solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal under OMB Delegated Authority to Extend for Three Years, With Revision, the Following Information Collection

Report title: Reports of Deposits: Report of Transaction Accounts, Other Deposits, and Vault Cash; Annual Report of Deposits and Reservable Liabilities; Report of Foreign (Non-U.S.) Currency Deposits; and Allocation of Low Reserve Tranche and Reservable Liabilities Exemption.

Agency form number: FR 2900; FR 2910a; FR 2915; and FR 2930.

OMB control number: 7100–0087.

Frequency: Weekly, quarterly, annually, and on occasion.

Respondents: Depository institutions.

Estimated number of respondents: FR 2900 (Weekly): 1,000; FR 2900 (Quarterly): 0; FR 2910a: 0; FR 2915: 116; and FR 2930: 0.

Estimated average hours per response: FR 2900 (Weekly): 1.0; FR 2900 (Quarterly): 0; FR 2910a: 0; FR 2915: 0.5; and FR 2930: 0.

Estimated annual burden hours: FR 2900 (Weekly): 52,000; FR 2900 (Quarterly): 0; FR 2910a: 0; FR 2915: 232; and FR 2930: 0.

General description of report: Data from these mandatory reports are used by the Board for administering reserve requirements and for constructing, analyzing, and monitoring the monetary aggregates. The FR 2900 is the primary source of data for the construction and analysis of the monetary aggregates and was used for the calculation of required reserves and applied vault cash. The FR 2910a report has been a key data source for determining which depository institutions need to file the FR 2900. FR 2900 respondents that offer deposits denominated in foreign currencies at their U.S. offices file the FR 2915. Foreign currency deposits are subject to reserve requirements and, therefore, are included in the FR 2900 data. However, because foreign currency deposits are not included in the monetary aggregates, the FR 2915 data are used to net foreign currency-denominated deposits from the FR 2900 data to exclude them from measures of the monetary aggregates. The FR 2930 data are used in the calculation of reserve requirements; typically, depository institutions file this report after being informed of updates to key reserve requirement thresholds toward the end of each calendar year or upon the establishment of an office outside the home state or Federal Reserve District.

Proposed revisions: The Board proposes to take steps to reduce reporting burden associated with reserve requirements by discontinuing the collection of the FR 2910a and FR 2930, ceasing the quarterly collection of the FR 2900, and refocusing items on the weekly collection of the FR 2900 and the FR 2915 to those that support the construction and analysis of the monetary aggregates.

Legal authorization and confidentiality: The FR 2900 report and the FR 2915 report are authorized to be collected from depository institutions (commercial banks, credit unions, and savings and loan associations) pursuant to section 11(a)(2) of the Federal Reserve Act (FRA); from agreement corporations pursuant to section 25(5) and (7) of the FRA and section 604a of the FRA; from banking Edge corporations pursuant to section 25A(17) of the FRA; and from branches and agencies of foreign banks pursuant to section 7 of the International Banking Act. The FR 2900 and FR 2915 are mandatory.

The data collected under the FR 2900 is considered confidential commercial and financial information, and respondents are assured that the data being collected will be treated as confidential by the Federal Reserve (except that aggregate data, which does not identify any individual institution, may be disclosed). Accordingly, the data collected on these reports is considered confidential pursuant to exemption 4 of the Freedom of Information Act, which protects confidential commercial or financial information from public disclosure.

Board of Governors of the Federal Reserve System, August 27, 2020.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2020–19335 Filed 9–1–20; 8:45 am]

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FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. 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(s) 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 October 2, 2020.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *AgCom Holdings, Inc., Holstein, Iowa;* to become a bank holding company by acquiring Maxwell State Bank, Maxwell, Iowa.

Board of Governors of the Federal Reserve System, August 28, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–19405 Filed 9–1–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–0438]

Determination That MICRO-K LS (Potassium Chloride) Extended-Release Liquid Suspension, 20 Milliequivalents/Packet, Was 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 MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 milliequivalents (mEq)/packet, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@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.

MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, is the subject of NDA 019561, held by KV Pharmaceutical Co., and initially approved on August 26, 1988. MICRO-K LS is indicated for the treatment of patients with hypokalemia, with or without metabolic alkalosis; in digitalis intoxication; and in patients with hypokalemic familial periodic paralysis. MICRO-K LS is also indicated for the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop, *e.g.,* digitalized patients or patients with significant cardiac arrhythmias, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium losing nephropathy, and certain diarrheal states.

In a letter dated October 8, 2010, KV Pharmaceutical Co. notified FDA that MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of June 8, 2011 (76 FR 33310), FDA announced that it was withdrawing approval of NDA 019561, effective July 8, 2011.

Hyman, Phelps, and McNamara, P.C. submitted a citizen petition dated January 27, 2020 (Docket No. FDA–2020–P–0438), under 21 CFR 10.30, requesting that the Agency determine whether MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, was 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 MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, 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 MICRO-K LS (potassium chloride) extended-release liquid suspension, 20 mEq/packet, 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: August 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19369 Filed 9–1–20; 8:45 am]

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