providers. Most recently, CDC published guidelines for health care providers on pre-exposure prophylaxis (PrEP) and recommendations for HIV prevention with adults and adolescents with HIV. Despite clear and compelling guidance from CDC, past studies have shown that patient-provider communication about HIV testing and prevention is uncommon and conversations that do take place tend to be brief.

CDC has developed four social marketing campaigns to support patient-provider communication about HIV. These campaigns have made great strides in addressing health care providers' information needs, thereby building their capacity to discuss HIV prevention with their patients. At this juncture, particularly with the evolving HIV prevention landscape, more data are needed to deepen our understanding of providers' interpretation and understanding of existing and emergent HIV prevention science; how providers use guidance or evidence-based approaches in their practices generally as well with populations that have been largely overlooked (*e.g.,* transgender individuals); and how to develop new or enrich existing provider materials to make them more informative, appealing, and usable.

The three-year study proposes a series of in-depth interviews with 600 healthcare providers (*i.e.,* physicians, physician assistants, and nurses) identified by contractor staff and professional recruiting firms. Data will be collected through one-time, hour-long, individual, in-depth interviews accompanied by a computer-assisted personal interview (total of 1 hour and 15 minutes per person). We anticipate screening 1,200 individuals to obtain 600 individuals who will participate in a 1-hour, in-depth interview and complete a 15-minute computer-assisted personal interview (web-based) survey. All data collections will be conducted only one time. Respondents who will participate in these interviews will be selected purposively to inform the development of appropriate messaging and materials for healthcare providers. Topic areas addressed within the interviews may include HIV prevention, HIV treatment, and linkage and referral to services. Data will be securely stored on password-protected computers and in locked file cabinets.

The information gathered through this data collection will allow CDC to develop timely, relevant, clear, and engaging materials that continue to support patient-provider communications related to HIV prevention. Participation of respondents is voluntary, and there is no cost to respondents other than their time.

The total estimated annualized burden hours are 950.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health care providers	Screener	1,200	1	10/60
	Web-based survey	600	1	15/60
	Interviews	*600*	*1*	*1*
	Exploratory guide—Prevention with positives and retention in care	50	1	1
	Exploratory guide—Transgender health	50	1	1
	Exploratory guide—HIV prevention	50	1	1
	Message testing guide	150	1	1
	Concept testing guide	150	1	1
	Materials testing guide	150	1	1

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–23340 Filed 9–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0400]

Determination of Regulatory Review Period for Purposes of Patent Extension; IONSYS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IONSYS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 28, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 27, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2007–E–0400, ''Determination of Regulatory Review Period for Purposes of Patent Extension; IONSYS.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the 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 IONSYS (fentanyl hydrochloride). IONSYS is indicated for the short-term management of acute postoperative pain in adult patients requiring opioid analgesia during hospitalization. Subsequent to this approval, the USPTO received a patent term restoration application for IONSYS (U.S. Patent No. 5,697,896) from Alza Corp., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration and the product's regulatory review period. In a letter dated August 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of IONSYS represented the first permitted commercial marketing or use of the product.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for IONSYS is 4,835 days. Of this time, 3,862 days occurred during the testing phase of the regulatory review period, while 973 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* February 26, 1993. The applicant claims February 27, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 26, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 23, 2003. FDA has verified the applicant's claim that the new drug application (NDA) for IONSYS (NDA 21–338) was initially submitted on September 23, 2003.

3. *The date the application was approved:* May 22, 2006. FDA has verified the applicant's claim that NDA 21–338 was approved on May 22, 2006.

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 5 years 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 ask for a redetermination (see **DATES**). Furthermore, 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 be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (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 *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23330 Filed 9–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; The Division of Independent Review Grant Reviewer Recruitment Form

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than November 28, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–29, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Division of Independent Review Grant Reviewer Recruitment Form.

OMB No. 0915–0295—Extension.

Abstract: HRSA's Division of Independent Review (DIR) is responsible for administering the review of eligible grant applications submitted to HRSA. DIR ensures that the objective review process is independent, efficient, effective, economical, and complies with the applicable statutes, regulations, and policies. Applications are reviewed by subject experts knowledgeable in health and public health disciplines for which support is requested. Review findings are advisory to HRSA programs responsible for making award decisions.

This request continues a Web-based data collection system, the Reviewer Recruitment Module (RRM), used to gather critical review participant information. The RRM uses standardized categories of information in drop down menu format for data such as the following: Degree, specialty, occupation, work setting, and in select instances affiliations with organizations and institutions that serve special populations. Some program regulations require that application objective review committees contain consumers of health services. Other demographic data may be voluntarily provided by a potential review participant. Defined data elements assist HRSA in finding and selecting expert grant review participants for objective review committees.

HRSA maintains a roster of approximately 6,000 qualified individuals who served on HRSA objective review committees. The Web-based RRM simplifies review participant registration entry using a user-friendly Graphical User Interface (GUI) with a few data drop down menu choices and a search engine that supports key word queries in the actual resume or Curriculum Vitae text. Review participants can also update their information electronically. The RRM is 508 compliant and accessible by the general public using any of the commonly used Internet browsers via a link on the HRSA ''Grants'' Internet site or by keying the RRM URL into their browser.

Need and Proposed Use of the Information: HRSA uses the RRM to collect information from individuals who are willing to volunteer as objective review committee participants for the Agency's discretionary and competitive grant or cooperative agreement funding opportunities. The RRM provides HRSA with an effective search and communication functionality with which to identify and contact qualified potential grant review participants. The RRM has an enhanced search and reporting capability to help DIR ensure that HRSA's review participant pool has the necessary skills and diversity to meet the ever-evolving need for qualified grant review participants. When DIR identifies an expertise, demographic need, or any other specific needs that are under-represented in the RRM pool, DIR can recruit specifically to address those needs. Expertise is always the primary determinant in selecting potential review participants for any grant review and no participant is required to provide demographic information to join the pool or be selected as a reviewer for any competition.

Likely Respondents: Individuals with experience in social, cultural, and health care fields who are knowledgeable about HRSA's mission and competitive program needs to deliver quality health care to all Americans.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.