MD 20993, 301–796–0674, *OMPTfeedback@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is responsible for protecting and promoting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by helping to ensure the safety of the nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Included in this is a mandate to advance the public health mission by helping to speed innovations that make medical products more effective, safer, and more affordable, and helping the public access accurate science-based information for FDA-regulated products. Just as the science and technology underlying new medical products is advancing, the science of development and evaluation of medical products and clinical care is also dramatically improving. To enable FDA to continue to effectively evaluate these innovative developments, a specialized workforce is required to support the Agency's regulatory science and operations initiatives.

Over the past 5 years, the Agency has struggled with challenges related to its hiring processes, including challenges in managing the hiring process and bringing the right skills to the Agency. FDA has demonstrated that diagnosing the current state and drastically reimagining the hiring process is a top priority and is committed to implementing new, bold, consistent, and high quality hiring processes to tackle these challenges. The criticality of these priorities is consistent with the PDUFA VI and BsUFA II user-fee commitments. These commitments include the use of a qualified, independent contractor with expertise in assessing human resources operations and transformation to perform an initial baseline assessment no later than December 31, 2017, and a public meeting no later than December 31, 2017, to present and discuss report findings.[1] [2]

[1] PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

[2] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.*

II. Topics for Discussion at the Assessment of FDA Hiring and Retention Public Meeting

The agenda will be posted prior to the meeting at: *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm577055.htm,* and will involve a plenary presentation related to the assessment findings summarized in the ''Initial Assessment of FDA's Hiring and Retention'' report and an open public comment period.

Registration: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by webcast) (see *Streaming Webcast of the Public Meeting),* please register online by 12 noon on Friday, November 24, Eastern Time at the following Web site: *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm577055.htm.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. You will receive confirmation of your registration.

If you need special accommodations due to a disability, please contact *OMPTfeedback@fda.hhs.gov* no later than Friday, November 24, at 12 noon Eastern Time.

Streaming Webcast of the Public Meeting: This public meeting will also be live webcast. To join the meeting via the webcast, please go to *https://collaboration.fda.gov/fdahiringretention.* If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm577055.htm.*

Dated: October 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23899 Filed 11–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0998]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection in the regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

DATES: Submit either electronic or written comments on the collection of information by January 2, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 2, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 2, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2010–N–0988 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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(c) 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

OMB Control Number 0910–0409—Extension

This information collection supports FDA regulations found in 21 CFR part 315. These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new indication for use of an approved diagnostic radiopharmaceutical. The regulations also describe the kinds of indications for diagnostic radiopharmaceuticals and some of the criteria that the Agency uses to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (the FD&C Act) and section 351 of the Public Health Service Act (42 U.S.C. 262) (the PHS Act). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The regulations clarify existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the FD&C Act and the PHS Act. The information, which is usually submitted as part of a new drug application or biologics license application or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug

are set forth in 21 CFR 314.50, and approved under OMB control number 0910–0001. This information collection supports part 315, currently approved under OMB control number 0910–0409.

Based on past submissions (human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals), we estimate two submissions will be received annually. We estimate the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulations do not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved under OMB control number 0910–0001). In fact, clarification in these regulations of FDA's criteria for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Diagnostic Radiopharmaceuticals—315.4, 315.5, and 315.6	2	1	2	2,000	4,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by the applicable regulations. This estimate does not include time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Dated: October 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23836 Filed 11–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; NINR Clinical Trial Planning Grant.

Date: November 17, 2017.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Nursing Research, One Democracy Plaza, 6701 Democracy Boulevard, Room 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Room 710, Bethesda, MD 20892, (301) 594–5966, *wli@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: October 30, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–23865 Filed 11–1–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact Michael Shmilovich, *shmilovm@nih.gov* at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR 404 to achieve commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Endo-Cameral Closure Device

Description of Technology: Devices and methods for closing a hole in the wall of a cardiovascular structure from the inside using a self-assembling closure device. The closure device can be delivered to the subject hole from the inside of the cardiovascular chamber using a transcatheter approach. The methods are techniques involve deploying the closure device from the delivery device such that an endo-cameral portion of the closure device self-expands first to cover the hole from the inside, and then extra-cameral arms of the device are released to self-deploy against the outside of the wall by