

Rules and Regulations

Federal Register

Vol. 81, No. 73

Friday, April 15, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 324

RIN 3064-AE12

Regulatory Capital Rules: Regulatory Capital, Final Revisions Applicable to Banking Organizations Subject to the Advanced Approaches Risk-Based Capital Rule

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Correcting amendment.

SUMMARY: The FDIC is correcting a Final Rule that appeared in the **Federal Register** on July 15, 2015 (80 FR 41409), regarding Regulatory Capital Rules: Regulatory Capital, Final Revisions Applicable to Banking Organizations Subject to the Advanced Approaches Risk-Based Capital Rule (“prior **Federal Register** publication”). This publication corrects a technical error in the instructions to the regulatory text appearing at page 41426 of the prior **Federal Register** publication, where the inadvertent omission of certain language in the instructions to the FDIC’s amendatory text in § 324.403 caused the unintended deletion of § 324.403(b)(2) through § 324.403(d) as published in the Code of Federal Regulations.

DATES: The correction is effective April 15, 2016.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: This document sets out in full the text of section 324.403 as adopted by the FDIC Board of Directors, including the revisions published in the **Federal Register** of July 15, 2015 (80 FR 41426) and the text inadvertently deleted in the Code of Federal Regulations as 12 CFR 324.403.

List of Subjects in 12 CFR Part 324

Administrative practice and procedure, Banks, Banking, Capital adequacy, Reporting and recordkeeping requirements, Savings associations, State non-member banks.

12 CFR CHAPTER III

Authority and Issuance

For the reasons stated in the preamble, the Federal Deposit Insurance Corporation amends part 324 of chapter III of Title 12, Code of Federal Regulations as follows:

PART 324—CAPITAL ADEQUACY

■ 1. The authority citation for part 324 continues to read as follows:

Authority: 12 U.S.C. 1815(a), 1815(b), 1816, 1818(a), 1818(b), 1818(c), 1818(t), 1819(Tenth), 1828(c), 1828(d), 1828(i), 1828(n), 1828(o), 1831o, 1835, 3907, 3909, 4808; 5371; 5412; Pub. L. 102-233, 105 Stat. 1761, 1789, 1790 (12 U.S.C. 1831n note); Pub. L. 102-242, 105 Stat. 2236, 2355, as amended by Pub. L. 103-325, 108 Stat. 2160, 2233 (12 U.S.C. 1828 note); Pub. L. 102-242, 105 Stat. 2236, 2386, as amended by Pub. L. 102-550, 106 Stat. 3672, 4089 (12 U.S.C. 1828 note); Pub. L. 111-203, 124 Stat. 1376, 1887 (15 U.S.C. 78o-7 note).

■ 2. Section 324.403 is revised to read as follows:

§ 324.403 Capital measures and capital category definitions.

(a) *Capital measures.* For purposes of section 38 of the FDI Act and this subpart H, the relevant capital measures shall be:

- (1) The total risk-based capital ratio;
- (2) The Tier 1 risk-based capital ratio; and
- (3) The common equity tier 1 ratio;
- (4) The leverage ratio;
- (5) The tangible equity to total assets ratio; and
- (6) Beginning January 1, 2018, the supplementary leverage ratio calculated in accordance with § 324.11 for advanced approaches FDIC-supervised institutions that are subject to subpart E of this part.

(b) *Capital categories.* For purposes of section 38 of the FDI Act and this subpart, an FDIC-supervised institution shall be deemed to be:

- (1) “Well capitalized” if it:
 - (i) Has a total risk-based capital ratio of 10.0 percent or greater; and
 - (ii) Has a Tier 1 risk-based capital ratio of 8.0 percent or greater; and
 - (iii) Has a common equity tier 1 capital ratio of 6.5 percent or greater; and
 - (iv) Has a leverage ratio of 5.0 percent or greater;
 - (v) Is not subject to any written agreement, order, capital directive, or prompt corrective action directive issued by the FDIC pursuant to section 8 of the FDI Act (12 U.S.C. 1818), the International Lending Supervision Act of 1983 (12 U.S.C. 3907), or the Home Owners’ Loan Act (12 U.S.C. 1464(t)(6)(A)(ii)), or section 38 of the FDI Act (12 U.S.C. 1831o), or any regulation thereunder, to meet and maintain a specific capital level for any capital measure; and

(vi) Beginning on January 1, 2018 and thereafter, an FDIC-supervised institution that is a subsidiary of a covered BHC will be deemed to be well capitalized if the FDIC-supervised institution satisfies paragraphs (b)(1)(i) through (v) of this section and has a supplementary leverage ratio of 6.0 percent or greater. For purposes of this paragraph, a covered BHC means a U.S. top-tier bank holding company with more than \$700 billion in total assets as reported on the company’s most recent Consolidated Financial Statement for Bank Holding Companies (FR Y-9C) or more than \$10 trillion in assets under custody as reported on the company’s most recent Banking Organization Systemic Risk Report (FR Y-15).

(2) “Adequately capitalized” if it:

- (i) Has a total risk-based capital ratio of 8.0 percent or greater; and
- (ii) Has a Tier 1 risk-based capital ratio of 6.0 percent or greater; and
- (iii) Has a common equity tier 1 capital ratio of 4.5 percent or greater; and

(iv) Has a leverage ratio of 4.0 percent or greater; and

(v) Does not meet the definition of a well capitalized bank.

(vi) Beginning January 1, 2018, an advanced approaches FDIC-supervised institution will be deemed to be “adequately capitalized” if it satisfies

paragraphs (b)(2)(i) through (v) of this section and has a supplementary leverage ratio of 3.0 percent or greater, as calculated in accordance with § 324.11 of subpart B of this part.

(3) “Undercapitalized” if it:

(i) Has a total risk-based capital ratio that is less than 8.0 percent; or
 (ii) Has a Tier 1 risk-based capital ratio that is less than 6.0 percent; or
 (iii) Has a common equity tier 1 capital ratio that is less than 4.5 percent; or
 (iv) Has a leverage ratio that is less than 4.0 percent.

(v) Beginning January 1, 2018, an advanced approaches FDIC-supervised institution will be deemed to be “undercapitalized” if it has a supplementary leverage ratio of less than 3.0 percent, as calculated in accordance with § 324.11.

(4) “Significantly undercapitalized” if it has:

(i) A total risk-based capital ratio that is less than 6.0 percent; or
 (ii) A Tier 1 risk-based capital ratio that is less than 4.0 percent; or
 (iii) A common equity tier 1 capital ratio that is less than 3.0 percent; or
 (iv) A leverage ratio that is less than 3.0 percent.

(5) “Critically undercapitalized” if the insured depository institution has a ratio of tangible equity to total assets that is equal to or less than 2.0 percent.

(c) *Capital categories for insured branches of foreign banks.* For purposes of the provisions of section 38 of the FDI Act and this subpart H, an insured branch of a foreign bank shall be deemed to be:

(1) “Well capitalized” if the insured branch:

(i) Maintains the pledge of assets required under § 347.209 of this chapter; and

(ii) Maintains the eligible assets prescribed under § 347.210 of this chapter at 108 percent or more of the preceding quarter’s average book value of the insured branch’s third-party liabilities; and

(iii) Has not received written notification from:

(A) The OCC to increase its capital equivalency deposit pursuant to 12 CFR 28.15, or to comply with asset maintenance requirements pursuant to 12 CFR 28.20; or

(B) The FDIC to pledge additional assets pursuant to § 347.209 of this chapter or to maintain a higher ratio of eligible assets pursuant to § 347.210 of this chapter.

(2) “Adequately capitalized” if the insured branch:

(i) Maintains the pledge of assets required under § 347.209 of this chapter; and

(ii) Maintains the eligible assets prescribed under § 347.210 of this chapter at 106 percent or more of the preceding quarter’s average book value of the insured branch’s third-party liabilities; and

(iii) Does not meet the definition of a well capitalized insured branch.

(3) “Undercapitalized” if the insured branch:

(i) Fails to maintain the pledge of assets required under § 347.209 of this chapter; or

(ii) Fails to maintain the eligible assets prescribed under § 347.210 of this chapter at 106 percent or more of the preceding quarter’s average book value of the insured branch’s third-party liabilities.

(4) “Significantly undercapitalized” if it fails to maintain the eligible assets prescribed under § 347.210 of this chapter at 104 percent or more of the preceding quarter’s average book value of the insured branch’s third-party liabilities.

(5) “Critically undercapitalized” if it fails to maintain the eligible assets prescribed under § 347.210 of this chapter at 102 percent or more of the preceding quarter’s average book value of the insured branch’s third-party liabilities.

(d) *Reclassifications based on supervisory criteria other than capital.* The FDIC may reclassify a well capitalized FDIC-supervised institution as adequately capitalized and may require an adequately capitalized FDIC-supervised institution or an undercapitalized FDIC-supervised institution to comply with certain mandatory or discretionary supervisory actions as if the FDIC-supervised institution were in the next lower capital category (except that the FDIC may not reclassify a significantly undercapitalized FDIC-supervised institution as critically undercapitalized) (each of these actions are hereinafter referred to generally as “reclassifications”) in the following circumstances:

(1) *Unsafe or unsound condition.* The FDIC has determined, after notice and opportunity for hearing pursuant to § 308.202(a) of this chapter, that the FDIC-supervised institution is in unsafe or unsound condition; or

(2) *Unsafe or unsound practice.* The FDIC has determined, after notice and opportunity for hearing pursuant to § 308.202(a) of this chapter, that, in the most recent examination of the FDIC-supervised institution, the FDIC-supervised institution received and has not corrected a less-than-satisfactory rating for any of the categories of asset

quality, management, earnings, or liquidity.

Dated at Washington, DC, this 12th day of April, 2016.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–08717 Filed 4–14–16; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. FDA–2014–D–0044]

Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.” The guidance describes our current thinking on the manufacturing of exempt infant formula in relation to the requirements for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to non-exempt infant formulas.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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