held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. By the end of FY 2015, FDA will initiate another public process for determining the disease areas for FY 2016–2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm*.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will gather patient and patient stakeholder input on symptoms of narcolepsy that matter most to patients and on current approaches to treating narcolepsy. Narcolepsy is a chronic disorder of the central nervous system caused by the brain's inability to control sleep-wake cycles and is characterized by excessive daytime sleepiness, cataplexy, hallucination, and disturbed nocturnal sleep. Although there is no cure for narcolepsy, medications and lifestyle modifications can help patients manage their symptoms. FDA is interested in obtaining a better understanding of patients' perspectives on the severity of the disease and assessments of available therapies.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through the public docket (see **ADDRESSES**).

Topic 1: Disease symptoms and daily impacts that matter most to patients:

1. Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include excessive daytime sleepiness, cataplexy, etc.)

2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, work and school performance, etc.)

3. How have your symptoms changed over time?

3.1. Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

Topic 2: Patients' perspectives on current approaches to treating narcolepsy:

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include FDA-approved medicines, over-the-counter products, and other therapies including non-drug therapies such as lifestyle modifications.)

1.1. What specific symptoms do your therapies address?

1.2. How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

2.1. How well do these therapies improve your ability to do specific activities that are important to you in your daily life?

2.2. How well have these therapies worked for you as your condition has changed over time?

3. What are the most significant downsides to your current therapies, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, inconvenient dosing schedules, access issues, etc.)

4. Assuming there is no complete cure for your condition, what specific things would you look for in an ideal therapy for your condition?

B. Meeting Attendance and/or Participation

If you wish to attend this meeting, visit *http://patientfocused narcolepsy.eventbrite.com*. Please register by September 13, 2013. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Pujita Vaidya (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will also be asked to send a brief summary of responses to the topic questions to *PatientFocused@fda.hhs.gov.* Panelists will be notified of their selection soon after the close of registration on September 13, 2013. FDA will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Interested members of the public, including those who attend the meeting in person or through the webcast, are invited to provide electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**). Comments may be submitted until November 25, 2013.

Dated: July 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17327 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0845]

Bracco Diagnostics et al.; Withdrawal of Approval of 52 New Drug Applications and 77 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 52 new drug applications (NDAs) and 77 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 August 19, 2013.

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 011620	Cardiografin (diatrizoate meglumine USP, 85%) Injection	Bracco Diagnostics, 107 College Rd. East, Princeton, NJ 08540.
NDA 012828	Travase (sutilains) Ointment	Abbott Laboratories, PA 77/Bldg. AP30–1E, 200 Abbott Park Rd., Abbott Park, IL 60064–6157.
NDA 014215	Celestone (betamethasone) Oral Solution	Merck Sharp & Dohme Corp., One Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 014685	Aventyl (nortriptyline hydrochloride (HCl) Oral Solution, 10 milligrams (mg)/5 milliliters (mL).	Ranbaxy Inc., U.S. Agent for Ranbaxy Laboratories Limited, 600 College Rd. East, Princeton, NJ 08540.
NDA 014860	Aralen Phosphate (chloroquine phosphate) with primaquine phosphate Tablets.	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807–0890.
NDA 016017	Cloroquine-Primaquine (chloroquine phosphate and primaquine phosphate) Tablets.	Do.
NDA 016019	Questran Resin (cholestyramine resin)	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 016640	Questran Powder (cholestyramine for oral suspension)	Do.
NDA 016721	Dalmane (flurazepam HCl) Capsules	Valeant Pharmaceuticals North America, LLC, 700 Route 202/206 North, Bridgewater, NJ 08807.
NDA 016732	Talwin 50 (pentazocine HCl USP), Tablets, 50 mg	Sanofi-Aventis U.S., LLC.
NDA 016891	Talwin Compound (pentazocine HCl USP and aspirin USP), Equivalent to (EQ) 12.5 mg (base) and 325 mg.	Do.
NDA 016927	Demulen 1/50–21 (ethynodiol diacetate/ethinyl estradiol) Tablets.	G.D. Searle, LLC, c/o Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 016936	Demulen 1/50–28 (ethynodiol diacetate/ethinyl estradiol) Tablets.	Do.
NDA 017557	Danocrine (danazol) Capsules	Sanofi-Aventis U.S., LLC.
NDA 017633	Glycine Irrigation USP, 1.5%	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 017821	Flexeril (cyclobenzaprine HCl) Tablets, 5 mg and 10 mg	Janssen Research & Development, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 017850	Klotrix (potassium chloride) Extended-Release Tablets	Bristol-Myers Squibb Co.
NDA 017857	Stadol (butorphanol tartrate USP) Injection	Do.
NDA 018160	Demulen 1/35–28 (ethynodiol diacetate/ethinyl estradiol) Tablets.	G.D. Searle, LLC, c/o Pfizer Inc.
NDA 018168	Demulen 1/35–21 (ethynodiol diacetate/ethinyl estradiol) Tablets.	Do.
ANDA 018398	Dopamine HCl Injection USP, 40 mg/mL and 80 mg/mL	Baxter Healthcare Corp., 25212 W. Illinois Route 120, Round Lake, IL 60073.
NDA 018458	Talacen (pentazocine HCl USP and acetaminophen USP), Tablets, EQ 25 mg (base) and 650 mg.	Sanofi-Aventis U.S., LLC.
ANDA 018581	Sodium Nitroprusside for Injection USP, 50 mg/vial	Baxter Healthcare Corp.
NDA 018733	Talwin Nx (pentazocine HCl and naloxone HCl) Tablets, 50 mg and 0.5 mg.	Sanofi-Aventis U.S., LLC.
NDA 018981	Enkaid (encainide HCl) Capsules	Bristol-Myers Squibb Co.
NDA 019057	Hytrin (terazosin HCl) Tablets, 1 mg, 2 mg, 5 mg, and 10 mg.	Abbott Laboratories.
NDA 019436	Primacor (milrinone lactate) Injection, EQ 1 mg (base)/mL	Sanofi-Aventis U.S., LLC.
NDA 019507	Kerlone (betaxolol HCl) Tablets, 10 mg and 20 mg	Do.
NDA 019578	Mefloquine HCl Tablets, 250 mg	U.S. Army Office of the Surgeon General, Department of the Army, 1430 Veterans Dr., Fort Detrick, MD 21702–5009.
NDA 019669	Questran Light, Questran II, and Questran Sugar Free (cholestyramine for oral suspension).	Bristol-Myers Squibb Co.
NDA 019807	Kerledex (betaxolol HCl and chlorthalidone) Tablets	Sanofi-Aventis U.S., LLC.
NDA 019977	Oramorph SR (morphine sulfate) Sustained-Release Tablets, 15 mg, 30 mg, 60 mg, and 100 mg.	Xanodyne Pharmaceuticals, Inc., One Riverfront Pl., Newport, KY 41071.
NDA 020036	Aredia (pamidronate disodium) for injection, 30 mg, 60 mg, and 90 mg.	Novartis Pharmacueticals Corp., One Health Plaza, East Hanover, NJ 07936–1080.
NDA 020038	Fludara (fludarabine phosphate) for Injection, 50 mg/vial	Genzyme Corp., 500 Kendall St., Cambridge, MA 02142.
NDA 020056	Atropine Sulfate Aerosol for Inhalation	U.S. Army Office of the Surgeon General.
NDA 020070	Cognex (tacrine HCl) Capsules, 10 mg, 20 mg, 30 mg, and 40 mg.	Shionogi Inc., 300 Campus Dr., Florham Park, NJ 07932.
NDA 020095	Zantac (ranitidine HCl) Geldose Capsules	GlaxoSmithKline, P.O. Box 13398, 5 Moore Dr., Research Triangle Park, NC 27709.
NDA 020151	Effexor (venlafaxine HCl) Tablets, 12.5 mg, 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg.	Wyeth Pharmaceuticals, Inc., 235 East 42nd St., New York, NY 10017.
NDA 020239	Kytril (granisetron HCl) Injection, EQ 1 mg (base)/mL and 0.1 mg (base)/mL, 1 mg (base)/mL, and 3 mg (base)/mL.	Hoffman-La Roche, Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020305	Kytril (granisetron HCl) Tablets, EQ 1 mg (base), EQ 2 mg (base).	Do.
NDA 020336	DynaCirc CR (isradipine) Controlled-Release Tablets	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406.
NDA 020343	Primacor (milrinone lactate) Injection	Sanofi-Aventis U.S., LLC.
NDA 020347	Hytrin (terazosin HCl) Capsules, 1 mg, 2 mg, 5, mg, and 10 mg.	Abbott Laboratories.
NDA 020441	Pulmicort Turbuhaler (budesonide) Inhalation Powder	AstraZeneca, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355.
NDA 020484	Innohep (tinzaparin sodium) Injection	LEO Pharma A/S, c/o Parexel International Corp., 4600 East-West Highway, Suite 350, Bethesda, MD 20814.
NDA 020611	Dovonex (calcipotriene) Topical Solution, 0.005%	LEO Pharma A/S, c/o LEO Pharma Inc., 1 Sylvan Way, Parsippany, NJ 07054.
NDA 020680	Norvir (ritonavir) Capsules, 100 mg	Abbott Laboratories.
NDA 021238	Kytril (granisetron HCl) Oral Solution, 2 mg/10 mL	Hoffman-La Roche, Inc., c/o Genentech, Inc.
NDA 021320	Plenaxis (abarelix) Injection, 100 mg/vial	Specialty European Pharma Limited, c/o Strategic Bioscience Corp., 93 Birch Hill Rd., Stow, MA 01775.
NDA 021744	Proquin XR (ciprofloxacin HCl) Tablets, 500 mg	Depomed Inc., 1360 O'Brien Dr., Menlo Park, CA 94025.
NDA 022021	Altace (ramipril) Tablets, 1.25 mg, 2.5 mg, 5 mg, and 10 mg.	King Pharmaceuticals Inc., c/o Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 022026	Amlodipine Besylate Orally Disintegrating Tablets, 2.5 mg, 5 mg, and 10 mg.	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709.
NDA 022456	Omeprazole, Sodium Bicarbonate, and Magnesium Hydroxide Tablets.	Santarus, Inc., 3721 Valley Centre Dr., Suite 400, San Diego, CA 92130.
ANDA 040015	Neosar (cyclophosphamide) for Injection, 100 mg, 200 mg, 500 mg, 1 gram (gm), and 2 gm vials.	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 040079	Thiamine HCl Injection USP, 100 mg/mL	Hospira, Inc.
ANDA 040131	Edrophonium Chloride Injection, 10 mg/mL	Do.
ANDA 040162	Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg	IVAX Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 040272	Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg.	Duramed Pharmaceuticals, Inc., Subsidiary of Barr Laboratories, Inc., Indirect Wholly Owned Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 040332	Leucovorin Calcium Injection USP, 10 mg (base)	Teva Parenteral Medicines, Inc.
ANDA 040364	Prednisolone Syrup, 15 mg/5 mL	Nesher Pharmaceuticals (USA) LLC, 13910 Saint Charles Rock Rd., Bridgton, MO 63044.
ANDA 040373	Hydralazine HCl Injection USP, 20 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 040423	Prednisolone Syrup, 5 mg/5 mL	Nesher Pharmaceuticals (USA) LLC.
ANDA 040505	Prochlorperazine Edisylate Injection USP, 5 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 040641	Methylprednisolone Sodium Succinate for Injection USP, 125 mg/vial, 500 mg/vial, and 1 gm/vial.	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 040662	Methylprednisolone Sodium Succinate for Injection USP, 40 mg/vial.	Do.
ANDA 040709	Methylprednisolone Sodium Succinate for Injection USP, 500 mg/vial and 1 gm/vial.	Do.
ANDA 040795	Benzonatate Capsules USP, 100 mg and 200 mg	Nesher Pharmaceuticals (USA) LLC.
ANDA 040909	Sodium Polystyrene Sulfonate Powder for Suspension, 454 gm/bottle.	Citrus Pharma, LLC, 3940 Quebec Ave. North, Minneapolis, MN 55427.
NDA 050261	Declomycin (demeclocycline HCl) Tablets, 75 mg, 150 mg, and 300 mg.	CorePharma, LLC, 215 Wood Ave., Middllesex, NJ 08846–2554.
ANDA 060003	V-Cillin K (pencillin V potassium tablets USP), 125 mg, 250 mg, and 500 mg.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
ANDA 060517	Fugizone (amphotericin B) for Injection	Bristol-Myers Squibb Co.
ANDA 060575	Mycostatin (nystatin) Cream, 100,000 units/gm	Do.
ANDA 061901	Kantrex (kanamycin sulfate injection USP) Injection,75 mg/2 mL, 500 mg/2 mL, and 1 gm/3 mL.	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038–0446.
ANDA 062008	Nebcin (tobramycin for injection USP)	Eli Lilly and Co.
ANDA 062311	Amikin (amikacin sulfate injection USP), 50 mg/mL and 250 mg/mL.	Brisol-Myers Squibb Co.
ANDA 062707	Nebcin (tobramycin for injection USP)	Eli Lilly and Co.
ANDA 063041	Clindamycin Injection USP	Teva Parenteral Medicines, Inc.
ANDA 063080	Tobramycin Injection USP	Hospira, Inc.
ANDA 063149	Gentamicin Injection USP, 10 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 063282	Clindamycin Phosphate Injection, EQ 150 mg (base)/mL	Do.
ANDA 063253	Erythromycin Lactobionate for Injection USP, 500 mg (base)/vial and 1 gm (base)/vial.	Do.
ANDA 064021	Tobramycin Sulfate Injection	Bristol-Myers Squibb Co.
	Amphotericin B for Injection USP, 50 mg/vial	Teva Parenteral Medicines, Inc.
ANDA 064212	Daunorubicin HCl for Injection USP, 20 mg (base)/vial and 50 mg (base)/vial.	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 065037	Idarubicin HCl for Injection USP, 5 mg/vial, 10 mg/vial, and 20 mg/vial.	Do.
ANDA 065321	Nystatin Topical Powder USP, 100,000 units/gm	Nesher Pharmaceuticals (USA) LLC.
ANDA 065433	Mycophenolate Mofetil Capsules, 250 mg	Zydus Pharmaceuticals (USA) Inc., 73 Route 31 North, Pennington, NJ 08534.
ANDA 065477	Mycophenolate Mofetil Tablets, 500 mg	Do.
ANDA 070159	Tolazamide Tablets USP, 100 mg	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 070160	Tolazamide Tablets USP, 250 mg	Do.
ANDA 070161	Tolazamide Tablets USP, 500 mg	Do.
ANDA 070431	Valproic Acid Capsules, 250 mg	Do.
ANDA 070577	Verapamil HCl Injection USP, 2.5 mg/mL	Hospira, Inc.
ANDA 070818	Ibuprofen Tablets USP, 400 mg	Ohm Laboratories, c/o Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540.
ANDA 070980	Potassium Chloride Extended-Release Capsules USP, 10 milliequivalents.	Nesher Pharmaceuticals (USA) LLC.
ANDA 071200	Disopyramide Phosphate Extended-Release Capsules USP, 150 mg.	Do.
ANDA 071726	Metaproterenol Sulfate Inhalation Solution, 0.6%	Nephron Pharmaceuticals Corp., 4121 South West 34th St., Orlando, FL 32811.
ANDA 071855	Metaproterenol Sulfate Inhalation Solution, 0.4%	Do.
ANDA 072273	Albuterol Inhalation Aerosol[1]	Armstrong Pharmaceuticals, Inc. 25 John Rd., Canton, MA 02021.
ANDA 072437	Fenoprofen Calcium Capsules USP, 200 mg	Par Pharmaceuticals, Inc.
ANDA 072974	Methyldopate HCl Injection USP	Teva Parenteral Medicines, Inc.
ANDA 073000	Dopamine HCl Injection USP, 80 mg/mL	Do.
ANDA 073117	Metoclopramine Injection USP, 5 mg/mL	Hospira, Inc.
ANDA 073465	Sodium Nitroprusside Injection, 25 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 073617	Pentamidine Isethionate for Injection, 300 mg/vial	Baxter Healthcare Corp.
ANDA 073683	Cyclobenzaprine HCl Tablets, 10 mg	Sandoz Inc.
ANDA 074013	Pindolol Tablets USP, 5 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505–4310.
ANDA 074018	Pindolol Tablets USP, 10 mg	Do.
ANDA 074105	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	DAVA Pharmaceuticals, Inc., Parker Plaza, 400 Kelby St., 10th Floor, Fort Lee, NJ 07024.
ANDA 074147	Metoclopramide Injection USP, 5 mg/mL	Hospira, Inc.
ANDA 074206	Dobutamine Injection USP, 250 mg (base)/20 mL	Teva Parenteral Medicines, Inc.
ANDA 074252	Cimetidine HCl Injection, EQ 300 mg (base)/2 mL	Do.
ANDA 074519	Captopril Tablets, 12.5 mg, 25 mg, 50 mg, and 100 mg	Sandoz Inc.
ANDA 074613	Bumetanide Injection USP, 0.25 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 074616	Inamrinone Lactate Injection, 5 mg/mL	Hospira, Inc.
ANDA 074629	Iopamidol Injection USP, 41%, 51%, 61%, and 76%	Baxter Healthcare Corp.
ANDA 074637	Iopamidol Injection USP, 61%	Hospira, Inc.
ANDA 074753	Atracurium Besylate Injection USP, 10 mg/mL (preserved)	Baxter Healthcare Corp.
ANDA 074768	Atracurium Besylate Injection USP, 10 mg/mL (preservative free).	Do.
ANDA 074784	Atracurium Besylate Injection USP, 10 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 074795	Fluphenazine Decanoate Injection USP, 25 mg/mL	Do.
ANDA 074969	Acyclovir for Injection USP, 500 mg/vial and 1,000 mg/vial	Do.
ANDA 075004	Diltiazem HCl Injection, 5 mg/mL	Hospira, Inc.
ANDA 075005	Iopamidol Injection USP, 51%, 61%, and 76%	Do.
ANDA 075012	Etodolac Tablets USP, 400 mg and 500 mg	Mylan Pharmaceuticals, Inc.
ANDA 075071	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 075119	Buspirone HCl Tablet USP, 5 mg, 10 mg, and 15 mg	Egis Pharmaceuticals PLC, c/o GlobePharm Inc., 313 Pine St., Suite 204, Deerfield, IL 60015.
NDA 075166	Isosorbide Mononitrate Extended-Release Tablets, 60 mg	SkyePharma AG, c/o Compliance Resources, LLC, 7100 Farmington Lane, Hillsborough, NC 27278.
ANDA 075328	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811.
ANDA 075392	Propofol Injectable Emulsion, 10 mg/mL	Teva Parenteral Medicines, Inc.

[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 metered-dose inhalers (see 70 FR 17168, April 4, 2005).

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 August 19, 2013. 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 that are in inventory on the date that this notice becomes effective (see

DATES) 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: July 15, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–17324 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request Evaluation of a Kidney Disease Education and Awareness Program in the Hispanic Community

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Kidney Disease Education Program, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Eileen Newman, Associate Director, National Kidney Disease Education Program, OCPL, NIDDK, NIH, Building 31, Room 9A06, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–435–8116 or Email your request, including your address to: *Eileen.newman@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Evaluation of a Kidney Disease Education Program with Promotores in the Hispanic Community, 0925–NEW, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: NKDEP is developing a kidney disease education program to raise awareness among the Hispanic community at risk for kidney disease. Since diabetes is the most common cause of kidney disease, the program is being developed for inclusion in existing diabetes programs being conducted by ''promotores de salud'' (Spanish/English-speaking community health workers). A pilot evaluation will assess: (a) Overall quality of the program from the client and promotor/a perspective, including strengths and weaknesses of the program and the training, and areas for program improvement; (b) effectiveness of the program on the clients (the community members being educated); and (c) effectiveness of materials and training, including promotores' ability to deliver education to the client and administer the client pre-test/post-test surveys. The pilot study will deliver strategic and actionable guidance for refining the educational and training materials for national dissemination. Based on outcomes from the pilot study, a national evaluation is planned that will use the client pre-test/post-test surveys to assess: (a) Knowledge gains about kidney disease, (b) awareness of NKDEP resources and importance of kidney health, (c) reported behavior change outcomes and (d) reported health status.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 101 (see table below).

TABLE A.12.A—ESTIMATE ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Response burden (hours)	Total burden hours
Pilot study collection:					
Promotores	Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2).	12	1	5/60	1
Promotores	Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3).	20	17	15/60	85
Client Group	Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3).	85	1	10/60	14
Client Group (partial)	Client qualitative in-depth interview post-client session (Attachment 4).	4	1	10/60	1
Total		121			101