Supplements Under GDUFA.'' The Generic Drug User Fee Amendments of 2012 (GDUFA) enables FDA to assess user fees to fund critical and measurable improvements to FDA's generic drugs program. This draft guidance is intended to assist applicants preparing to submit to FDA prior approval supplements (PASs) and amendments to PASs for abbreviated new drug applications (ANDAs). It describes FDA's performance metric goals for PASs and clarifies how FDA will handle a PAS and amendments to a PAS for an ANDA subject to the GDUFA performance metric goals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 9, 2014.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin Chacko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993–0002, 240–402–7924 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDA Submissions—Prior Approval Supplements Under GDUFA.'' On July 9, 2012, the President signed GDUFA (Pub. L. 112–144, Title III) into law. GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry to address a growing number of regulatory challenges. GDUFA aims to ensure timely access to safe, high-quality, low-cost generic drugs. GDUFA enables FDA to assess user fees to fund critical and measurable improvements to FDA's generic drugs program and to bring greater predictability and timeliness to the review of generic drug applications.

GDUFA requires that FDA and human generic drug manufacturers meet certain commitments. In the GDUFA Commitment Letter, FDA committed to review and act on a certain percentage of PASs within a specified time period from the date of submission for receipts in fiscal years (FY) 2015–2017. The percentage of PASs that FDA has committed to review and act on varies for each fiscal year, and the deadlines for review depend on whether a PAS requires an inspection.

This draft guidance describes the performance metric goals that FDA agreed to in the Commitment Letter and clarifies how FDA will review a PAS and amendments to a PAS for an ANDA subject to the GDUFA performance metric goals. The GDUFA performance metrics described in this draft guidance only apply to ANDA applicants that submit a PAS on or after October 1, 2014. These performance metrics do not apply to new drug applications (NDAs), biologics license applications (BLAs), supplements filed for NDAs or BLAs, or changes being effected (CBE) supplements and annual report filings to NDAs, BLAs, or ANDAs.

Elsewhere in this issue of the **Federal Register**, FDA is publishing another draft guidance entitled ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA,'' which explains how the GDUFA performance metric goals apply to amendments made to ANDAs and to PASs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent the Agency's current thinking on how GDUFA relates to prior approval supplements for ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information for supplements and amendments in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collection of information for manufacturer registration in 21 CFR part 207 has been approved under OMB control number 0910–0045. The collection of information for manufacturer compliance with current good manufacturing practices in 21 CFR part 211 has been approved under OMB control number 0910–0139.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidance/default.htm,* or *http://www.regulations.gov.*

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16236 Filed 7–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0894]

2014 Scientific Meeting of the National Antimicrobial Resistance Monitoring System; 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) is announcing a public meeting entitled ''2014 Scientific Meeting of the National Antimicrobial Resistance Monitoring System.'' The purpose of the meeting is to discuss progress made in achieving the goals of the National Antimicrobial Resistance Monitoring System (NARMS) Strategic Plan: 2012–2016.

Dates And Time: The public meeting will be held on August 12 and 13, 2014, from 8 a.m. to 5 p.m.

ADDRESSES: *Location:* The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, Great Room (rm. 1503A), Silver Spring, MD 20993–0002. Please note that visitors to the White Oak Campus must enter through Building 1. The White Oak Campus location is a Federal facility with security procedures. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

FOR FURTHER INFORMATION CONTACT: Laura Bradbard, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9109, FAX: 240–276–9115, *laura.bradbard@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: NARMS periodically conducts public meetings to inform stakeholders of NARMS activities and receive comments on ways to improve. The last two public NARMS meetings (held in 2010 and 2011) focused on recommendations made by the FDA Science Board Advisory Subcommittee in 2007. These meetings dealt with enhancing international partnerships, and improving NARMS sampling. Since then, NARMS created the 2012–2016 Strategic Plan that addressed all of the Science Board's recommendations (*http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM236283.pdf*). A number of strategic planning goals already have been achieved and several of the objectives outlined in the plan are ongoing. The purpose of this meeting will be to provide updates on progress of the NARMS 2012–2016 strategic plan, discuss possible future activities, and receive comments for the official record. A number of items will be discussed including comparisons of new and old slaughter sampling methods, the role of NARMS in foodborne outbreaks, results of interagency research projects using advanced detection methods, and how these scientific advances impact FDA decisionmaking.

Registration and Requests for Oral Presentations: Interested persons may make oral presentations on the topic of the discussion of the meeting. Oral presentations from the public during the open public comment period will be scheduled between approximately 3:50 p.m. and 4:50 p.m. on August 13, 2014. Those desiring to make oral presentations should notify the contact person by July 29, 2014, and submit a brief statement of the general nature of information they wish to present. In an effort to accommodate all who desire to speak, time allotted for each presentation may be limited. The contact person will inform each speaker of their schedule prior to the meeting.

Registration is required for the meeting. Please send registration information (including name, title, organization, address, and telephone and fax numbers) by email to Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) by July 29, 2014. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis.

If you need special accommodations due to a disability, please contact Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding the topic to be discussed at the meeting. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. The docket will remain open for written or electronic comments for 30 days following the meeting.

Agenda: The meeting will address monitoring and research for NARMS. The final agenda for the public meeting will be made available on the Agency's Web site at *http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059135.htm* and will be posted to the docket at*http://www.regulations.gov* no later than 2 weeks prior to the meeting.

Transcripts: FDA will prepare a meeting transcript and make it available on the Agency's Web site (see *Agenda*) after the meeting. FDA anticipates that transcripts will be available approximately 60 business days after the meeting. The transcript will be available for public examination at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. A transcript will also be available in either hardcopy or on CD–ROM after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: July 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16207 Filed 7–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Revising OIG's Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and Opportunity for Comment.

SUMMARY: This **Federal Register** notice informs the public that OIG: (1) Is considering revising the Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act (62 FR 67392, December 24, 1997), and (2) is soliciting input from the public for OIG to consider in developing the revised criteria.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on September 9, 2014.

ADDRESSES: In commenting, please refer to file code OIG–1271–N. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):