Department of Health and Human Services announced the adoption of the Health Level 7 (HL7) units of measure standard by all U.S. Federal Agencies, which had been developed under the Consolidated Health Informatics (CHI) initiative (see 70 FR 76287, December 23, 2005 (available at *https://www.govinfo.gov/content/pkg/FR-2005-12-23/pdf/05-24289.pdf*). The CHI initiative was a Federal government-wide collaborative effort intended to implement health care information interoperability standards to enable the Federal government to more efficiently exchange electronic health care information. The UCUM units of standard measure is found in HL7 Vocabulary Table 0396 (*https://www.hl7.org/special/committees/vocab/table_0396/index.cfm*).

UCUM is a mature standard in the Interoperability Standards Advisory (ISA) (*https://www.healthit.gov/isa/representing-units-measure-use-numerical-references-and-values*). The ISA process represents the model by which the Office of the National Coordinator for Health Information Technology coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the health care industry to address specific interoperability needs, including, but not limited to, interoperability for clinical, public health, and research purposes.

FDA currently supports the use of UCUM codes (available at *http://unitsofmeasure.org/trac/*) in certain structured product labeling (SPL) submissions, such as labeling and electronic drug establishment registration and drug listing requirements. The SPL web page provides a list of UCUM names FDA currently accepts (available at *https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm168397.htm*).

Technical Specification for creating electronic files using UCUM for units of measure is provided in the Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing, which can be found on the FDA Structured Product Labeling Resources web page (*https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm*).

Although FDA currently supports the UCUM standard, the FDA Data Standards Catalog will be updated to announce immediate implementation of the UCUM standard. After receiving comments, the Agency may consider further actions regarding the adoption of the UCUM standard and/or its implementation date.

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19346 Filed 9–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3658]

Eli Lilly and Co., et al.; Withdrawal of Approval of 25 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 25 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of October 9, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table 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.

Application No.	Drug	Applicant
NDA 007529	Quinidine Gluconate Injection, 80 milligrams (mg)/milliliters (mL).	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 016096	Mintezol (thiabendazole) Chewable Tablet, 500 mg	Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889–0100.
NDA 016097	Mintezol (thiabendazole) Suspension 500 mg/5 mL	Do.
NDA 017439	Hydroxyprogesterone Caproate Injection, 125 mg/mL and 250 mg/mL.	Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940.
NDA 017831	Didronel (etidronate disodium) Tablet, 200 mg and 400 mg.	Allergan Pharmaceuticals International Limited, c/o Allergan Sales, LLC., 2525 Dupont Dr., Irvine, CA 92612.
NDA 019081	Estraderm (estradiol transdermal system), 0.05 mg/24 hour (h) and 0.1 mg/24 h.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936–1080.
NDA 019596	Magnevist (gadopentetate dimeglumine) Injection, 469.01 mg/mL.	Bayer HealthCare Pharmaceuticals, Inc., 100 Bayer Blvd., P.O. Box 915, Whippany, NJ 07981–0915.
NDA 020071	Desogen (desogestrel and ethinyl estradiol) Tablets, 0.15 mg/0.03 mg.	Organon USA, Inc., a subsidiary of Merck and Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 020120	AllerNaze (triamcinolone acetonide) Nasal Spray, 0.05 mg/spray.	Lupin Atlantis Holdings, S.A., c/o Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 24th Floor, Baltimore, MD 21202.
NDA 020628	Invirase (saquinavir mesylate) Capsules, equivalent to (EQ) 200 mg base.	Hoffmann-La Roche, Inc., 1 DNA Way, South San Francisco, CA, 94080–4990.

Application No.	Drug	Applicant
NDA 020937	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Liebel-Flarsheim Co., LLC., 1034 South Brentwood Blvd., Suite 800, Richmond Heights, MO 63117.
NDA 020947	Pennsaid (diclofenac sodium) Topical Solution, 1.5% weight by weight (w/w).	Nuvo Pharmaceuticals, Inc., c/o Dwayne R.J. Moore, 41 Campus Dr., Suite 202, New Gloucester, ME 04260.
NDA 020975	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Liebel-Flarsheim Co., LLC.
NDA 020976	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Do.
NDA 021037	Magnevist (gadopentetate dimeglumine) Injection, 469.01 mg/mL.	Bayer HealthCare Pharmaceuticals, Inc.
NDA 021105	Sulfamethoxazole and Trimethoprim Tablets, 800 mg/160 mg; and Phenazopyridine HCL Tablets, 200 mg.	Able Laboratories, Inc., 1 Able Dr., Cranbury, NJ 08512.
NDA 021144	Ketek (telithromycin) Tablets, 300 mg and 400 mg	Sanofi-Aventis U.S., LLC., 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 021178	Glucovance (glyburide and metformin hydrocholoride (HCl)) Tablets, 1.25 mg/250 mg, 2.5 mg/500 mg, 5 mg/500 mg.	Bristol-Myers Squibb Co., P.O. Box 4000, Mail Stop: D.2341, Princeton, NJ 08543–4000.
NDA 021235	Prozac Weekly (fluoxetine delayed-release capsules) 90 mg.	Eli Lilly and Co.
NDA 021490	Femcon Fe (ethinyl estradiol and norethindrone tablets, 0.035 mg/0.4 mg; and ferrous fumarate tablets, 75 mg).	Allergan Pharmaceuticals International Limited, c/o Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940.
NDA 022011	Tyzeka (telbivudine) Tablets, 600 mg	Novartis Pharmaceuticals Corp.
NDA 022154	Tyzeka (telbivudine) Solution, 100 mg/5 mL	Do.
NDA 022328	Intermezzo (zolpidem tartrate) Sublingual Tablets, 1.75 mg and 3.5 mg.	Purdue Pharmaceutical Products L.P., 1 Stamford Forum, Stamford, CT 06901–3431.
NDA 050456	Statrol (neomycin sulfate and polymyxin B sulfate ophthalmic solution, USP) EQ 3.5 mg base/mL; equal to 16,250 units polymyxin B/mL.	Alcon Laboratories, Inc., 6201 South Freeway, Mail Stop: TC–45, Fort Worth, TX 76134–2099.
NDA 204553	ColPrep Kit (magnesium sulfate, potassium sulfate, and sodium sulfate) for Oral Solution, 1.6 grams (g)/3.13 g/17.5 g.	Gator Pharmaceuticals, Inc., 194 Inlet Dr., Saint Augustine, FL 32080.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 9, 2019. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on October 9, 2019 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: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19348 Filed 9–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6069]

Acceptance Review for De Novo Classification Requests; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Acceptance Review for De Novo Classification Requests.'' The purpose of this guidance is to explain the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. This guidance discusses De Novo acceptance review policies and procedures, ''Refuse to Accept'' principles, and the elements of the De Novo Acceptance Checklist and the Recommended Content Checklist and is being issued to be responsive to an explicit deliverable identified in the Medical Device User Fee Amendments of 2017 (MDUFA IV).

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the