more accurately describe the information collection content.

Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (Public Law 109–43) amends section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse, may identify itself using a detachable label that is intended to be affixed to the patient record.

The requirements of section 502(u) of the act impose a minimal burden on industry. This section of the act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 10 establishments that distribute approximately 1,000 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 100 hours.

In the **Federal Register** of November 17, 2008 (73 FR 67873), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received one comment in support of the collection of information stating that it is necessary to help reprocessors of SUDs comply with section 502(u) of the act. The comment further stated that the estimated reporting burden did not appear excessive.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
502(u)	10	100	1,000	.1	100

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2902 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0026]

Apothecon et al.; Withdrawal of Approval of 103 New Drug Applications and 35 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 103 new drug applications (NDAs) and 35 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 March 13, 2009.

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 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 7–335	Pronestyl (procainamide hydrochloride (HCl)) Capsules and Injection	Apothecon, c/o Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000
NDA 7–935	Phenergan (promethazine HCl) Tablets	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 9–193	Cogentin (benztropine mesylate) Tablets	Merck & Co., Inc., Sunneytown Pike, P.O. Box 4, BLA–20, West Point, PA 19486
NDA 9–986	Deltasone (prednisone) Tablets	Pharmacia & Upjohn Co., c/o Pfizer, Inc., 235 East 42d St., New York, NY 10017
NDA 10–374	Medihaler-Epi (epinephrine bitartrate)	3M Pharmaceuticals, 3M Center, Bldg. 0275–05–W–12, St. Paul, MN 55144–1000
NDA 10–375	Medihaler-ISO (isoproterenol)	Do.
NDA 10–598	Bendectin (doxylamine succinate and pyridoxine HCl) Tablets	Sanofi-Aventis, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807–0977

Application No.	Drug	Applicant
NDA 10–796	Harmonyl (deserpidine) Tablets	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064–6154
NDA 10–800	Tralgon (acetaminophen) Elixir	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000
NDA 10–927	Phosphotope (sodium phosphates solution USP) Oral Solution	Bracco Diagnostics, P.O. Box 5225, Princeton, NJ 08543–5225
NDA 10–928	Aureotope (gold injection)	Do.
NDA 11–161	Aristocort (triamcinolone) Tablets	Astellas Pharma US, Inc., Three Parkway North, Deerfield, IL 60015–2537
NDA 11–467	Trancopal (chlormezanone) Tablets	Sanofi-Aventis
NDA 11–721	Neptazane (methazolamide) Tablets	Lederle Laboratories, c/o Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 11–751	Prolixin (fluphenazine HCl) Injection and Tablets	Apothecon, c/o Bristol-Myers Squibb Co.
NDA 11–832	Vasodilan (isoxsuprine HCl)	Do.
NDA 12–097	Kenalog in Orabase (triamcinolone acetonide dental paste USP)	Do.
NDA 12–164	Naturetin (bendroflumethiazide USP), 2.5 milligrams (mg), 5 mg, and 10 mg	Do.
NDA 12–515	Kenacort (tramcinolone diacetate) Syrup	Bristol-Meyers Squibb Co.
NDA 13–296	Duo-Medihaler (phenyleprine bitartrate and isoproterenol HCl)	3M Pharmaceuticals
NDA 13–601	Mucomyst (acetylcysteine solution USP)	Apothecon, c/o Bristol-Myers Squibb Co.
NDA 14–715	Triavil (perphenazine and amitriptyline HCl) Tablets	New River Pharmaceuticals, Inc., 2200 Kraft Dr., suite 2050, Blacksburg, VA 24060
NDA 15–419	Hipputope (iodohippurate sodium I-131 injection USP)	Bracco Diagnostics
NDA 16–033	Vontrol (diphenidol HCl) Tablets, 25 mg	GlaxoSmithKline, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709
NDA 16–090	Rubratope-60 (cyanocobalamin CO-60)	Bracco Diagnostics
NDA 16–224	Robengatope (rose bengal sodium I-131 injection USP)	Do.
NDA 16–727	Prolixin Decanoate (fluphenazine decanoate) Injection	Bristol-Myers Squibb Co.
NDA 16–783	Vascoray (iothalamate meglumine, 52% and iothalamate sodium, 26% injection)	Tyco Healthcare/Mallinckrodt Inc., P.O. Box 5840, St. Louis, MO 63134–0840
NDA 16–906	Technetope II (technetium Tc-99m sodium pertechnetate sterile generator	Bracco Diagnostics
NDA 16–923	Tesuloid (technetium Tc-99m sulfur colloid kit)	Do.
NDA 16–929	FUDR (floxuridine) Injection, 500 mg/5 milliliters (mL)	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045–5046
NDA 16–996	Hyperstat (diazoxide) Injection	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 17–024	Strotope (strontium nitrate Sr-85) Injection	Bracco Diagnostics
NDA 17–045	Renotec (technetium Tc-99m ferpenetate kit)	Do.
NDA 17–047	Sethotope (selenomethionine Se-75) Injection	Do.
NDA 17–269	Chlormerodrin Hg-197 Injection	Do.
NDA 17–339	Minitec (technetium Tc-99m sodium pertechnetate generator)	Do.

Application No.	Drug	Applicant
NDA 17–371	Pronestyl (procainamide HCl) Tablets	Apothecon, c/o Bristol-Myers Squibb Co.
NDA 17–395	Intropin (dopamine HCl) Injection, 40 mg/mL, 80 mg/mL, and 160 mg/mL	Hospira, Inc.
NDA 17–598	Septra (trimethoprim and sulfamethoxazole) Oral Suspension	Monarch Pharmaceutcals, Inc., 501 5th St., Bristol, TN 37620
NDA 17–685	Conray 325 (iothalamate sodium)	Mallinckrodt Inc., 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134
NDA 17–787	Radionuclide-Labeled (I-125) Fibrinogen Sensor	Abbott Laboratories
NDA 17–834	Albumotope-LS (albumin aggregated iodinated I-131-serum)	Bracco Diagnostics
NDA 17–902	Renovue-65 (iodamide meglumine) Injection, 65%	Do.
NDA 17–903	Renovue-Dip (iodamide meglumine) Injection	Do.
NDA 17–931	Iletin I (insulin pork)	Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 17–932	Protamine Zinc and Iletin I (insulin suspension protamine zinc beef/pork)	Do.
NDA 17–935	Ultralente Iletin I (insulin zinc suspension extended beef/pork)	Do.
NDA 17–936	NPH Iletin I (insulin suspension isophane beef/pork)	Do.
NDA 17–943	Proloprin (trimethoprim) Tablets, 100 mg and 200 mg	Monarch Pharmaceuticals, Inc.
NDA 17–970	Nolvadex (tamoxifen citrate) Tablets	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355
NDA 17–979	Heparin Sodium Injection USP	Abraxis Pharmaceutical Products, Riverway One, 6133 North River Rd., suite 500, Rosemont, IL 60018
NDA 18–017	Blocadren (timolol maleate) Tablets	Merck & Co., Inc., UG2C–50, P.O. Box 1000, North Wales, PA 19454–1099
NDA 18–061	Timolide (timolol maleate and hydrochorothiazide) Tablets, 10 mg/25mg	Do.
NDA 18–076	Cholovue (iodoxamate meglumine) Injection, 40.3%	Bracco Diagnostics
NDA 18–077	Cholovue (iodoxamate meglumine) for Infusion	Do.
NDA 18–116	Cyclocort (amcinonide) Cream, 0.1%	Astellas Pharma US, Inc.
NDA 18–211	Ditropan (oxybutynin chloride) Syrup, 5 mg	Ortho-McNeil-Janssen Pharmaceuticals, Inc., 1000 U.S. Highway 202, P.O. Box 3000, Raritan, NJ 08869–0602
NDA 18–344	Iletin II (insulin purified pork)	Eli Lilly & Co.
NDA 18–345	NPH Iletin II (insulin suspension isophane purified pork)	Do.
NDA 18–346	Protamine, Zinc, and Iletin II (insulin suspension protamine zinc purified pork)	Do.
NDA 18–347	Lente Iletin II (insulin zinc suspension purified pork)	Do.
NDA 18–354	Ortho-Novum 10/11-21 and 10/11-28 (norethindrone and ethinyl estradiol) Tablets	Ortho-McNeil Pharmaceutical, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, LLC, 920 Rt. 202 South, P.O. Box 300, Raritan, NJ 08869
NDA 18–452	Septra (sulfamethoxazole and trimethorprim) Injection	Monarch Pharmaceuticals, Inc.

Application No.	Drug	Applicant
NDA 18–476	Protamine, Zinc, and Iletin II (insulin suspension protamine zinc purified beef)	Eli Lilly & Co.
NDA 18–477	Lente Iletin II (insulin zinc suspension purified beef)	Do.
NDA 18–478	Regular Iletin II (insulin purified beef)	Do.
NDA 18–479	NPH Iletin II (insulin suspension isophane purified beef)	Do.
NDA 18–498	Cyclocort (amcinonide) Ointment, 0.1%	Astellas Pharma US, Inc.
NDA 18–537	Tridil (nitroglycerin) Injection	Hospira, Inc.
NDA 18–831	Tracrium (atracurium besylate) Injection	Hospira, Inc.
NDA 18–873	Mexitil (mexiletine HCl) Capsules, 150 mg, 200 mg, and 250 mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368
NDA 18–922	Lodine (etodolac) Capsules and Tablets	Wyeth Pharmaceuticals, Inc.
NDA 19–085	Atrovent (ipratropium bromide) Aerosol	Boehringer Ingelheim Pharmaceuticals, Inc.
NDA 19–166	Regular Insulin (insulin zinc suspension beef) Injection	Eli Lilly & Co.
NDA 19–167	NPH Insulin Beef (insulin zinc suspension beef)	Do.
NDA 19–529	Humulin BR (insulin recombinant human)	Do.
NDA 19–729	Cyclocort (amcinonide) Lotion, 0.1%	Astellas Pharma US, Inc.
NDA 19–816	Oruvail (ketoprofen) Extended-Release Capsules	Wyeth Pharmaceuticals, Inc.
NDA 19–890	Stadol (butorphanol tartrate) Nasal Spray	Bristol-Myers Squibb Co.
NDA 19–965	Novolin L (insulin zinc suspension recombinant human)	Novo Nordisk, Inc., 100 College Road West, Princeton, NJ 08540
NDA 20–152	Serzone (nefazodone HCl) Tablets	Bristol-Myers Squibb Co.
NDA 20–219	Livostin (levocabastine HCl) Ophthalmic Suspension, 0.05%	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936–1080
NDA 20–225	Indur (isosorbide mononitrate) Extended-Release Tablets, 30 mg, 60 mg, and 120 mg	Schering Corp.
NDA 20–326	Neutrexin (trimetrexate glucuronate) Injection, 25 mg and 200 mg vials	MedImmune Oncology, Inc., One MedImmune Way, Gaithersburg, MD 20878
NDA 20–377	Cordarone (amiodarone HCl), Injection, 50 mg/mL	Wyeth Pharmaceuticals, Inc.
NDA 20–429	Orudis KT (ketoprofen) Tablets, 12.5 mg	Wyeth Consumer Healthcare, Five Giralda Farms, Madison, NJ 07940
NDA 20–584	Lodine XL (etodolac) Extended-Release Tablets	Wyeth Pharmaceuticals, Inc.
NDA 20–698	MiraLax (polyethylene glycol 3350) Powder for Solution	Braintree Laboratories, Inc., 60 Columbian Street West, P.O. Box 850929, Braintree, MA 02185–0929
NDA 20–784	Nasacort HFA (triamcinolone acetonide) Nasal Spray	Sanofi-Aventis
NDA 20–974	Prozac (fluoxetine HCl) Tablets	Eli Lilly & Co.
NDA 21–028	Velosulin BR (insulin recombinant injection)	Novo Nordisk, Inc.
NDA 21–369	Codeprex (codeine polistirex and chlorpheniramine polistirex) Extended-Release Suspension	UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080
NDA 21–387	Pravigard Pak (copackaged) (pravastatin sodium and aspirin) Tablets	Bristol-Meyers Squibb Co.

Application No.	Drug	Applicant
ANDA 40–305	Meperidien HCl Injection USP, 10 mg/mL	Hospira, Inc.
NDA 50–155	Chloromycetin Sodium Succinate (chloramphenicol sodium succinate for injection USP)	Parkedale Pharmaceuticals, Inc., c/o King Pharmaceuticals, Inc., 501 5th St., Bristol, TN 37620
NDA 50–205	Chloromycetin (chloramphenicol) Otitic Solution	Do.
NDA 50–285	Mycifradin (neomycin sulfate) Oral Suspension	Pharmacia & Upjohn Co., c/o Pfizer, Inc.
NDA 50–339	Albamycin (novobiocin sodium) Capsules	Do.
NDA 50–435	Geocillin (carbenicillin indanyl sodium) Tablets, 382 mg	Pfizer, Inc., 235 East 42d St., New York, NY 10017
NDA 50–504	Mandol (cefamandole nafate) Injection	Eli Lilly & Co.
NDA 50–589	Cefizox (ceftizoxime sodium)	Astellas Pharma US, Inc.
NDA 50–621	Suprax (cefixime) Tablets, 200 mg and 400 mg	Lederle Laboratories, c/o Wyeth Pharmaceuticals, Inc.
NDA 50–622	Suprax (cefixime) Powder for Suspension	Do.
ANDA 60–591	Chloromycetin (chloramphenicol capsules USP), 50 mg, 100 mg, and 250 mg	Parkedale Pharmaceuticals, Inc., c/o King Pharmaceuticals, Inc.
ANDA 61–922	Vidarabine Monohydrate Micronized Powder, Sterile	Do.
ANDA 62–655	Tazidime (ceftazidime for injection USP)	Eli Lilly & Co.
ANDA 63–350	Amikacin Sulfate Injection USP, 50 mg base/mL and 250 mg base/mL	Hospira, Inc.
ANDA 70–847	Metoclopramide Injection USP, 5 mg base/mL	Hospira, Inc.
ANDA 71–291	Metoclopramide Injection USP, 5 mg base/mL	Do.
ANDA 71–364	Acetylcysteine Solution USP	Do.
ANDA 71–365	Acetylcysteine Solution USP	Do.
ANDA 71–645	Droperidol Injection USP, 2.5 mg/mL	Do.
ANDA 73–272	Albuterol Inhalation Aerosol	IVAX Pharmaceuticals Ireland, c/o IVAX Pharmaceuticals, Inc., Two University Plaza, suite 220, Hackensack, NJ 07601
ANDA 74–966	Fluphenazine Decanoate Injection, 25 mg/mL	Hospira, Inc.
ANDA 75–106	Diltiazem HCl Injection, 5 mg/mL	Do.
ANDA 75–242	Labetalol HCL Injection, 5 mg/mL	Do.
ANDA 75–342	Butorphanol Tartrate Injection USP, 1 mg/mL and 2mg/mL	Do.
ANDA 75–396	Midazolam HCl Injection	Do.
ANDA 75–484	Midazolam HCl Injection, 5 mg base/mL	Do.
ANDA 75–571	Enalaprilat Injection, 1.25 mg/mL	Do.
ANDA 75–669	Famotidine Injection, 10 mg/mL	Do.
ANDA 75–705	Famotidine Injection, 10 mg/mL	Do.
ANDA 75–816	Calcitriol Injection	Do.
ANDA 75–830	Milrinone Lactate Injection, 1 mg base/mL	Do.
ANDA 75–108	Amiodarone HCl Injection, 50 mg/mL	Do.
ANDA 76–233	Paclitaxel Injection	Do.
ANDA 76–473	Carboplatin for Injection USP	Do.

Application No.	Drug	Applicant
ANDA 76–978	Ondansetron HCl and Dextrose Injection	Do.
ANDA 77–362	Amlodipine Besylate Tablets	King and Spalding, U.S. Agent for Genpharm Inc., 1700 Pennsylvania Ave., NW., Washington, DC 20006–4706
ANDA 77–925	Meloxicam Tablets, 7.5 mg and 15 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 85–153	Alkergot (ergoloid mesylates) Sublingual Tablets, 0.5 mg	Sandoz, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413
ANDA 85–916	Diethylpropion HCl Tablets, 25 mg	Do.
ANDA 86–172	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 86–174	Meclizine HCl Tablets, 25 mg	Do.
ANDA 86–184	Sulfasalazine Tablets, 500 mg	Do.
ANDA 87–417	Alkergot (ergoloid mesylates) Sublingual Tablets, 1 mg	Do.
ANDA 89–565	Vinblastine Sulfate Injection, 10 mg/vial	Hospira, Inc.

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 March 13, 2009.

Dated: January 12, 2009.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E9–2901 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2008E0091; Docket No. FDA2008E0099; Docket No. FDA2008E0204]

Determination of Regulatory Review Period for Purposes of Patent Extension; MACROPLASTIQUE IMPLANTS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MACROPLASTIQUE IMPLANTS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that medical device.

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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device MACROPLASTIQUE IMPLANTS. MACROPLASTIQUE IMPLANTS are indicated for transurethral injection in the treatment of adult women diagnosed with stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency (ISD). Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for MACROPLASTIQUE IMPLANTS (U.S. Patent Nos. 5,258,028;. 5,336,263; and 5,571,182) from Uroplasty, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In a letter dated May 6, 2008, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of MACROPLASTIQUE IMPLANTS represented the first permitted commercial marketing or use of the product. 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 MACROPLASTIQUE IMPLANTS is 2,651 days. Of this time, 1,973 days occurred during the testing phase of the