applicant to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsor stating so, and indicating that FDA would not consider it to be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant or its agent.

Requesting or obtaining such a letter from FDA is not a legal requirement. If a prospective ANDA applicant chooses to request such a letter, this guidance is intended to clarify the process for doing so.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on how a prospective generic applicant can obtain a letter stating that its BE study protocols contain safety protections comparable to those in the applicable REMS for the RLD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 1, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28540 Filed 12–4–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1795]

Mallinckrodt Inc. et al.; Withdrawal of Approval of 23 New Drug Applications and 68 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 23 new drug applications (NDAs) and 68 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:* January 5, 2015.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, 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 pursuant to 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 002852	Plexofer (multivitamins) Syrup	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042.
NDA 008719	Levo-Dromoran (levorphanol tartrate) Injection, 2 milligrams (mg)/milliliter (mL).	Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 008720	Levo-Dromoran (levorphanol tartrate) Tablets, 2 mg	Do.
NDA 011777	Sodium Phosphate P 32 Solution	Mallinckrodt Inc.
NDA 012366	Soma Compound with Codeine (carisoprodol, aspirin, and codeine phosphate).	Meda Pharmaceuticals Inc., 265 Davidson Ave., Suite 300, Somerset, NJ 08873–4120.
NDA 012708	Diutensen-R (methyclothiazide and reserpine) Tablets, 2.5 mg/0.1 mg.	Do.
NDA 016245	Vercyte (pipobroman) Tablets	AbbVie, Inc., 1 North Waukegan Rd., Dept. PA 77/Bldg. AP30, North Chicago, IL 60064.
NDA 017463	Motrin (ibuprofen) Tablets, 300 mg, 400 mg, 600 mg, and 800 mg.	McNeil Consumer Healthcare Division of McNeil-PPC, Inc., 7050 Camp Hill Rd., Fort Washington, PA 19034–2299.
NDA 018310	Lymphazurin (isosulfan blue), 1%	Covidien, 60 Middletown Ave., North Haven, CT 06473.
NDA 018340	Aerobid (flunisolide) Inhalation Aerosol [1]	Roche Palo Alto LLC, c/o Genentech Inc., 1 DNA Way, South San Francisco, CA 94080–4990.
NDA 018731	Buspar (buspirone hydrochloride (HCl)) Tablets, 5 mg, 10 mg, 15 mg, and 30 mg.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 019453	Drixoral (dexbrompheniramine maleate, pseudoephedrine sulfate, and acetaminophen) Extended-Release Tablets, 3 mg, 60 mg, and 500 mg.	Merck Consumer Care, 556 Morris Ave., Summit, NJ 07901.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 019842	Motrin (ibuprofen) Suspension, 100 mg/5 mL	McNeil Consumer Healthcare Division of McNeil-PPC, Inc.
NDA 020150	Nicotrol TD (nicotine transdermal system), 5 mg/16 hour (hr), 10 mg/16 hr, and 15 mg/16 hr.	Do.
NDA 020707	Skelid (tiludronate disodium) Tablets	Sanofi-Aventis U.S. LLC, 55 Corporate Dr., Mailstop 55C–205A, Bridgewater, NJ 08807.
NDA 021043	RID Mousse (pyrethrins 0.33% and piperonyl butoxide 4.0%) Topical Aerosol.	Bayer Healthcare LLC, 100 Bayer Blvd., Whippany, NJ 07981–0915.
NDA 021082	Tavist Allergy Sinus Headache (clemastine fumarate, pseudoephedrine HCl, and acetaminophen) Tablets, 0.335 mg, 30 mg, and 500 mg.	Novartis Consumer Health, Inc., 200 Kimball Dr., Parsippany, NJ 07054.
NDA 021190	Buspar (buspirone HCl) Capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg.	Bristol-Myers Squibb Co.
NDA 021335	Gleevac (imatinib mesylate) Capsules, 50 mg and 100 mg ...	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936.
NDA 021745	Ryzolt (tramadol HCl) Extended-Release Tablets, 100 mg, 200 mg, and 300 mg.	Purdue Pharma Products L.P., One Stamford Forum, Stamford, CT 06901–3431.
NDA 022217	Valturna (aliskiren and valsartan) Tablets	Novartis Pharmaceuticals Corp.
NDA 022470	Nexcede (ketoprofen) Oral Soluble Films, 12.5 mg	Novartis Consumer Health, Inc.
ANDA 040034	Theophylline Extended-Release Tablets, 450 mg	Inwood Laboratories, Inc., Subsidiary of Forest Laboratories, Inc., Harborside Financial Center, Plaza Five, Suite 1900, Jersey City, NJ 07311.
ANDA 040052	Theophylline Extended-Release Capsules, 100 mg, 125 mg, 200 mg, and 300 mg.	Do.
ANDA 040365	Dextroamphetamine Sulfate Tablets, 5 mg	Nesher Pharmaceutical (USA) LLC, 13910 Saint Charles Rock Rd., Bridgeton, MO 63044.
ANDA 040367	Dextroamphetamine Sulfate Tablets, 10 mg	Do.
ANDA 060578	Mycostatin Topical Powder (nystatin topical powder USP) 100,000 units/gram (g).	Delcor Asset Corp., c/o Prestium Pharma Inc., 411 South State St., Suite E–100, Newtown, PA 18940.
ANDA 062162	Erythromycin Estolate Capsules USP, 125 mg and 250 mg ..	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 062256	Erythromycin Ethylsuccinate Tablets USP, 400 mg	Do.
ANDA 062773	Cephalexin Capsules USP 250 mg	Do.
ANDA 062850	Cephradine Capsules USP 250 mg	Do.
ANDA 062851	Cephradine Capsules USP 500 mg	Do.
ANDA 062858	Cephradine for Oral Suspension USP 125 mg/5 mL	Do.
ANDA 062859	Cephradine for Oral Suspension USP, 250 mg/5 mL	Do.
ANDA 063016	Cefazolin for Injection USP 250 mg/vial, 500 mg/vial, and 1 g/vial.	Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044.
ANDA 063028	Erythromycin Delayed-Release Tablets USP, 333 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA.
ANDA 063086	Erythromycin Delayed-Release Tablets, 333 mg	Do.
ANDA 063098	Erythromycin Delayed-Release Capsules USP, 250 mg	Do.
ANDA 063179	Erythromycin Stearate Tablets USP 500 mg	ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623.
ANDA 064191	Cefuroxime for Injection USP 7.5 g/vial	Teva Pharmaceuticals USA.
ANDA 064192	Cefuroxime for Injection USP 750 mg/vial and 1.5 g/vial	Do.
ANDA 065032	Doxycycline Capsules USP 50 mg and 100 mg	Sandoz Inc., 4700 Sandoz Dr., Wilson, NC 27893.
ANDA 065227	Ceftriaxone for Injection USP, 250 mg/vial, 500 mg/vial, 1 g/vial, and 2 g/vial.	Teva Pharmaceuticals USA.
ANDA 065262	Ceftriaxone for Injection USP, 1 g/vial and 2 g/vial	Do.
ANDA 065274	Ceftriaxone for Injection USP, 10 g/vial	Do.
ANDA 070034	Sulfamethoxazole and Trimethoprim Tablets USP 400 mg/80 mg.	Teva Pharmaceuticals USA.
ANDA 070216	Sulfamethoxazole and Trimethoprim Tablets USP 800 mg/160 mg.	Barr Laboratories Inc., Subsidiary of Teva Pharmaceuticals.
ANDA 072410	Indomethacin Extended-Release Capsules, 75 mg	Inwood Laboratories, Inc., Subsidiary of Forest Laboratories, Inc.
ANDA 072499	Propranolol HCl Extended-Release Capsules, 60 mg	Do.
ANDA 072500	Propranolol HCl Extended-Release Capsules, 80 mg	Do.
ANDA 072501	Propranolol HCl Extended-Release Capsules, 120 mg	Do.
ANDA 072502	Propranolol HCl Extended-Release Capsules, 160 mg	Do.
ANDA 072619	Albuterol Sulfate Tablets USP 2 mg	Teva Pharmaceuticals USA.
ANDA 072620	Albuterol Sulfate Tablets USP 4 mg	Do.
ANDA 073095	Clemastine Fumerate Syrup, 0.5 mg/5 mL	Do.
ANDA 073531	Potassium Chloride Extended-Release Capsules USP, 8 milliequivalents (mEq).	Do.
ANDA 073532	Potassium Chloride Extended-Release Capsules USP, 10 mEq.	Do.
ANDA 073667	Nortriptyline HCl Capsules, 10 mg, 25 mg, 50 mg, and 75 mg.	Do.
ANDA 074043	Piroxicam Capsules USP, 10 mg and 20 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 074126	Atenolol Tablets USP, 25 mg, 50 mg, and 100 mg	Do.
ANDA 074589	Minoxidil Topical Solution, 2%	Teva Pharmaceuticals USA.
ANDA 074828	Acyclovir Capsules, 200 mg	Do.
ANDA 074849	Clomipramine HCl Capsules, 25 mg, 50 mg, and 75 mg	Do.
ANDA 074879	Ketoprofen Extended-Release Capsules, 200 mg	Alkermes Gainesville LLC, 1300 Gould Dr., Gainesville, GA 30504.
ANDA 074976	Acyclovir Tablets USP, 400 mg and 800 mg	Mylan Pharmaceuticals, Inc.
ANDA 074977	Acyclovir Capsules USP, 200 mg	Do.
ANDA 075161	Ticlopidine HCl Tablets USP, 250 mg	Do.
ANDA 075472	Enalapril Maleate Tablets USP, 2.5 mg, 5 mg, 10 mg, and 20 mg.	Do.
ANDA 075934	Nizatidine Capsules USP, 150 mg and 300 mg	Do.
ANDA 076036	Quinapril Tablets USP, 5 mg, 10 mg, 20 mg, and 40 mg	Do.
ANDA 076969	Metoprolol Succinate Extended-Release Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg.	Sandoz, Inc.
ANDA 077136	Terbinafine HCl Tablets, 250 mg	Mylan Pharmaceuticals, Inc.
ANDA 077163	Sumatriptan Succinate Tablets, 25 mg, 50 mg, and 100 mg ..	Do.
ANDA 077254	Divalproex Sodium Delayed-Release Tablets USP, 125 mg, 250 mg, and 500 mg.	Do.
ANDA 077486	Glimepiride Tablets USP, 1 mg, 2 mg, and 4 mg	Do.
ANDA 077705	Fosinopril Sodium and Hydrochlorothiazide Tablets, 10 mg/12.5 mg and 20 mg/12.5 mg.	Do.
ANDA 077934	Meloxicam Tablets USP, 7.5 mg and 15 mg	Do.
ANDA 077976	Cromolyn Sodium Nasal Solution USP, 5.2 mg/1 spray	HH & P LLC, c/o Kuker Regulatory Consulting, LLC, 18 Dunbar Way, Mahtomedi, MN 55115.
ANDA 078638	Alendronate Sodium Tablets USP, 35 mg and 70 mg	Mylan Pharmaceuticals, Inc.
ANDA 078731	Levetiracetam Tablets, 250 mg, 500 mg, 750 mg, and 1,000 mg.	Do.
ANDA 079184	Ursodiol Tablets USP, 250 mg and 500 mg	Teva Pharmaceuticals USA.
ANDA 081295	Estradiol Tablets USP, 0.5 mg	Bristol-Myers Squibb Co.
ANDA 084499	Estradiol Tablets USP, 1 mg	Do.
ANDA 084500	Estradiol Tablets USP, 2 mg	Do.
ANDA 085794	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124.
ANDA 085795	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Do.
ANDA 087176	Chlorthalidone Tablets USP, 50 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 087653	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Mutual Pharmaceutical Co., Inc.
ANDA 088833	Triprolidine HCl, pseudoephedrine HCl, and Codeine Phosphate Cough Syrup, 1.25 mg/5 mL, 30 mg/5 mL, and 10 mg/5 mL.	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 088896	Promethazine VC with Codeine (promethazine HCl, phenylephrine HCl, and codeine phosphate) Cough Syrup, 6.25 mg/5 mL, 5 mg/5 mL, and 10 mg/5 mL.	Do.
NDA 202343	Juvisync (sitagliptin and simvastatin) Tablets, 100 mg/10 mg, 100 mg/20 mg, and 100 mg/40 mg.	Merck Sharp & Dohme Corp., 351 North Sumneytown Pike, P.O. Box 1000, UG2CD–015, North Wales, PA 19454.

[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 flunisolide metered-dose inhalers (see 75 FR 19213, April 14, 2010).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the 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 January 5, 2015. 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 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: December 1, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28541 Filed 12–4–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork