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FDA is announcing the availability of a draft guidance for industry and FDA staff entitled “Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C.” The draft guidance, when finalized, will establish official guidance for industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and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 The intent of the draft guidance is to increase and expedite the appropriate and accurate use of public warnings and public notification, to increase public health protection by better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 The draft guidance clarifies and supplements existing policy for industry and FDA staff regarding the use of public warnings and public notification.
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 This draft guidance is not subject to Executive Order 12866.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This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Safety/Recalls/default.htm or https://www.regulations.gov.


Leslie Kux, Associate Commissioner for Policy.

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

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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


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 Dulaney 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...