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