

**INFORMATION CONTACT**) at least 7 days in advance.

A live Web cast of this meeting will be viewable at <https://collaboration.fda.gov/opmr/> on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

#### IV. 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. To ensure consideration, submit comments by June 19, 2014. 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>.

#### V. Transcripts

As soon as possible after a transcript of the public meeting is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management

(see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: April 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-09123 Filed 4-21-14; 8:45 am]

**BILLING CODE 4160-01-P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2014-N-0398]

#### Eli Lilly and Company, et al.; Withdrawal of Approval of 3 New Drug Applications and 41 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing

approval of 3 new drug applications and 41 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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 May 22, 2014.

#### 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—REQUESTS TO WITHDRAW APPROVAL OF APPLICATIONS

Application No.	Drug	Applicant
NDA 050440 .....	Keflet (cephalexin) Tablets .....	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 050614 .....	Keftab (cephalexin hydrochloride) Tablets .....	Do.
NDA 050673 .....	Ceclor CD (cefaclor) Tablets .....	Do.
ANDA 075457 ....	Famotidine Tablets USP, 20 milligrams (mg) and 40 mg .....	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505-4310.
ANDA 075559 ....	Butorphanol Tartrate Injection USP, 1 mg/milliliter (mL) and 2 mg/mL.	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
ANDA 075572 ....	Bupirone HCl Tablets USP, 5 mg, 10 mg, and 15 mg .....	Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044.
ANDA 075594 ....	Pamidronate Disodium for Injection, 30 mg/vial and 90 mg/vial.	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 075609 ....	Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg ...	Nesher Pharmaceuticals (USA) LLC.
ANDA 075613 ....	Bupropion HCl Tablets, 75 mg and 100 mg .....	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038-0446.
ANDA 075627 ....	Acyclovir Injection, 50 mg/mL .....	Teva Parenteral Medicines, Inc.
ANDA 075730 ....	Thiotepa for Injection USP, 15 mg/vial and 30 mg/vial .....	Do.
ANDA 075793 ....	Famotidine Tablets USP, 20 mg and 40 mg .....	Sandoz Inc.
ANDA 075847 ....	Oxaprozin Tablets USP, 600 mg .....	Mylan Pharmaceuticals, Inc.
ANDA 075905 ....	Famotidine Injection, 10 mg/mL .....	Hospira, Inc.
ANDA 075943 ....	Etodolac Extended-Release Tablets, 400 mg, 500 mg, and 600 mg.	Sandoz Inc.
ANDA 075950 ....	Fluvoxamine Maleate Tablets, 50 mg and 100 mg .....	Mylan Pharmaceuticals, Inc.
ANDA 076018 ....	Amiodarone HCl Injection, 50 mg/mL .....	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 076042 ....	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg ..	Mylan Pharmaceuticals, Inc.
ANDA 076044 ....	Potassium Chloride Extended-Release Tablets USP, 20 milliequivalents.	Nesher Pharmaceuticals (USA) LLC.
ANDA 076088 ....	Amiodarone HCl Injection, 50 mg/mL .....	Bedford Laboratories.
ANDA 076193 ....	Propafenone HCl Tablets, 150 mg, 225 mg, and 300 mg .....	Nesher Pharmaceuticals (USA) LLC.
ANDA 076259 ....	Milrinone Lacate in 5% Dextrose Injection .....	Baxter Healthcare Corp., 25212 W. Illinois Route 120, Round Lake, IL 60073.
ANDA 076299 ....	Amiodarone HCl Injection, 50 mg/mL .....	Bedford Laboratories.

TABLE 1—REQUESTS TO WITHDRAW APPROVAL OF APPLICATIONS—Continued

Application No.	Drug	Applicant
ANDA 076315 ....	Topiramate Tablets, 25 mg, 100 mg, and 200 mg .....	Barr Laboratories, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 076372 ....	Brimonidine Tartrate Ophthalmic Solution, 0.2% .....	Teva Parenteral Medicines, Inc.
ANDA 076398 ....	Tamoxifen Citrate Tablets USP, 10 mg and 20 mg .....	Aegis Pharmaceuticals PLC, c/o GlobePharm Inc., 313 Pine St., Suite 204, Deerfield, IL 60015.
ANDA 076424 ....	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg ..	Pliva Inc., c/o Barr Laboratories Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, U.S. Agent, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 076448 ....	Topiramate Capsules, 15 mg and 25 mg .....	Barr Laboratories, Inc.
ANDA 076529 ....	Loratadine Syrup (loratadine oral solution USP), 1 mg/mL .....	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc., U.S., 600 College Rd. East, Princeton, NJ 08540.
ANDA 076540 ....	Sertraline HCl Tablets, 25 mg, 50 mg, and 100 mg .....	Mylan Pharmaceuticals, Inc.
ANDA 076612 ....	Benazepril HCl and Hydrochlorothiazide Tablets, 5 mg/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg.	Do.
ANDA 076640 ....	Metoprolol Succinate Extended-Release Tablets, 100 mg and 200 mg.	Nesher Pharmaceuticals (USA) LLC.
ANDA 076865 ....	Fluticasone Propionate Cream, 0.05% .....	Do.
ANDA 076982 ....	Prednisolone Sodium Phosphate Oral Solution USP, 5 mg/5 mL.	Do.
ANDA 076992 ....	Ciprofloxacin Injection USP, 10 mg/mL .....	Bedford Laboratories.
ANDA 076993 ....	Ciprofloxacin Injection USP, 10 mg/mL .....	Do.
ANDA 077074 ....	Lorazepam Injection USP (Preservative-Free), 2 mg/mL and 4 mg/mL.	Do.
ANDA 077076 ....	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL, 10 mL per vial.	Do.
ANDA 077080 ....	Amlodipine Besylate Tablets, 2.5 mg, 5 mg, and 10 mg .....	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709.
ANDA 077085 ....	Leflunomide Tablets, 10 mg and 20 mg .....	Sandoz Inc.
ANDA 077311 ....	Hydromorphone HCl Tablets USP, 2 mg, 4 mg, and 8 mg ....	Nesher Pharmaceuticals (USA) LLC.
ANDA 085917 ....	Acetaminophen and Codeine Phosphate Tablets, 30 mg .....	Sandoz Inc.
ANDA 087423 ....	Acetaminophen and Codeine Phosphate Tablets, 300 mg/60 mg.	Do.
ANDA 087433 ....	Acetaminophen and Codeine Phosphate Tablets, 300 mg/15 mg.	Do.

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 May 22, 2014. 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: April 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-09124 Filed 4-21-14; 8:45 am]

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**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 Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than May 22, 2014.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Children's Hospitals Graduate Medical Education Payment Program.

*OMB No.:* 0915-0247 Revision.

*Abstract:* The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106-129 to provide federal support for graduate medical education (GME) to freestanding children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation requires that eligible children's hospitals receive payments for both direct and indirect medical