This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 13, 2021.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *Independent Bank Corp., (''Independent'') through its subsidiary, Bradford Merger Sub Inc., both of Rockland, Massachusetts;* to merge with Meridian Bancorp, Inc., Peabody, Massachusetts (''Meridian''), with Meridian as the survivor, and thereby indirectly acquire East Boston Savings Bank, Boston, Massachusetts. Immediately after, Meridian to merge with Independent, with Independent as the survivor, and East Boston Savings Bank to merge with and into Rockland Trust, Rockland, Massachusetts, a wholly owned subsidiary bank of Independent, with Rockland Trust as the surviving bank.

Board of Governors of the Federal Reserve System, July 9, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–14997 Filed 7–13–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10341]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice; partial withdrawal.

SUMMARY: On Friday, July 9, 2021, the Centers for Medicare & Medicaid Services (CMS) published a notice entitled, ''Agency Information Collection Activities: Submission for OMB Review; Comment Request.'' That notice invited public comments on three separate information collection requests specific to document identifiers: CMS–10215, CMS–10249, and CMS–10341. Through the publication of this document, we are withdrawing the portion of the notice requesting public comment on the information collection request titled ''Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428.'' Form number CMS–10341 (OMB control number 0938–1162). The withdrawn information collection request will be replaced by another 30-day notice in July or August of this year.

DATES: For CMS–10215 and CMS–10249, the original comment period for the notice that published on July 9, 2021, remains in effect and ends August 9, 2021.

SUPPLEMENTARY INFORMATION: In FR document, 2021–14671, published on July 9, 2021 (86 FR 36281), we are withdrawing item 3 ''Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428'' which posted on page 36282.

Dated: July 9, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–15005 Filed 7–13–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0191]

Determination That STROMECTOL (Ivermectin) Tablets, 6 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that STROMECTOL (ivermectin) tablets, 6 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for STROMECTOL (ivermectin) tablets, 6 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3600, *Christopher.Koepke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

STROMECTOL (ivermectin) tablets, 6 mg, are the subject of NDA 050742, held by Merck Sharp and Dohme Corp., and initially approved on November 22, 1996. STROMECTOL is indicated for strongyloidiasis of the intestinal tract and onchocerciasis.

In a letter dated September 14, 2007, Merck and Co., Inc. notified FDA that STROMECTOL (ivermectin) tablets, 6 mg, were being discontinued, and FDA

moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Foley and Lardner, LLP submitted a citizen petition dated February 16, 2021 (Docket No. FDA–2021–P–0191), under 21 CFR 10.30, requesting that the Agency determine whether STROMECTOL (ivermectin) tablets, 6 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that STROMECTOL (ivermectin) tablets, 6 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that STROMECTOL (ivermectin) tablets, 6 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of STROMECTOL (ivermectin) tablets, 6 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list STROMECTOL (ivermectin) tablets, 6 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to STROMECTOL (ivermectin) tablets, 6 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14935 Filed 7–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3361]

Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of final guidance for industry (GFI) #261 entitled ''Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.'' This guidance is intended for sponsors and potential sponsors who may be interested in pursuing conditional approval of new animal drugs for certain major uses in major species. Eligibility for conditional approval has been expanded beyond minor uses in major species and use in minor species (MUMS) to include certain major uses in major species. The Center for Veterinary Medicine (CVM or we) refers to the process for conditionally approving new animal drugs that are not intended for MUMS indications as ''expanded conditional approval.'' The purpose of expanded conditional approval is to incentivize development of new animal drugs for serious or life-threatening conditions or unmet animal or human health needs under circumstances where a demonstration of effectiveness would require a complex or particularly difficult study or studies. This guidance defines certain terms, clarifies the eligibility criteria for expanded conditional approval, and describes the criteria CVM intends to consider when determining expanded conditional approval eligibility.

DATES: The announcement of the guidance is published in the **Federal Register** on July 14, 2021.

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 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–D–3361 for ''Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.'' 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, 240–402–7500.

- 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