entering either the title of the collection or the OMB Control Number 0648–0613.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–24211 Filed 11–4–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Designation of Fishery Management Council Members and Application for Reinstatement of State Authority

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 6, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0314 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Morgan Corey, Fishery Management Specialist, Office of Sustainable Fisheries, 1315 East-West Highway, Silver Spring, MD 20910, (301) 427–8535, and *morgan.corey@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection. The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the establishment of eight Regional Fishery Management Councils to manage fisheries within regional jurisdictions. This collection pertains to several sections of the Magnuson-Stevens Act related to the Councils. Section 302(b) provides for appointment of Council members nominated by State Governors, Territorial Governors, or Tribal Governments and for designation of a principal state fishery official for the purposes of the Magnuson-Stevens Act. Section 306(b)(2) provides for a request by a state for reinstatement of state authority over a managed fishery. Nominees for Council membership must provide their State Governor, Territorial Governor, or Tribal Government leadership with background documentation, which is then submitted to NOAA, on behalf of the Secretary of Commerce to review qualifications for Council membership. The information collected with these actions is used to ensure that the requirements of the Magnuson-Stevens Act are being met in regards to Council membership and state authority.

II. Method of Collection

State Governors, Territorial Governors, and Tribal Governments submit written nominations to the Secretary of Commerce, together with recommendations and statements of candidates' qualifications. Designations of state officials and requests for reinstatement of state authority are also made in writing in response to regulations. NMFS provides guidance on what information to include in order to comply with current regulations. *See 50 CFR 600.215.* No forms are used.

III. Data

OMB Control Number: 0648–0314.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved collection).

Affected Public: State, local, or Tribal government.

Estimated Number of Respondents: 275.

Estimated Time per Response: 80 hours for a nomination for Council appointment; 16 hours for background documentation for nominees; 1 hour to designate a principal state fishery official(s) or for a request to reinstate authority.

Estimated Total Annual Burden Hours: 4,607.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–24210 Filed 11–4–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2022–0037]

Joint USPTO–FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments

AGENCY: United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Notice of public listening session; request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO), Department of Commerce, in collaboration with the United States Food and Drug Administration (FDA), Department of Health and Human Services, is announcing a public listening session

on January 19, 2023, titled ''Listening Session on Joint USPTO–FDA Collaboration Initiatives.'' The purpose of the listening session is to seek public comments on proposed initiatives for collaboration between the agencies to advance President Biden's Executive Order on ''Promoting Competition in the American Economy'' and to promote greater access to medicines for American families. To assist in gathering public input, the USPTO and the FDA are announcing the establishment of a docket to track feedback received through this notice and a request for comments on these collaborative efforts.

DATES: The public listening session will be held on Thursday, January 19, 2023, from 10 a.m. to 5 p.m. ET. Persons seeking to speak at the listening session must register by 5 p.m. on January 5, 2023. Persons seeking to attend, either in person or virtually, but not speak at the event must register by January 17, 2023. Seating is limited for in-person attendance. Written comments will be accepted until February 6, 2023.

ADDRESSES:

Public Listening Session

The public listening session will take place in person in the Clara Barton Auditorium at the USPTO, 600 Dulany Street, Alexandria, VA 22313. The session will also be available via live feed for those wishing to attend remotely. Registration is required for both in-person and virtual attendance. Information on registration is available at www.uspto.gov/initiatives/uspto-fda-collaboration/engagements. Registrants must indicate whether they are registering as a listen-only attendee or as a speaker participant.

Requests to participate as a speaker must include:

1. The name of the person desiring to participate;
2. The organization(s) that person represents, if any;
3. Contact information (address, telephone number, and email); and
4. Information on the specific topic(s) of interest to the speaker (or their organization) and identification of the primary topic of interest.

Speaking slots are limited; preference will be given to speakers wishing to address one of the questions raised in this request for comments. We will attempt to group speakers by topic. Topics and speakers will be announced a few days prior to the public listening session. Speakers must attend in person and are required to submit their remarks for the listening session in advance through the Federal eRulemaking Portal at *www.regulations.gov*. We will inform each speaker in advance of their assigned time slot. If we receive more requests to speak than time allows and are unable to assign a time slot as requested, we will invite the requestor to submit written comments. Time slots will be at least three minutes but may be longer, depending on the number of speakers registered. A panel of USPTO and FDA personnel may reserve time to ask questions of particular speakers after the delivery of a speaker's remarks.

Request for Comments

You may submit written comments as follows. For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov*. To submit comments via the portal, enter docket number PTO–P–2022–0037 on the homepage and click ''search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for comments and click on the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format (PDF) or MICROSOFT WORD® format. 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.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery.

FOR FURTHER INFORMATION CONTACT: Linda Horner, Administrative Patent Judge, USPTO, at 571–272–9797 or *USPTO-FDAcollaboration@uspto.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2021, President Biden issued an Executive Order on ''Promoting Competition in the American Economy,'' 86 FR 36987 (July 14, 2021) (Competition E.O.). To advance the Biden Administration's goals of promoting greater access to medicines for American families and increasing competition in the marketplace, section 5(p)(vi) of the Competition E.O. directs the Secretary of Health and Human Services, ''through the Commissioner of Food and Drugs'' and ''not later than 45 days after the date of this order,'' to ''write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA,'' in order ''to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.''

In response to the Competition E.O., on September 10, 2021, the FDA sent a letter to the USPTO outlining ideas for further engagement with the USPTO (FDA Letter). On July 6, 2022, the USPTO sent a responsive letter (USPTO Letter) discussing specific initiatives the USPTO was exploring to collaborate with the FDA to ensure that our patent system properly and adequately protects innovation while not unnecessarily delaying getting generic, biosimilar, and more affordable versions of pharmaceuticals into the hands of Americans who need them. The letters are available at www.uspto.gov/initiatives/fda-collaboration.

The FDA–USPTO exchange of letters recognizes that, while the two agencies have different missions and authorities, we share a commitment to ensuring our innovation system strikes the appropriate balance—encouraging meaningful innovation in drug development while supporting a competitive marketplace that can promote greater access to medicines for American families.

The United States is a global leader in the development of drugs and biologics due to its strong patent system, and the USPTO Letter describes ongoing efforts to further promote robust and reliable patent rights across all technologies. Robust and reliable patents are needed to incentivize and protect the immense research and development investment that is essential to bringing life-saving and life-altering products to market. Patent rights can spur the collaboration necessary for quick and speedy drug and biological product development. Congress also enacted laws to establish approval pathways for generic and biosimilar medicines, and these laws set forth patent dispute resolution mechanisms in the drug and biologic innovation space to encourage generic and biosimilar manufacturers to timely resolve patent issues in order to enter the market to increase competition.

The FDA Letter highlights the FDA's commitment to facilitating increased drug competition through its abbreviated pathways for the approval

of generic drugs and biosimilars, which play a foundational role in ensuring access to high-quality, safe, effective, and affordable medicines for American patients. The FDA has a ministerial role with regard to the patent listing provisions of the Federal Food, Drug, and Cosmetic Act. New drug application sponsors are statutorily required to submit certain patent information for listing, and the FDA is statutorily required to publish that information, which it does in Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). Orange Book-listed patents may impact the timing of generic approval. In addition, under section 351(l) of the Public Health Service Act, if a reference product sponsor (*i.e.,* biologics license application holder) provides a list of patents to a biosimilar applicant within the context of patent litigation, then the FDA is statutorily required to publish that patent list. The FDA publishes such lists in the Purple Book Database of Licensed Biological Products (the Purple Book).

To further the objectives of the Competition E.O., the letters the FDA and the USPTO exchanged outline a number of initiatives to execute the President's agenda, with a focus on areas in which the agencies' functions overlap. The initiatives for collaboration with the FDA, as discussed in paragraph 1 of the USPTO Letter, are reproduced below.

1. Enhance collaboration with other agencies on key technology areas, including pharmaceuticals and biologics. The USPTO will seek to create formal mechanisms to collaborate with other agencies such as the Food and Drug Administration (FDA).[1] Specifically, the USPTO will:

a. Continue discussions with the FDA on this topic and the initiatives outlined here and work collaboratively on these and other initiatives.

b. Explore joint USPTO–FDA public engagement through listening sessions, dissemination of a Request for Comments and other procedures for collecting broader stakeholder input.

c. Provide examiners with training, in collaboration with the FDA, on publicly available FDA resources that can be utilized in prior art searches and on the state of the art in the pharmaceutical and biopharma areas and provide resources to the FDA to support its work on matters influenced by patent law and policy.

d. Explore consistency in representations made to the USPTO and the FDA. The USPTO will work with the FDA to evaluate consistency in representations to the USPTO (made both during prosecution of patent applications and in America Invents Act (AIA) and other post-issuance proceedings) and the FDA. The USPTO is also exploring initiatives to require patent applicants to provide relevant information to the USPTO that has been submitted to other agencies and to remind patent applicants of their disclosure obligations and the ramifications of failing to disclose required information at the USPTO.[2] The USPTO will explore with the FDA whether other avenues exist to determine whether patent applicants have submitted inconsistent statements between the agencies.

e. Engage in greater FDA collaboration in AIA proceedings. In addition to improving the robustness and reliability of patents that are granted in the first place, the USPTO will work with the FDA on processes and procedures for (1) notifying the FDA of AIA proceeding filings on any Orange Book-listed patents and/or Purple Book-listed patents, and (2) potentially sharing more information between the agencies. The USPTO will also work with the FDA to assess why there have been so few filings of AIA proceedings on Orange Book-listed patents and biologic patents and why the number of AIA filings for pharmaceutical patents has generally declined.[3]

f. Revisit patent term extension practice, required under 35 U.S.C. 156 due to the product being subject to an FDA regulatory review period. Though a recent report found that the USPTO accurately and fairly grants patent term extensions based on FDA regulatory review periods, the USPTO will collaborate with the FDA to determine if there are any areas for improvement through information sharing or otherwise. The USPTO also is exploring ways to facilitate public access to information on patent term extension applications and grants.

g. Work with the FDA to understand how else the agencies' authorities and responsibilities overlap, such as exploring the policies surrounding the use of ''skinny labels,'' the connection between method of use patents and associated use codes, and the patenting of risk evaluation and mitigation strategies that the FDA requires for certain medications with serious safety concerns. Where the agencies' functions overlap, the USPTO will work with FDA to optimize information sharing and policy within our respective frameworks and legal restrictions.

h. Remain open to discussing with the FDA, other agencies, the Administration, and stakeholders the FDA's concerns over practices referred to as ''patent thickets,'' ''evergreening,'' and ''product hopping.''

In this notice of public listening session and request for comments, the USPTO and the FDA seek public comments on the proposed initiatives outlined in the USPTO Letter (1(a)–1(h)) reproduced above.[4]

II. Purpose and Scope of the Listening Session and Request for Comments

The purpose of this listening session and request for comments is to obtain public input on areas for USPTO–FDA collaboration and engagement. We are seeking feedback from a broad group of stakeholders, including, but not limited to, patients and their caregivers, patient advocates, representatives from regulated industry, including companies that sell branded medicines, generics drugs and biosimilars, healthcare organizations, payors and insurers, academic institutions, public interest groups, and the general public.

To facilitate stakeholder feedback on the initiatives listed above, we provide the questions below. These questions are not meant to be exhaustive. We encourage interested stakeholders to address these and/or other related issues and to submit research and data that inform their comments on these topics. Commenters are welcome to respond to any or all of the questions and are encouraged to indicate which questions their comments address.

1. What publicly available FDA resources should be included when training USPTO patent examiners on tools they can use to assess the patentability of claimed inventions?

2. What mechanisms could assist patent examiners in determining

[1] Although these initiatives focus mostly on collaboration with the FDA, the USPTO is interested in exploring further interagency collaborations.

[2] On July 29, 2022, the USPTO published a **Federal Register** Notice clarifying the duty of disclosure and the duty of reasonable inquiry, including as to materials or statements material to patentability, or statements made to the USPTO that are inconsistent with statements submitted to the FDA and other Government agencies. *See* Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 FR 45764.

[3] Orange Book patent/biologic patent study update through June 2021, available at *www.uspto.gov/sites/default/files/documents/PTABOBbiologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf.*

[4] The USPTO is also working in parallel on the other proposed initiatives described in the USPTO Letter that are not the focus of this listening session and request for comments. *See, e.g.,* Request for Comments on Initiatives Ensuring Robust and Reliable Patents, 87 FR 60130 (October 4, 2022).

whether patent applicants or patent owners have submitted inconsistent statements to the USPTO and the FDA? Please explain whether such mechanisms present confidentiality concerns and, if so, how those concerns could be addressed.

3. What are the opportunities and challenges related to the use of AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, including with respect to how such proceedings may intersect with Hatch-Waxman paragraph IV disputes and the Biologics Price Competition and Innovation Act ''patent dance'' framework that biosimilar applicants and reference product sponsors use to address any patent infringement concerns?

4. How can the USPTO and the FDA reinforce their collaboration and information exchange in relation to determining whether a patent qualifies for a patent term extension (PTE) and the length of any extension under 35 U.S.C. 156, as described in the Manual of Patent Examining Procedure § 2756? Identify any specific areas for improvement in the effectiveness of the current USPTO–FDA process for adjudicating applications for PTE and in the opportunity for public comment on such applications.

5. The FDA already publishes PTE applications on *www.regulations.gov*, and the USPTO publishes PTE applications on its Patent Center portal (*https://patentcenter.uspto.gov/*), which replaced the Public Patent Application Information Retrieval (PAIR) system. The USPTO also recently provided centralized access to a listing of PTE applications filed during the last five years at *www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156.* This list includes the patent application number, patent number, link to the electronic file wrapper in Patent Center, PTE application filing date, and trade name identified in the PTE application. The status of each PTE application, including disposition, may be determined by reviewing the electronic file wrapper in Patent Center. What additional information would be useful to include on this web page?

6. What policy considerations or concerns should the USPTO and the FDA explore as they relate to method of use patents and, as applicable, associated FDA use codes, including with respect to generic drug, 505(b)(2), and biosimilar applicants who do not seek approval for (*i.e.,* who seek to carve out from their labeling) information related to a patent-protected method of use (sometimes described as ''skinny labeling'')?

7. What policy considerations or concerns should the USPTO and the FDA explore in relation to the patenting of risk evaluation and mitigation strategies associated with certain FDA-approved products? What other types of patent claims associated with FDA-regulated products raise policy considerations or concerns for the USPTO and the FDA to evaluate?

8. Apart from, or in conjunction with, the initiatives set forth in the USPTO Letter, what other steps could the USPTO and the FDA take collaboratively to address concerns about the potential misuse of patents to improperly delay competition or to promote greater availability of generic versions of scarce drugs that are no longer covered by patents?

9. What additional input on any of the initiatives listed in the USPTO Letter (1(a)–1(h)), or any other related suggestions for USPTO–FDA collaboration, should the agencies consider?

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–24107 Filed 11–4–22; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038–0025, Practice by Former Members and Employees of the Commission

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is announcing an opportunity for public comment on the proposed renewal of an information collection by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments regarding the reporting requirement imposed on former members and employees of the Commission who are employed or retained by third parties to appear before the Commission.

DATES: Comments must be submitted on or before January 6, 2023.

ADDRESSES: You may submit comments, identified by ''Practice by Former Members and Employees of the Commission, OMB Control No. 3038–0025,'' by any of the following methods:

- The Agency's website, at *https://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Frank Walsh, Alternate Designated Agency Ethics Official, Office of the General Counsel, Commodity Futures Trading Commission, (202) 418–6250; email: *fwalsh@cftc.gov,* and refer to OMB Control No. 3038–0025.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of a proposed extension of the currently approved information collection listed below. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.[1]

Title: Practice by Former Members and Employees of the Commission (OMB Control No. 3038–0025). This is a request for an extension of a currently approved information collection.

[1] 44 U.S.C. 3512, 5 CFR 1320.5(b)(2)(i) and 1320.8 (b)(3)(vi).