rulemaking among the responsible agencies as provided in section 619 of the Dodd-Frank Act. Therefore, the Agencies are extending the comment period for the proposed rule from January 13, 2012 to February 13, 2012.

Dated: December 22, 2011.

John Walsh,

Acting Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary under delegated authority, December 23, 2011.

Jennifer J. Johnson,

Secretary of the Board.

By delegated authority from the Board of Directors of the Federal Deposit Insurance Corporation.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

By the Securities and Exchange Commission.

Dated: December 23, 2011.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–33623 Filed 12–30–11; 8:45 am]

BILLING CODE 4810–33–P; 6714–10–P; 6210–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 230

[Release No. 34–66058; File No. S7–38–11]

RIN 3235–AL04

Prohibition Against Conflicts of Interest in Certain Securitizations

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Securities and Exchange Commission is extending the comment period for a release proposing a new rule to implement Section 621 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the ''Dodd-Frank Act'') on material conflicts of interest in connection with certain securitizations (the ''ABS Conflicts Proposal''). The original comment period for the ABS Conflicts Proposal was scheduled to end on December 19, 2011. On December 13, 2011, the comment period was extended until January 13, 2012. Today, the Commission is again extending the time period in which to provide the Commission with comments on the ABS Conflicts Proposal until February 13, 2012. This action will allow interested persons additional time to analyze the issues and prepare their comments.

DATES: Comments should be received on or before February 13, 2012.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*);

- Send an email to *rule-comments@sec.gov.* Please include File Number S7–38–11 on the subject line; or
- Use the Federal Rulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–38–11. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sandoe, Senior Special Counsel, Anthony Kelly, Special Counsel, or Barry O'Connell, Attorney Advisor, Office of Trading Practices, Division of Trading and Markets, at (202) 551–5720, and David Beaning, Special Counsel and Katherine Hsu, Chief, Office of Structured Finance, Division of Corporation Finance, at (202) 551–3850.

SUPPLEMENTARY INFORMATION: The Commission has requested comment on Proposed Rule 127B under the Securities Act of 1933 (''Securities Act'') in the ABS Conflicts Proposal to implement Section 621 of the Dodd-Frank Act.[1] Proposed Rule 127B under the Securities Act would prohibit certain persons who create and distribute an asset-backed security, including a synthetic asset-backed security, from engaging in transactions, within one year after the date of the first closing of the sale of the asset-backed security, that would involve or result in a material conflict of interest with respect to any investor in the asset-backed security. The proposed rule also would provide exceptions from this prohibition for certain risk-mitigating hedging activities, liquidity commitments, and bona fide market-making. The ABS Conflicts Proposal was published in the **Federal Register** on September 28, 2011.

The Commission originally requested that comments on the ABS Conflicts Proposal be received by December 19, 2011, including comment about any potential interplay[2] between Proposed Rule 127B and the ''Volcker Rule Proposal.''[3] The Volcker Rule Proposal would implement Section 619 of the Dodd-Frank Act concerning prohibitions and restrictions on proprietary trading and certain interests in, and relationships with, hedge funds and private equity funds. The original comment period for the Volcker Rule Proposal was scheduled to end on January 13, 2012.

On December 13, 2011, the Commission extended the ABS Conflicts Proposal comment period from December 19, 2011 to January 13, 2012 to coincide with the end of the comment period for the Volcker Rule Proposal. The Commission extended the Volcker Rule Proposal comment period until February 13, 2012.[4] In an effort to provide the public with a better opportunity to consider any potential interplay between the ABS Conflicts and Volcker Rule Proposals, the Commission is also extending the ABS Conflicts Proposal comment period until February 13, 2012.

The Commission has determined to provide the public additional time to consider simultaneously the ABS Conflicts and the Volcker Rule Proposals. This extended opportunity to submit comprehensive comments regarding the ABS Conflicts Proposal and any potential interplay with the Volcker Rule Proposal would benefit the Commission in its consideration of any final rules. Therefore, the Commission is again extending the comment period for the ABS Conflicts Proposal until February 13, 2012 to coincide with the

[1] Exchange Act Release No. 34–65355 (September 19, 2011), 76 FR 60320 (September 28, 2011).

[2] *See, e.g.,* 76 FR 60320, 60341.

[3] Exchange Act Release No. 34–65545 (October 12, 2011), 76 FR 68846 (November 7, 2011).

[4] Exchange Act Release No. 34–66057.

end of the Volcker Rule Proposal comment period.

By the Commission.

Dated: December 23, 2011.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–33614 Filed 12–30–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. FDA–2011–N–0697]

Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain regulations relating to citizen petitions, petitions for stay of action, and the submission of documents to the Agency. In particular, the proposed rule would establish new regulations to implement certain provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which concern certain citizen petitions and petitions for stay of action (PSAs) that involve a request for FDA to take any form of action relating to a pending abbreviated new drug application (ANDA) or 505(b)(2) application. We are making these changes to implement provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit either electronic or written comments by April 2, 2012. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 2, 2012, (see section ''VI. Paperwork Reduction Act of 1995'' of this document). See section II.E of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0697, by any of the following methods; except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

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.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0697 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading 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.regulations.gov* and insert the docket number(s), 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:

Nicole Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6312, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

A. Enactment of Section 505(q)

On September 27, 2007, Congress enacted FDAAA (Pub. L. 110–85). Section 914 of title IX of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)). Section 505(q) applies to certain citizen petitions and PSAs (collectively referred to as petitions) that request FDA to take any form of action related to a pending application submitted under section 505(b)(2) or (j) of the FD&C Act (21 U.S.C. 355(b)(2) or (j)). An application submitted under section 505(b)(2) of the FD&C Act is a type of new drug application (NDA) described in that subsection and is referred to in this document as a ''505(b)(2) application.'' An application submitted under section 505(j) is an ANDA for a generic drug product.

Section 505(q) governs the manner in which FDA handles certain citizen petitions and PSAs that ask the Agency to take any form of action related to pending 505(b)(2) applications or ANDAs. Over the years, FDA has received numerous petitions asking the Agency not to approve a particular ANDA or 505(b)(2) application (or classes of these applications concerning a particular drug product or active ingredient) unless certain criteria set forth in the petition are met. In many cases, the petitions have raised scientific and/or legal issues relating to the standards for approval of an application. Examples include: Petitions suggesting a particular method for determining the bioequivalence of a proposed generic product to the reference listed drug (RLD) and petitions maintaining that a proposed generic product does not contain the same active ingredient as the RLD. When submitted early, such as when we are making decisions about the bioequivalence requirements for a generic drug product or before we have received the first ANDA or 505(b)(2) application for a drug product, a petition containing material information can assist us in establishing standards for these applications. However, when petitions are submitted late in the review process for challenged applications and do not raise valid scientific and/or legal issues, they may have the effect of improperly delaying the approval of an application. By enacting section 505(q), Congress indicated a desire to ensure that petitions not be used to improperly delay approval of ANDAs and 505(b)(2) applications.

B. Provisions of Section 505(q) of the FD&C Act

Section 505(q)(1)(A) of the FD&C Act specifies that FDA must not delay approval of a pending ANDA or 505(b)(2) application because of any request to take any form of action relating to the application, unless the request is in writing and in a citizen petition submitted under § 10.30 (21 CFR 10.30) or a PSA submitted under § 10.35 (21 CFR 10.35), and the Agency determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Section 505(q)(1)(F) of the FD&C Act governs the timeframe for final Agency action on a petition. Under this provision, FDA must take final Agency action on a petition not later than 180 days after the date on which the petition