

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](mailto: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]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-P-0191]

#### Determination That STROMEKTOL (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 STROMEKTOL (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 STROMEKTOL (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](mailto: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.

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

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