**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 7**

**[Docket No. FDA–2016–D–3548]**

## Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Draft Guidance for Industry and FDA Staff.'' The draft guidance, when finalized, establishes official guidance for industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and public notification of voluntary recalls under Federal regulations. The intent of the draft guidance is to increase and expedite the appropriate and accurate use of public warnings and public notification, to increase public health protection by better informing the public about violative products being recalled. The draft guidance clarifies and supplements existing policy for industry and FDA staff regarding the use of public warnings and public notification.

**DATES:** Submit either electronic or written comments on the draft guidance by March 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2016–D–3548 for ''Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Draft Guidance for Industry and FDA Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Chris Henderson, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8186, *Christopher.henderson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C.'' The draft guidance, when finalized, will establish official guidance for industry and FDA staff regarding the use, content, and timing of public warnings and public notification of recalls under part 7 (21 CFR part 7). The draft guidance is part of a larger effort FDA is undertaking to give additional guidance to industry and FDA staff regarding the execution and oversight of voluntary recalls under part 7.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on public warnings and notification of recalls. It does not establish any rights for any person and is not binding on

FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

**II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Any collection of information, including a firm's public warning (§ 7.42(b)(2)), has been approved under OMB control number 0910–0249.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Safety/Recalls/default.htm* or *https://www.regulations.gov.*

Dated: January 16, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–00918 Filed 1–18–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

### 37 CFR Parts 1 and 42

**[Docket No.: PTO–P–2017–0034]**

**RIN 0651–AD25**

### Changes To Eliminate Unnecessary Regulations

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) proposes to remove its regulations governing reservation clauses, petitions from the refusal of a primary examiner to admit an amendment, the publication of amendments to the regulations, and limits that the Director can impose on the number of inter partes reviews and post-grant reviews heard by the Patent Trial and Appeal Board. These regulations are unnecessary or superfluous and in some cases have expired, and their removal will help streamline USPTO's body of regulations without reducing the availability of services for the public. This proposed rule arises out of the USPTO's work during FY 2017 to identify and propose regulations for removal, modification, and streamlining because they are outdated, unnecessary, ineffective, costly, or unduly burdensome on the agency or the private sector. The revisions proposed herein would put into effect the work the USPTO has done, in part through its participation in the Regulatory Reform Task Force established by the Department of Commerce pursuant to Executive Order 13777, to review and identify regulations that are candidates for removal.

**DATES:** Written comments must be received on or before February 20, 2018.

**ADDRESSES:** Comments on the changes set forth in this proposed rulemaking should be sent by electronic mail message to: *AD25.comments@uspto.gov.* Comments may also be submitted by postal mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313–1450, marked to the attention of Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration. Comments concerning ideas to improve, revise, and streamline other USPTO regulations, not discussed in this proposed rulemaking, should be submitted to: *RegulatoryReformGroup@uspto.gov.*

Comments may also be submitted via the Federal eRulemaking Portal at *http://www.regulations.gov.* See the Federal eRulemaking Portal website for additional instructions on providing comments via the Federal eRulemaking Portal. Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the internet because the Office may easily share such comments with the public. Electronic comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's internet website (*http://www.uspto.gov*) and at *http://www.regulations.gov.* Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

**FOR FURTHER INFORMATION CONTACT:** Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at (571) 272–7728, for questions regarding the changes to 37 CFR 1.79 and/or 1.127; Susan L. C. Mitchell, Lead Administrative Patent Judge, Patent Trial and Appeal Board, at (571) 272–8715, for questions regarding the changes to 37 CFR part 42; and Nicolas Oettinger, Senior Counsel for Regulatory and Legislative Affairs, Office of the General Counsel, at (571) 272–7832, for questions regarding the change to 37 CFR 1.351 and general questions regarding regulatory reform.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with Executive Order 13777, ''Enforcing the Regulatory Reform Agenda,'' the Department of Commerce established a Regulatory Reform Task Force (Task Force), comprising, among others, agency officials from the National Oceanic and Atmospheric Administration, the Bureau of Industry and Security, and the USPTO, and charged the Task Force with evaluating existing regulations and identifying those that should be repealed, replaced, or modified because they are potentially outdated, unnecessary, ineffective, costly, or unduly burdensome to both government and private sector operations.

To support its regulatory reform efforts on the Task Force, the USPTO assembled a Working Group on Regulatory Reform (Working Group), consisting of subject matter experts from each of the business units that implement the USPTO's regulations, to consider, review, and recommend ways that the regulations could be improved, revised, and streamlined. In considering the revisions, the USPTO, through its Working Group, incorporated into its analyses all presidential directives relating to regulatory reform. The Working Group reviewed existing regulations, both discretionary and required by statute or judicial order. The USPTO also solicited comments from stakeholders through a web page established to provide information on the USPTO's regulatory reform efforts, and through the Department's **Federal Register** Notice titled ''Impact of Federal Regulations on Domestic Manufacturing'' (82 FR 12786, Mar. 7, 2017), which addressed the impact of regulatory burdens on domestic manufacturing. These efforts led to the development of candidate regulations for removal based on the USPTO's assessment that these regulations were not needed and/or that elimination