

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.

FEDERAL HOUSING FINANCE AGENCY

12 CFR Chapter XII

[No. 2013–N–06]

Notice of Regulatory Review

AGENCY: Federal Housing Finance Agency.

ACTION: Request for comment.

SUMMARY: The Federal Housing Finance Agency (FHFA) is issuing a notice of a regulatory review that will be conducted in accordance with the process set forth in the regulatory review plan published by FHFA last year,¹ and requesting comments on how its regulations may be made more effective and less burdensome.

DATES: Written comments on this notice of regulatory review must be received no later than June 18, 2013.

ADDRESSES: You may submit your comments, identified by “Regulatory Review [No. 2013–N–06]”, by any of the following methods:

- *Email:* Comments to Alfred M. Pollard, General Counsel may be sent by email to RegComments@fhfa.gov. Please include “Regulatory Review [No. 2013–N–06]” in the subject line of the message.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal*, please also send it by email to FHFA at RegComments@fhfa.gov to ensure timely receipt by FHFA. Please include “Regulatory Review [No. 2013–N–06]” in the subject line of the message.

- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/Regulatory Review [No. 2013–N–06], Federal Housing Finance Agency, Constitution

Center, (OGC) Eighth Floor, 400 Seventh Street SW., Washington, DC 20024.

- *Hand Delivered/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/Regulatory Review [No. 2013–N–06], Federal Housing Finance Agency, Constitution Center, (OGC) Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. The package should be logged at the FHFA Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

All comments received will be posted without change on FHFA’s Web site at <http://www.fhfa.gov>, and will include any personal information provided, such as name, address (mailing and email), and telephone numbers. In addition, copies of all comments received will be available without charge for public inspection on business days between the hours of 10:00 a.m. and 3:00 p.m., at the Federal Housing Finance Agency, Constitution Center, (OGC) Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 649–3804.

FOR FURTHER INFORMATION CONTACT:

Christopher T. Curtis, Senior Deputy General Counsel, christopher.curtis@fhfa.gov, (202) 649–3051 (this is not a toll-free number), Federal Housing Finance Agency, Constitution Center, (OGC) Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Establishment of FHFA; Transfer and Review of Regulations

The Housing and Economic Recovery Act of 2008 (HERA) established FHFA on July 30, 2008, as an independent regulatory agency to supervise and regulate the Federal National Mortgage Association (Fannie Mae), the Federal Home Loan Mortgage Corporation (Freddie Mac), and the Federal Home Loan Banks (collectively, regulated entities), and the Office of Finance of the Federal Home Loan Bank System. HERA transferred to the new agency the employees, functions, and regulations of the Office of Federal Housing Enterprise Oversight (OFHEO), the Federal Housing Finance Board (Finance Board),

and the Government-Sponsored Enterprise mission team within the U.S. Department of Housing and Urban Development (HUD).

HERA and, most recently, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) mandate that FHFA issue new regulations on specific matters in connection with FHFA’s supervision and regulation of the regulated entities and the Office of Finance. Currently, in determining whether to revise, adopt without change, or repeal transferred OFHEO, Finance Board, and certain HUD regulations, FHFA reviews such regulations to determine the appropriate action and publishes the regulations for comment. Public comments provide additional information to FHFA on how to make the regulations more effective and less burdensome.

Executive Order 13579

Executive Order 13579, “Regulation and Independent Regulatory Agencies,” (July 11, 2011), requests that each independent regulatory agency, such as FHFA, analyze its existing regulations and modify, streamline, expand, or repeal them in accordance with the findings of the analysis. Executive Order 13579 also requests each independent regulatory agency to make public a plan under which the agency will periodically review its existing significant regulations to make the agency’s regulatory program more effective or less burdensome in achieving regulatory objectives.

FHFA’s Regulatory Review Plan Under Executive Order 13579

After notice and request for comment,² FHFA published its regulatory review plan on February 22, 2012.³ The plan provides for FHFA to review its regulations for effectiveness and burden every five years, beginning not later than August of this year, applying factors enumerated in the plan. The regulatory review plan is available at the following location: http://www.fhfa.gov/webfiles/23372/77_FR_10351_Feb_22_2012.pdf. FHFA regulations published in Chapter XII of Title 12 of the Code of Federal Regulations are available at the following locations: (1)

² Notice of Regulatory Review Plan, 76 FR 59066 (Sept. 23, 2011).

³ Regulatory Review Plan, 77 FR 10351 (Feb. 22, 2012).

¹ Regulatory Review Plan, 77 FR 10351 (Feb. 22, 2012).

The Government-wide public Web site at: http://www.ecfr.gov/cgi-bin/text-idx?SID=7c0e5ce2b44677c52dbb9e542ffb2d2e&c=ecfr&tpl=/ecfrbrowse/Title12/12cfrv9_02.tpl; (2) FHFA's Internet Web site at: http://www.fhfa.gov/Default.aspx?Page=89&ListNumber=5&ListYear=2012&SortBy=#Year_2012; and (3) <http://www.regulations.gov>. FHFA's Office of General Counsel will conduct the reviews, culminating in a report to the agency's Director.

This Notice initiates the first such review.

II. Request for Comment

FHFA hereby requests comment on its existing regulations for purposes of improving their effectiveness and reducing their burden. Included in the review are all current regulations, including those not yet transferred from the predecessor agencies, but not including rules of agency organization, procedure, or practice, or regulations adopted or substantially amended within the last two years. Members of the public may nonetheless comment on those recently adopted or amended regulations, and FHFA will take those comments into account as appropriate, however, FHFA does not anticipate responding to individual comments.

Factors that FHFA's regulatory review plan identifies as relevant to the review, and which FHFA suggests should guide commenters, include:

(1) Legal or regulatory developments, including new laws, executive orders or judicial decisions that have been adopted since the promulgation of a regulation that make such regulation inefficient, obsolete, contrary to controlling legal precedent, or unduly burdensome;

(2) Marketplace developments, technological evolution, and related changes that may have rendered an existing regulation, in whole or in part, inefficient, outmoded, or outdated;

(3) Whether the provisions of the regulation are written in plain language or otherwise need clarification;

(4) Compelling evidence that a consolidation of two or more regulations, elimination of a duplicative regulation, or other revision to regulatory requirements would facilitate compliance by or supervision of a regulated entity or the Office of Finance;

(5) A demonstrated better alternative method to effect a regulatory purpose or requirement supported by compelling evidence of significantly less intrusive means or of a substantially more efficient method of accomplishing the same supervisory purpose.⁴

As stated in the regulatory review plan, FHFA's Office of General Counsel will review all comments received, will consult with other FHFA offices and divisions, and will make a report of findings and recommendations to the FHFA Director on a timely basis. The report of findings and recommendations will be privileged and confidential. After receiving the report of findings and recommendations, the FHFA Director will determine what steps may be necessary to relieve any unnecessary burden, including amendment to or repeal of existing regulations or issuance of less formal guidance.

This regulatory review is not a formal or informal rulemaking proceeding under the Administrative Procedure Act and creates no right of action against FHFA. The determination of FHFA to conduct or not to conduct a review of a particular regulation, and any determinations, findings, or recommendations resulting from this review, are not final agency actions and, therefore, are not subject to judicial review.

Dated: April 12, 2013.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2013-09265 Filed 4-18-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 660, 801, and 809

[Docket No. FDA-2013-N-0125]

RIN 0910-AG74

Use of Certain Symbols in Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise medical device and biological product labeling regulations to explicitly allow for the inclusion of stand-alone graphical representations of information, or symbols, if the symbol has been established as part of a standard developed by a nationally or internationally recognized standards development organization (SDO) (referred to in this document as a "standardized symbol") and such standardized symbol is part of a standard recognized by FDA for use on the labeling of medical devices (or on a subset of medical devices), provided

that such symbol is explained in a symbols glossary that contemporaneously accompanies the medical device. FDA is also proposing to revise prescription device labeling regulations to authorize the use of the symbol statement "Rx only" on the labeling of prescription devices.

DATES: Submit electronic or written comments on the proposed rule by June 18, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by May 20, 2013, (see section VII). See section IX for the proposed effective date of a final rule based on the proposed rule in this document.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0125 and/or Regulatory Information Number (RIN) 0910-AG74, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see section VII).

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 way:

- *Mail/Hand delivery/Courier (for paper 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, Docket No. FDA-2013-N-0125, and RIN 0910-AG74 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 section VIII.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> 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: Michael Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New

⁴ 77 FR at 10351-02.