actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, SYMPROIC (naldemedine tosylate). SYMPROIC is indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (*e.g.,* weekly) opioid dosage escalation. Subsequent to this approval, the USPTO received a patent term restoration application for SYMPROIC (U.S. Patent No. RE46365) from Shionogi & Co., Ltd., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 9, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SYMPROIC represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SYMPROIC is 2,523 days. Of this time, 2,157 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* April 28, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was April 28, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 23, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for SYMPROIC (NDA 208854) was initially submitted on March 23, 2016.

3. *The date the application was approved:* March 23, 2017. FDA has verified the applicant's claim that NDA 208854 was approved on March 23, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,140 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07459 Filed 4–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0390]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 14, 2019.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0390–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Challenge and Prize Competition Solicitations.

Type of Collection: Reinstatement w/ chg.

OMB No. 0990–0390–OS/Office of the Assistant Secretary for Administration (ASA).

Abstract: This request, pursuant to the requirement of section 3506(c)(2)(A) of the PRA, is to seek generic clearance for the collection of routine information requested of responders to solicitations HHS makes during the issuance of challenge and prize competitions posted on a publicly accessible government website, such as *Challenge.gov.* Since passage of the America COMPETES Reauthorization Act in 2011, Federal agencies including HHS were given prize authority for administering challenges and prize competitions. Challenges and prize competitions enable HHS and its family of agencies (henceforth referred to broadly as ''HHS'') to tap into the expertise and creativity of the public in new ways, as well as extend awareness of HHS programs and priorities. HHS's goal is to engage a broader number of stakeholders who are inspired to work on some of our most pressing health issues, thus supporting a new ecosystem of scientists, developers, and entrepreneurs who can continue to innovate for public health.

In order for HHS to quickly and effectively launch challenges and prize competitions on a continual basis, HHS seeks generic clearance to collect

information for these challenges and prize competitions, which will generally include first name, last name, email, city, state, and, when applicable, other demographic information of participants (or, ''solvers'') or other stakeholders. It can also include other information necessary to evaluate submissions and understand their impact related to the general goals of the challenge or prize competition, as well as additional information relevant to the particular challenge or prize competition through structured questions.

The information collected will be used to understand whether the participant has met the technical requirements for the challenge or prize competition, assist in the technical review and judging of the solutions that are provided, and understand the impact and consequences of administering the challenge or prize competition and developing solutions for submission. Information may be collected during the challenge or prize competition or after its completion.

HHS may also ask for additional information pertaining to the solver's engagement in the challenge or prize competition, such as how they learned about the challenge or prize competition, their technical background, ethnicity, age range, what they currently understand about the HHS agency hosting the challenge or prize competition, etc. This information will enable HHS to better understand the diversity of entrants, the effect of the challenge or prize competition on increasing public awareness of HHS programs and priorities, and generally, to enable the Department to improve its outreach strategies to ensure a diverse and broad innovator constituency is fostered through the use of challenges and prize competitions.

The information collected will be used to understand whether the participant has met the technical requirements for the challenge or prize competition, assist in the technical review and judging of the solutions that are provided, and understand the impact and consequences of administering the challenge or prize competition and developing solutions for submission. Information may be collected during the challenge or prize competition or after its completion. The submissions are evaluated by the agency hosting the challenge or prize competition and prizes (monetary or non-monetary) are awarded to the winning entries.

Likely Respondents: Likely respondents include individuals, businesses, and state and local governments who choose to participate in a challenge or prize competition hosted or overseen (*i.e.,* via contract, etc.) by HHS.

ANNUALIZED BURDEN HOUR TABLE

Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response (hours)	Total burden hours
Individuals or Households	1,000	1	10/60	166.7
Organizations	500	1	10/60	83.3
Businesses	440	1	10/60	73.3
State, territory, tribal or local governments	60	1	10/60	10
Total		2,000		333.3

Terry Clark,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2019–07379 Filed 4–12–19; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0138]

Boston Area Maritime Security Advisory Committee; Vacancies, Coast Guard Sector Boston, MA

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Solicitation for membership.

SUMMARY: This notice requests individuals interested in serving on the Boston Area Maritime Security Committee (AMSC) to submit their applications for membership, to the Captain of the Port (COTP), Boston, MA.

DATES: Requests for membership should reach the U.S. Coast Guard COTP Boston May 15, 2019.

ADDRESSES: Applications for membership should be submitted to the Captain of the Port Boston at the following address: Commander (sx), USCG Sector Boston, 427 Commercial Street, Boston, MA 02109 or by email to *Ronald.J.Catudal@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: For questions about submitting an application or about the AMSC in general, contact Mr. Ron Catudal at 617–223–5727 or by email to *Ronald.J.Catudal@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Authority

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107–295) added section 70112 to Title 46 of the U.S. Code, and authorized the Secretary of the Department in which the Coast Guard is operating to establish Area Maritime Security Advisory Committees for any port area of the United States. Under 46 U.S.C. 70112(b)(7), the Federal Advisory Committee Act (FACA) does not apply to AMSCs.

Boston AMSC Purpose

The AMSCs shall assist the Captain of the Port in the development, review, update, and exercise of the Area Maritime Security Plan for their area of responsibility. Such matters may include, but are not limited to: Identifying critical port infrastructure and operations; Identifying risks (threats, vulnerabilities, and consequences); Determining mitigation strategies and implementation methods; Developing strategies to facilitate the recovery of the MTS after a Transportation Security Incident; Developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied

AMSC Composition

The composition of an AMSC, to include the Boston AMSC, is prescribed under 33 CFR 103.305. Pursuant to that