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.


   Michele Taylor Fennell,
   Deputy Associate Secretary of the Board.

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

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Determination That STROMECTOL (ivermectin) Tablets, 6 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA or Agency) has determined that STROMECTOL (ivermectin) tablets, 6 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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, 10003 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 and Co., Inc. In 2004, Merck and Co., Inc. notified FDA that STROMECTOL (ivermectin) tablets, 6 mg, were being discontinued, and FDA