Dated: October 30, 2017.

Anna K. Abram,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6129]

Assessment of Food and Drug Administration Hiring and Retention; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Assessment of FDA Hiring and Retention''. The purpose of the public meeting is to share high-level findings from a recently completed diagnostic assessment of FDA's hiring process conducted by a qualified, independent contractor with expertise in assessing human resources operations and transformation. The purpose also is to outline a set of near-term actions FDA will or can take to improve the hiring process, provide an update on FDA's progress toward Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA) user fee hiring and retention commitments, and solicit input on actions FDA is taking and any further recommendations or priorities FDA should pursue with regard to the hiring process.

DATES: The public meeting will be held on November 30, 2017, from 9 a.m. to 12 noon. Submit either electronic or written comments on this public workshop by January 15, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Section A, Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

A summary report of evaluation findings related to the hiring process, conducted by an independent third party contractor, will be published in the docket by November 15, 2017, and will be titled ''Initial Assessment of FDA Hiring and Retention.''

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 15, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 15, 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–2017–N–6129 for ''Assessment of FDA Hiring and Retention; Public Meeting; Request for Comments.'' 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: Daniel Brounstein, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1312, Silver Spring,

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.

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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://*