inc.
NDA 12–122	Glucagon (glucagon HCl) for Injection	Eli Lilly & Co.
NDA 12–281	Robaxisal (methocarbamol USP and aspirin USP) Tablets	A.H. Robins Co., c/o Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 12–649	Periactin (cyproheptadine HCl)	Merck & Co., Inc.
NDA 12–703	Elavil (amitriptyline HCl) Tablets	AstraZeneca Pharmaceuticals, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355
NDA 12–704	Elavil (amitriptyline HCl) Injection	Do.
NDA 13–220	Periactin (cyproheptadine HCl) Syrup, 2 milligrams (mg)/5 milliliters (mL)	Merck & Co., Inc.
NDA 13–400	Aldomet (methyldopa) Tablets	Do.
NDA 13–401	Aldomet (methyldopate HCl) Injection, 50 mg/mL	Do.
NDA 13–413	Dexacort Phosphate (dexamethasone sodium phosphate) in Respihaler	Celltech Pharmaceuticals, Inc.
NDA 16–016	Aldoclor–150 and -250 (methyldopa and chlorothiazide) Tablets, 250 mg/150 mg and 250 mg/250 mg	Merck & Co., Inc.
NDA 16–030	Bayer 8 Hour Aspirin and Measurin Aspirin (aspirin extended-release tablets), 650 mg	Bayer Healthcare, LLC, 36 Columbia Rd., P.O. Box 1910, Morristown, NJ 07962–1910
NDA 16–099	Atromid-S (clofibrate) Capsules	Wyeth Pharmaceuticals
NDA 16–745	Jergens Antibacterial Deodorant (triclocarban, 1%) Soap	Kao Brands Co., 2535 Springs Grove Ave., Cincinnati, OH 45214–1773
NDA 16–888	Selsun Blue (selenium sulfide) Cream/Shampoo, 1%	Abbott Laboratories, 625 Cleveland Ave., Columbus, OH 43215–1724
NDA 17–569	Renoquid (sulfacytine) Tablets	Glenwood LLC, 111 Cedar Lane, Englewood, NJ 07631
NDA 17–573	Vanceril (beclomethasone dipropionate) Inhalation Aerosol	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 17–659	Alupent (metaproterenol sulfate) Inhalation Solution, 5%	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368
NDA 17–781	Diprosone (betamethasone dipropionate) Lotion	Schering Corp.
NDA 17–820	Dobutrex (dobutamine HCl) Sterile Injection	Eli Lilly & Co.
ANDA 18–023	Lactated Ringer's Injection USP	B. Braun Medical, Inc., 2525 McGaw Ave., P.O. Box 19791, Irvine, CA 92623–9791
ANDA 18–026	5% Dextrose and 0.9% Sodium Chloride (NaCl) Injection	Do.
ANDA 18–046	10% Dextrose Injection USP	Do.
ANDA 18–047	10% Dextrose and 0.9% NaCl Injection USP	Do.
ANDA 18–184	0.45% NaCl Injection USP	Do.
ANDA 18–186	1/6 Molar Sodium Lactate Injection USP in Plastic Container	Do.
ANDA 18–197	Ibuprofen Tablets	BASF Corp., 8800 Line Ave., Shreveport, LA 71106
ANDA 18–252	Isolyte S (multi-electrolyte injection) Injection	B. Braun Medical, Inc.
ANDA 18–256	5% Dextrose in Ringer's Injection	Do.
NDA 18–257	Tonocard (tocainide HCl) Tablets, 400 mg and 600 mg	AstraZeneca Pharmaceuticals

Application No.	Drug	Applicant
ANDA 18–274	Isolyte S (multi-electrolyte injection) with 5% Dextrose in Plastic Container	B. Braun Medical, Inc.
NDA 18–389	Aldomet (methyldopa) Oral Suspension, 250 mg/5 mL	Merck & Co., Inc.
NDA 18–682	TZ–3 (1% tioconazole) Dermal Cream	Pfizer, Inc., 235 East 42nd St., New York, NY 10017
NDA 18–686	Normodyne (labetalol HCl USP) Injection, 5 mg/mL	Schering Corp.
NDA 18–687	Normodyne (labetalol HCl USP) Tablets	Do.
ANDA 18–721	Ringer's Injection USP	B. Braun Medical, Inc.
NDA 18–754	Orudis (ketoprofen) Capsules, 25 mg, 50 mg, and 75 mg	Wyeth Pharmaceuticals
NDA 18–792	Neopham (amino acids) Injection	Hospira, Inc., 275 North Field Dr., Dept. 389, Bldg. 2, Lake Forest, IL 60045
NDA 18–901	Aminess (essential amino acids injection with histidine)	Do.
NDA 18–911	Heparin Sodium in 5% Dextrose Injection and Heparin Sodium in NaCl Injection	Do.
NDA 19–083	Theophylline and 5% Dextrose Injection	B. Braun Medical, Inc.
NDA 19–107	Protropin (somatrem) for Injection	Genentech, Inc., 1 DNA Way MS1242, South San Francisco, CA 94080–4990
ANDA 19–138	Alphatrex (betamethasone dipropionate cream USP) 0.05%	Savage Laboratories, 60 Baylis Rd., Melville, NY 11747
ANDA 19–143	Alphatrex (betamethasone dipropionate ointment USP) 0.05%	Do.
NDA 19–383	Proventil (albuterol sulfate extended-release tablets USP) Repetabs	Schering Corp.
NDA 19–401	Pseudo–12 Suspension (pseudoephedrine polistirex extended-release suspension)	Celltech Pharmaceuticals, Inc.
NDA 19–523	Cysteine HCl Injection USP, 7.25%	Hospira, Inc.
NDA 19–589	Vancenase AQ (beclomethasone dipropionate) Nasal Spray	Schering Corp.
NDA 19–621	Ventolin (albuterol sulfate) Syrup	GlaxoSmithKline Pharmaceuticals, 5 More Dr., P.O. Box 13358, Research Triangle Park, NC 27709
NDA 20–035	Ergamisol (levamisole HCl) Tablets	Johnson & Johnson Pharmaceutical Research and Development, LLC, c/o Janssen Pharmaceutical Products, LP, 1125 Trenton-Harbourton Rd., K1–02B, Titusville, NJ 08560–0200
NDA 20–176	VitaPed (multivitamins)	Hospira, Inc.
NDA 20–338	Differin (adapalene) Solution, 0.1%	Galderma Laboratories, LP, 14501 North Freeway, Fort Worth, TX 76177
NDA 20–759	Trovan (trovafloxacin mesylate) Tablets, 100 mg and 200 mg	Pfizer, Inc.
NDA 20–760	Trovan (alatrofloxacin mesylate) Injection	Do.
NDA 20–847	Esclim (estradiol extended-release film) Transdermal System	Women First Healthcare, Inc., 380 Lexington Ave., New York, NY 10168
NDA 20–962	Emla (2.5% lidocaine and 2.5% prilocaine) Anesthetic Disc	AstraZeneca Pharmaceuticals
ANDA 40–023	Adrucil (fluorouracil injection USP), 50 mg/mL	Sicor Pharmaceuticals, Inc., 19 Hughes, Irvine, CA 92618
ANDA 40–147	Leucovorin Calcium Injection USP, 10 mg (base)/mL	Hospira, Inc.
NDA 50–039	Garamycin (gentamicin sulfate) Ophthalmic Solution	Schering Corp.

Application No.	Drug	Applicant
NDA 50–091	Chloroptic (chloramphenicol ophthalmic solution USP), 0.5%	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623–9534
NDA 50–322	Neodecadron (neomycin sulfate and dexamethasone sodium phosphate) Sterile Ophthalmic Solution	Merck & Co., Inc.
NDA 50–368	Ilotycin (erythromycin) Ophthalmic Ointment	Eli Lilly & Co.
NDA 50–571	CefMax (cefmenoxime HCl) Injection	TAP Pharmaceutical Products, Inc., 675 North Field Dr., Lake Forest, IL 60045
NDA 50–648	Clindamycin Phosphate Injection in 5% Dextrose	Baxter Healthcare Corp., Route 120 & Wilson Rd., Round Lake, IL 60073
ANDA 60–429	Sumycin Capsules (tetracycline HCl capsules USP)	Apothecon, c/o Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
ANDA 62–480	Gentacidin Solution (gentamicin sulfate ophthalmic solution USP)	Novartis Pharmaceuticals Corp., 1 Health Plaza, Bldg. 118, East Hanover, NJ 07936–1080
ANDA 62–597	Mytrex (nystatin and triamcinolone acetonide cream USP) 100,000 units/gram (g) and 1 mg/g	Savage Laboratories
ANDA 62–601	Mytrex (nystatin and triamcinolone acetonide ointment USP) 100,000 units/g and 1 mg/g	Do.
ANDA 62–750	Pipracil (piperacillin for injection), 2 g, 3 g, and 4 g	Wyeth Pharmaceuticals, Inc.
ANDA 63–186	Cephalexin Capsules USP, 250 mg and 500 mg	Apothecon, c/o Bristol-Myers Squibb Co.
ANDA 64–084	Sterile Bleomycin Sulfate for Injection USP, 15 and 30 units/vial	Sicor Pharmaceuticals, Inc.
ANDA 70–083	Ibuprofen Tablets USP, 400 mg	BASF Corp.
ANDA 70–099	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 70–273	Alphatrex (betamethasone dipropionate lotion USP), 0.05%	Savage Laboratories
ANDA 70–745	Ibuprofen Tablets USP, 800 mg	BASF Corp.
ANDA 72–621	Acetylcysteine Solution USP, 10%	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216
ANDA 72–622	Acetylcysteine Solution USP, 20%	Do.
ANDA 72–995	Metoclopramide HCl Oral Solution, 10 mg/mL	Do.
ANDA 73–562	Diflunisal Tablets USP, 250 mg	Do.
ANDA 73–563	Diflunisal Tablets USP, 500 mg	Do.
ANDA 74–166	Toposar (etoposide injection USP), 20 mg/mL	Sicor Pharmaceuticals, Inc.
ANDA 74–541	Cimetidine HCl Oral Solution, 30 mg/5 mL	Roxane Laboratories, Inc.
ANDA 74–663	Acyclovir Sodium for Injection USP, 500 mg base/vial and 1 g base/vial	Hospira, Inc.
ANDA 75–179	Nabumetone Tablets	Copley Pharmaceutical, Inc., 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454
ANDA 75–875	Carbamazepine Oral Suspension USP, 100 mg/5 mL	Taro Pharmaceutical Industries, Ltd., c/o Taro Pharmaceuticals, U.S. Agent, 5 Skyline Dr., Hawthorne, NY 10532
ANDA 80–643	Diphenhydramine HCl Elixir USP, 25 mg/10 mL	Roxane Laboratories, Inc.
ANDA 81–225	Adrucil (etopside injection USP), 50 mg/mL	Sicor Pharmaceuticals, Inc.
ANDA 83–261	Pentobarbital Sodium Injection USP	Wyeth Pharmaceuticals
ANDA 83–383	Diucardin (hydroflumethiazide tablets USP) Tablets, 50 mg	Do.

Application No.	Drug	Applicant
ANDA 84–015	Bleph–10 (sulfacetamide sodium ophthalmic ointment USP) Ophthalmic Ointment, 10%	Allergan, Inc.
ANDA 84–514	Dilor (dyphylline tablets USP), 200 mg	Savage Laboratories
ANDA 84–751	Dilor–400 (dyphylline tablets USP), 400 mg	Do.
ANDA 85–035	Diphenoxylate HCl and Atropine Sulfate Tablets USP, 2.5 mg and 0.025 mg	R & S Pharma, LLC, 8407 Austin Tracy Rd., Fountain Run, KY 42133
ANDA 85–961	Methocarbamol Tablets USP, 500 mg	Clonmel Healthcare Ltd., c/o STADA Pharmaceuticals, Inc., U.S. Agent, 5 Cedar Brook Dr., Cranbury, NJ 08512
ANDA 85–963	Methocarbomal Tablets USP, 750 mg	Do.
ANDA 86–899	Isoetharine HCl Inhalation Solution USP, 1%	Roxane Laboratories, Inc.
ANDA 87–450	Chlorthalidone Tablets USP, 50 mg	Clonmel Healthcare Ltd.
ANDA 87–451	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 87–500	Aminophylline Tablets USP, 100 mg	Roxane Laboratories, Inc.
ANDA 87–501	Aminophylline Tablets USP, 200 mg	Do.
ANDA 88–253	T-Phyl (theophylline) Extended-Release Tablets, 200 mg	The Purdue Frederick Co.

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 of Food and Drugs, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 16, 2006.

Dated: May 23, 2006.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E6–9440 Filed 6–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0254]

Determination of Regulatory Review Period for Purposes of Patent Extension; INSPRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INSPRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product INSPRA (eplerenone). INSPRA is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INSPRA (U.S. Patent No. 4,559,332) from Novartis Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of INSPRA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for