The estimated burden is based on the data in a similar collection for recommended glossary and educational outreach approved under OMB control number 0910–0553 (''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use''). As such, the PRA also covers the requirements of the final rule to submit the symbols glossary to FDA in otherwise required submissions during the premarket review process and to disclose it to third parties in otherwise required device labeling, which means adding to such submission or labeling a compiled listing of each SDO-established symbol used in the labeling for the device; the title and designation number of the SDO-developed standard containing the symbol; and the title of the symbol and its reference number, if any, in the standard; and the meaning or explanatory text for the symbol as provided in the FDA recognition or, if FDA has not recognized the standard or portion of the standard in which the symbol is located or the symbol is used not in accordance with the specifications for use of the symbol set out in the FDA section 514(c) recognition, the explanatory text as provided in the standard.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19351 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–3840]

Electronic Submissions; Data Standards; Support for Unified Code for Units of Measure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its adoption of the most current set of the Unified Code for Units of Measure (UCUM) codes. The UCUM is a terminology standard that contains a system of coding units of measure used in science and medicine. UCUM offers a single coding system for units of measure that does not contain ambiguities amongst electronic communication, and assigns a concise semantics to each defined unit. FDA is encouraging sponsors and applicants to use UCUM standard for drug establishment registration and drug listing, as well as for content of product labeling provided in regulatory submissions to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research.

ADDRESSES: You may submit either electronic or written comments 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 public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3840 for ''Electronic Submissions; Data Standards; Support for Unified Code for Units of Measure.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *cderdatastandards@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: On May 23, 2005, the Secretary of the

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.