

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

Issued in Washington, DC on October 12, 2007.

Alexander A. Karsner,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. E7-20555 Filed 10-17-07; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE-2007-BT-STD-0010]

RIN 1904-AA89

Energy Efficiency Program for Certain Commercial and Industrial Equipment: Public Meeting and Availability of the Framework Document for Residential Clothes Dryers and Room Air Conditioners; Correction

AGENCY: Department of Energy (DOE).

ACTION: Notice of public meeting and availability of the Framework Document; correction.

SUMMARY: DOE published in the **Federal Register**, Tuesday, October 9, 2007, a notice Energy Efficiency for Certain Commercial and Industrial Equipment: Public Meeting and Availability of the Framework Document for Residential Clothes Dryers and Room Air Conditioners. In that notice, there was an error in the date for accepting comments.

FOR FURTHER INFORMATION CONTACT: Stephen Witkowski, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE-2J, 1000 Independence Avenue, SW., Washington, DC 20585-0121. Telephone: (202) 586-7463. E-mail: Stephen.Witkowski@ee.doe.gov.

Correction

In proposed rule FR Doc. E7-19808 appearing on page 57254 in the issue of Tuesday, October 9, 2007, the following correction should be made:

On page 57255, second column, the date in lines twenty-six and twenty-seven is corrected to read: November 7, 2007.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 16

[Docket ID OCC-2007-0016]

RIN 1557-AD04

Securities Offering Disclosure Rules

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of the Comptroller of the Currency (OCC) is proposing to amend its securities offering disclosure rules at part 16 so that the organizing group of a national bank in organization will, in most cases, not need to provide audited financial statements as part of a public offering of securities.

DATES: Comments must be received by December 17, 2007.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—“Regulations.gov”:* Go to <http://www.regulations.gov>, select “Comptroller of the Currency” from the agency drop-down menu, then click “Submit.” In the “Docket ID” column, click on “OCC-2007-0016” to submit or view public comments and to view supporting and related materials for this notice of proposed rulemaking. The “User Tips” link at the top of the [Regulations.gov](http://www.regulations.gov) home page provides information on using [Regulations.gov](http://www.regulations.gov), including instructions for submitting or viewing public comments, viewing other supporting and related materials, and viewing the docket after the close of the comment period.

- *E-mail:* regs.comments@occ.treas.gov.

- *Fax:* (202) 874-4448.
- *Mail:* Office of the Comptroller of the Currency, 250 E Street, SW., Mail Stop 1-5, Washington, DC 20219.
- *Hand Delivery/Courier:* 250 E Street, SW., Attn: Public Information

Room, Mail Stop 1-5, Washington, DC 20219.

Instructions: You must include “OCC” as the agency name and “Docket ID OCC-2007-0016” in your comment. In general, OCC will enter all comments received into the docket and publish them on [Regulations.gov](http://www.Regulations.gov) without change, including any business or personal information that you provide such as name and address information, e-mail addresses, or phone numbers. Comments, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials by any of the following methods:

- *Viewing Comments Electronically:* Go to <http://www.regulations.gov>, select “Comptroller of the Currency” from the agency drop-down menu, then click “Submit.” In the “Docket ID” column, click on “OCC-2007-0016” to view public comments for this notice of proposed rulemaking.

- *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC’s Public Information Room, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874-5043. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

- *Docket:* You may also view or request available background documents and project summaries using the methods described above.

FOR FURTHER INFORMATION CONTACT: Lee Walzer, Counsel, Legislative and Regulatory Activities Division, (202) 874-4487; Stuart Feldstein, Assistant Director, Legislative and Regulatory Activities Division, (202) 874-5090; Ted Dowd, Senior Attorney, Securities and Corporate Practices, Division, (202) 874-5210; Beverly Evans, Director, Licensing Activities, (202) 874-5060.

SUPPLEMENTARY INFORMATION:

I. Background

12 CFR part 16 generally requires national bank securities offerings to conform to Securities and Exchange Commission (SEC) offering rules and procedures set forth in the Securities Act of 1933 (33 Act).¹ Part 16 cross-references SEC requirements for securities registration statements, including the requirement that companies provide audited financial statements.² This requirement applies to “developmental stage” companies, which includes entities that are analogous to national bank charter applicants.³ Thus, through the OCC’s incorporation of these SEC requirements, national bank charter applicants are required to provide audited financial statements in connection with their registration statements filed with the OCC for an offer and sale of securities.

This notice of proposed rulemaking (NPRM) is part of an ongoing OCC effort to reduce unnecessary regulatory burden on national banks, including applicants for national bank charters. For example, the OCC is working with the other federal banking agencies to produce a report required by section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA), which directs the federal banking agencies to identify regulations that are outdated, unnecessary, or unduly burdensome, and to eliminate them if appropriate. The OCC also recently proposed comprehensive regulatory revisions aimed at reducing regulatory burden by, among other things, removing obsolete provisions, streamlining procedures required in connection with particular types of changes in structure and the conduct of certain activities, and incorporating into our rules interpretive opinions that the OCC has previously published.⁴

As a complement to these burden reducing measures, the OCC also has sought to identify the considerations most relevant to organizing groups for new community banks. This review encompasses both the standards and the processes that the OCC applies to such applicants.

The requirement for an organizing group of a national bank charter applicant to have audited financial statements may not be warranted in

many cases. The process can be time-consuming and expensive. Applicants for a national bank charter have often found it difficult to schedule timely audits. This has resulted in costly delays for their securities offerings. Even after an auditing firm has been hired and the audit has been completed, there is a risk that an audit will become stale and need to be updated before the OCC can declare the registration statement effective.⁵

Moreover, an audited financial statement adds little that benefits potential investors, since there is no national bank business being transacted during the organizational phase, and the bank’s financial statements typically are rudimentary, reflecting little more than the bank account of the organizing group and organizational expenses incurred.

Finally, the OCC typically does not need to rely on audited financial statements in deciding applications for *de novo* national bank charters. In the case of national banks in organization before the OCC, unlike the establishment of most businesses whose registration statements are regulated by the SEC, the chartering of *de novo* national banks is a lengthy and comprehensive process that includes extensive ongoing review of the proposed bank’s management, financial resources, and business plan. This process provides the OCC the opportunity to carefully consider, on the basis of detailed information, whether the organizing group has the expertise and resources to operate a viable national bank.

II. The Proposal

For the reasons stated above, the OCC is proposing to amend part 16 to provide a general waiver of the requirement for an organizing group seeking to establish a national bank charter to use audited financial statements as part of a registration statement for the public offering of securities. The term “organizing group” would have the meaning set forth in 12 CFR 5.20(d)(6) of this chapter.

Under this proposed revision, however, the OCC would retain the authority to require an organizing group to furnish audited financial statements if the OCC concludes that to do so would be in the interest of investors or would further the safe and sound operation of a national bank. Examples of when the OCC may require audited

financial statements include situations where review of the registration statement, or any other aspect of the organizing group’s application to charter a national bank, uncovers incomplete or inaccurate information about the organizing group’s finances or capital, or other material inaccuracies or misstatements.

III. Regulatory Analysis

Regulatory Flexibility Act

Pursuant to Section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b) (RFA), the regulatory flexibility analysis otherwise required under Section 604 of the RFA is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a short, explanatory statement in the **Federal Register** along with its rule.

This change would reduce the costs and expenses associated with the formation of a national bank and will not have a significant economic impact. Therefore, pursuant to Section 605(b) of the RFA, the OCC hereby certifies that this proposal will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not needed.

Executive Order 12866

The OCC has determined that this proposal is not a significant regulatory action under Executive Order 12866. We have concluded that the changes made by this rule will not have an annual effect on the economy of \$100 million or more. The OCC further concludes that this proposal does not meet any of the other standards for a significant regulatory action set forth in Executive Order 12866.

Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Agencies may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The information collection requirements contained in this notice of proposed rulemaking have been submitted to OMB for review and approval under existing OMB control number 1557-0120 (Securities Offering Disclosure Rules).

The OCC is proposing to revise part 16 to add a waiver of audited financial statements for the organizing group of a national bank charter applicant for any

¹ See Securities Offering Disclosure Rules, 59 FR 54789, 90 (Nov. 2, 1994) (Final Rule).

² Regulation S-X, 17 CFR 210.3-01(a); Regulation S-B, 17 CFR 228.310(a).

³ See Rule 1-02(h), Regulation S-X, 17 CFR 210.1-02(h).

⁴ 74 FR 36550 (July 3, 2007).

⁵ Regulations S-X and S-B require that audited financial statements that are 135 days older than the effective date of the registration statement be updated with interim financial statements. 17 CFR 210.3-12 and 228.310.

registration statement for bank securities submitted by such group. The PRA burden in part 16 is currently approved under OMB Control No. 1557-0120. Therefore, we submitted the entire information collection for review. The numbers below reflect the entire burden for part 16 following adoption of the rule and the review of the entire information collection to ensure accuracy of the estimates.

Title of Information Collection: Securities Offering Disclosure Rules—12 CFR Part 16.

OMB Number: 1557-0120.

Estimated Number of Respondents: 48.

Estimated Number of Responses: 48.

Average Hours per Response: 9.375.

Total Estimated Annual Burden: 450.

Affected Public: National bank charter applicants.

Estimated Net Burden Change: -60 hours.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4 (2 U.S.C. 1532) (Unfunded Mandates Act), requires that an agency prepare a budgetary impact statement before promulgating any rule likely to result in a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year. If a budgetary impact statement is required, Section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC has determined that this proposed rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of \$100 million or more in any one year. Accordingly, this proposal is not subject to Section 202 of the Unfunded Mandates Act.

List of Subjects in 12 CFR Part 16

National banks, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, chapter I of title 12 of the Code of Federal Regulations is proposed to be amended as follows:

PART 16—SECURITIES OFFERING DISCLOSURE RULES

1. The authority citation for part 16 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.* and 93a.

2. Add § 16.15(e) to read as follows:

§ 16.15 Form and content.

* * * * *

(e) Notwithstanding paragraph (a) of this section, an organizing group seeking to establish a national bank charter pursuant to § 5.20 of this chapter shall not be required to include audited financial statements as part of its registration statement, unless the OCC determines that factors particular to the proposal indicate that inclusion of such statements would be in the interest of investors or would further the safe and sound operation of a national bank. The term “organizing group” shall have the meaning set forth in § 5.20(d)(6) of this chapter.

Dated: October 12, 2007.

John C. Dugan,

Comptroller of the Currency.

[FR Doc. E7-20600 Filed 10-17-07; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. 2007N-0284]

Revision of the Requirements for Live Vaccine Processing; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by providing options to the existing requirement for the processing of live vaccines. FDA is proposing to amend the regulations due to advances in technology that will allow processing of live vaccines to be performed in multiproduct manufacturing areas. We are publishing this rule because the existing requirement regarding facilities and equipment for processing live vaccines is too prescriptive and is no longer necessary. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments or electronic comments by January 2, 2008.

ADDRESSES: You may submit comments, identified by Docket No. 2007N-0284, by any of the following methods:
Electronic Submissions

Submit electronic comments in the following ways:

• Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

• Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

• FAX: 301-827-6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. 2007N-0284 for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments see the “Request for Comments” heading in section VII of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Live organisms are used in the production of certain vaccine products.