ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 25 and 26, 2012, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's phone number is 301–948–8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3063, email: *Jamie.Waterhouse@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda

On April 25, 2012, the committee will discuss, make recommendations and vote on information related to a supplement to the premarket approval application (PMA) for the HeartWare Ventricular Assist System (HVAS) sponsored by HeartWare, Inc. The HVAS is an implantable electrically powered centrifugal-flow rotary blood pump with external driver and power source(s). It is the first ventricular assist device that does not require the creation of an abdominal pump pocket. The HVAS is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory, advanced heart failure.

On April 26, 2012, the committee will discuss, make recommendations and vote on information related to the PMA for the Subcutaneous Implantable Cardioverter Defibrillator (S–ICD) System sponsored by Cameron Health, Inc. The S–ICD is the first implantable defibrillator that does not require the implantation of an electrode either on or in the heart. The S–ICD is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias. The device is capable of delivering high energy defibrillation shocks as well as bradycardia demand mode cardiac pacing. The study provides data from the treatment of induced acute and chronic episodes of ventricular tachycardia/ventricular fibrillation and spontaneous episodes. In addition to the investigational device exemption study, clinical data were also obtained from using studies outside the United States and registries.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 17, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 25 and 26, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 10, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 12, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, at *AnnMarie.Williams@fda.hhs.gov,* 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 13, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–6484 Filed 3–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0190]

Abbott Laboratories et al.; Withdrawal of Approval of 35 New Drug Applications and 64 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 35 new drug applications (NDAs) and 64 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:* April 18, 2012.

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 in this document have informed

FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under 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 005545	Dicumarol Tablets	Abbott Laboratories, PA77/Bldg. AP30–1E, 200 Abbott Park Rd., Abbott Park, IL 60064–6157.
NDA 005845	Benadryl (diphenhydramine hydrochloride (HCl)), Benadryl with Ephedrine Sulfate, and Caladryl (diphenhydramine HCl and calamine).	McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., 7050 Camp Hill Rd., Fort Washington, PA 19034–2299.
NDA 006146	Benadryl (diphenhydramine HCl)) Injection	Do.
NDA 006773	Artane (trihexyphenidyl HCl) Tablets and Capsules and Artane (trihexyphenidyl) Elixir.	Lederle Laboratories, d/b/a Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 009486	Benadryl (diphenhydramine HCl)) Injection Preservative Free.	McNeil Consumer Healthcare.
NDA 010021	Placidyl (ethchlorvynol) Capsules	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064.
NDA 011552	Stelazine (trifluoperazine HCl)	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709–3398.
NDA 012524	Enduron (methyclothiazide) Tablets, 2.5 milligrams (mg) and 5 mg.	Abbott Laboratories, PA77/Bldg. AP30–1E, 200 Abbott Park Rd., Abbott Park, IL 60064–6157.
NDA 012775	Enduronyl and Enduronyl Forte (methyclothiazide and deserpidine) Tablets.	Do.
NDA 014684	Aventyl (nortriptyline HCl) Capsules	Eli Lilly and Co., Lilly Corp. Center, Indianapolis, IN 46285.
NDA 017577	Ditropan (oxybutynin chloride) Tablets	Janssen Pharmaceuticals Inc., c/o Johnson & Johnson Pharmaceutical Research and Development, LLC, 920 Route 202, P.O. Box 300, Raritan, NJ 08869.
NDA 018473	Ventolin (albuterol) Inhalation Aerosol[1]	GlaxoSmithKline.
NDA 018557	Fansidar (sulfadoxine and pyrimethamine) Tablets, 500 mg and 25 mg.	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 018709	Capozide (captopril and hydrochlorothiazide) Tablets	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 018814	Heparin Sodium in 5% Dextrose Injection	Baxter Healthcare Corp., 1620 Waukegan Rd., MPGR–AL, McGaw Park, IL 60085.
NDA 019297	Novantrone (mitoxantrone HCl) Injection	EMD Serono, One Technology Place, Rockland, MA 02370.
NDA 019508	Axid (nizatidine) Capsules	SmithKline Beecham Corp., d/b/a GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709–3398.
NDA 019915	Monopril (fosinopril sodium) Tablets, 10 mg, 20 mg, and 40 mg.	Bristol-Myers Squibb Co.
NDA 019946	Nuromax (doxacurium chloride) Injection 1 mg/milliliter (mL).	Abbott Laboratories, P76/Bldg. AP30–1E, Abbott Park, IL 60064–6157.
NDA 019960	Manoplax (flosequinan) Tablets	Do.
NDA 020057	Ceredase (alglucerase) Injection	Genzyme Corp., 500 Kendall St., Cambridge, MA 02142.
NDA 020088	Norplant System (levonorgestrel) Implants	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 020101	Prozac (fluoxetine HCl) Oral Solution, 20 mg/5 mL	Eli Lilly and Co.
NDA 020236	Serevent (salmeterol xinafoate) Inhalation Aerosol[1]	GlaxoSmithKline.
NDA 020286	Monopril-HCT (fosinopril sodium and hydrochlorothiazide) Tablets, 20 mg/12.5 mg and 10 mg/12.5 mg.	Bristol-Myers Squibb Co.
NDA 020403	Zofran (ondansetron HCl) Injection	Glaxo Wellcome Manufacturing Pte Limited, d/b/a GlaxoSmithKline, 1250 Collegeville Rd., UP4110, Collegeville, PA 19426.
NDA 020627	Norplant II System (levonorgestrel) Implants	Wyeth Pharmaceuticals, Inc.
NDA 020828	Fortovase (saquinavir) Capsules, 200 mg	Hoffman-La Roche, Inc.
NDA 020860	Levlite (ethinyl estradiol and levonorgestrel) Tablets	Bayer HealthCare Pharmaceuticals Inc., P.O. Box 1000, Montville, NJ 07045.
NDA 020984	Raplon (rapacuronium bromide) for Injection	Organon USA Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 021120	Novantrone (mitoxantrone HCl) Injection	EMD Serono.
NDA 021793	Reglan ODT (metoclopramide) Tablets	Meda Pharmaceuticals Inc., 200 North Cobb Parkway, Suite 428, Marietta, GA 30062.
ANDA 040207	Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg.	Duramed Pharmaceuticals, Inc., 400 Chestnut Rd., Woodcliff Lake, NJ 07677.
ANDA 040231	Chlorpromazine HCl Oral Concentrate USP, 30 mg/mL	Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605.
NDA 050526	Staticin (erythromycin) Topical Solution, 1.5%	Bristol-Myers Squibb Co.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 050687	Banan (cefpodoxime proxetil) Tablets, 100 mg and 200 mg.	Daiichi Sankyo, Inc., 399 Thornall St., 11th Floor, Edison, NJ 08837.
NDA 050688	Banan (cefpodoxime proxetil) Granules for Oral Suspension, 50 mg/5 mL and 100 mg/5 mL.	Do.
ANDA 064098	Amikacin Sulfate Injection USP, 250 mg (base)/mL	Hospira, Inc., 275 North Field Dr., Bldg. H2–2, Lake Forest, IL 60045.
ANDA 064106	Mitomycin for Injection USP, 20 mg Vial	Do.
ANDA 070505	Metoclopramide Injection USP, 5 mg/mL	Do.
ANDA 070506	Metoclopramide Injection USP, 5 mg/mL	Do.
ANDA 070566	Nitropress (sodium nitroprusside for Injection USP), 50 mg.	Do.
ANDA 071015	Haloperidol Oral Solution USP, 2 mg/mL	Teva Pharmaceuticals USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454.
ANDA 071554	Thiothixene HCl Oral Solution USP, 5 mg/mL	Do.
ANDA 073058	Fluphenazine HCl Oral Solution USP, 5 mg/mL	Do.
ANDA 073479	Pentamidine Isethionate for Injection, 300 mg Vial	Hospira, Inc.
ANDA 074636	Iopamidol Injection USP, 41%, 51%, 61%, 76%	Do.
ANDA 074898	Iopamidol Injection USP, 41%, 51%, 61%, 76%	Do.
ANDA 075065	Acyclovir Sodium for Injection	Do.
ANDA 075176	Haloperidol Decanoate Injection, 50 mg/mL and 100 mg/mL.	Do.
ANDA 075409	Midazolam HCl Injection, 1 mg (base)/mL and 5 mg (base)/mL.	Do.
ANDA 075884	Milrinone Lactate Injection, 1 mg/mL	Do.
ANDA 076306	Topiramate Tablets, 25 mg, 50 mg, 100 mg, and 200 mg.	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 077138	Ciprofloxacin Injection USP in 5% Dextrose Injection	Teva Pharmaceuticals USA.
ANDA 077223	Terbinafine HCl Tablets, 250 mg (base)	Roxane Laboratories, Inc.
ANDA 077784	Risperidone Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg.	Ratiopharm Inc., c/o Columbia Pharma Consulting Services Inc., 490 Northwest Datewood Dr., Suite 400, Issaquah, WA 98027.
ANDA 078241	Sumatriptan Succinate Tablets, 25 mg, 50 mg, and 100 mg (base).	Roxane Laboratories, Inc.
ANDA 078318	Sumatriptan Injection, 4 mg (base)/0.5 mL and 6 mg (base)/0.5 mL.	TEVA Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 078416	Prednisolone Sodium Phosphate Oral Solution, 5 mg (base)/5 mL.	Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811.
ANDA 078517	Venlafaxine HCl Tablets, 25 mg (base), 37.5 mg (base), 50 mg (base), 75 mg (base), and 100 mg (base).	PLIVA Hrvatska d.o.o., c/o Barr Laboratories, Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 080997	Succinylcholine Chloride Injection USP, 20 mg/mL	Organon USA Inc.
ANDA 081125	Dexamethasone Sodium Phosphate Injection USP, 4 mg/mL.	TEVA Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 081126	Dexamethasone Sodium Phosphate Injection USP	Do.
ANDA 081298	Chlorzoxazone Tablets, 250 mg	Ranbaxy Inc., U.S. Agent for Ohm, 600 College Rd. East, Princeton, NJ 08540.
ANDA 081299	Chlorzoxazone Tablets, 500 mg	Do.
ANDA 081310	Fluphenazine HCl Elixir USP, 2.5 mg/5 mL	Teva Pharmaceuticals USA.
ANDA 087005	Trichlormethiazide Tablets, 4 mg	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 087007	Trichlormethiazide Tablets, 2 mg	Do.
ANDA 087032	Chlorpromazine HCl Oral Concentrate USP, 30 mg/mL	Morton Grove Pharmaceuticals, Inc., U.S. Agent for Wockhardt EU Operations (Swiss) AG, 6451 West Main St., Morton Grove, IL 60053.
ANDA 087053	Chlorpromazine HCl Oral Concentrate USP, 100 mg/mL.	Do.
ANDA 087406	Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg.	Barr Laboratories, Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 087585	Potassium Chloride for Injection Concentrate USP, 2 mEq/mL.	Luitpold Pharmaceuticals, Inc., One Luitpold Dr., P.O. Box 9001, Shirley, NY 11967.
ANDA 088143	Trifluoperazine Oral Solution USP, 10 mg/mL	Morton Grove Pharmaceuticals, Inc., U.S. Agent for Wockhardt EU Operations (Swiss) AG.
ANDA 088194	Thioridazine HCl Tablets USP, 50 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 088227	Thioridazine HCl Oral Solution USP (Concentrate), 100 mg/mL.	Morton Grove Pharmaceuticals, Inc., U.S. Agent for Wockhardt EU Operations (Swiss) AG.
ANDA 088258	Thioridazine HCl Oral Solution USP (Concentrate), 30 mg/mL.	Do.
ANDA 088270	Thioridazine HCl Tablets USP, 10 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA.
ANDA 088271	Thioridazine HCl Tablets USP, 15 mg	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 088272	Thioridazine HCl Tablets USP, 25 mg	Do.
ANDA 088273	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088456	Thioridazine HCl Tablets USP, 100 mg	Teva Pharmaceuticals USA.
ANDA 088493	Thioridazine HCl Tablets USP, 10 mg	Do.
ANDA 088850	Hydroflumethiazide Tablets USP, 50 mg	Par Pharmaceutical, Inc.
ANDA 088907	Reserpine and Hydroflumethiazide Tablets, 0.125 mg/50 mg.	Do.
ANDA 088933	Sulfinpyrazone Tablets, 100 mg	Do.
ANDA 088934	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 089135	Methyclothiazide Tablets, 2.5 mg	Do.
ANDA 089136	Methyclothiazide Tablets, 5 mg	Do.
ANDA 089173	A–MethaPred (methylprednisolone sodium succinate for injection USP), 500 mg (base)/Vial.	Hospira, Inc.
ANDA 089174	A–MethaPred (methylprednisolone sodium succinate for injection USP), 1 gram (base)/Vial.	Do.
ANDA 089207	Methylprednisolone Tablets USP, 16 mg	Par Pharmaceutical, Inc.
ANDA 089208	Methylprednisolone Tablets USP, 24 mg	Do.
ANDA 089209	Methylprednisolone Tablets USP, 32 mg	Do.
ANDA 089457	Perphenazine Tablets USP, 16 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA.
ANDA 089602	Thioridazine HCl Oral Solution USP, 30 mg/mL	Teva Pharmaceuticals USA.
ANDA 089603	Thioridazine HCl Oral Solution USP, 100 mg/mL	Do.
ANDA 089624	Reversol (edrophonium chloride injection USP), 10 mg/mL).	Organon USA Inc.
ANDA 089657	Methocarbamol and Aspirin Tablets, 400 mg/325 mg	Par Pharmaceutical, Inc.
ANDA 089708	Perphenazine Tablets USP, 4 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA.

[1] This product included an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any albuterol or salmeterol metered-dose inhalers (see 70 FR 17168, April 4, 2005; 71 FR 70870, December 7, 2006).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C 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 April 18, 2012. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C 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: February 16, 2012.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2012–6591 Filed 3–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915–0327)—Revision

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate.