TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
k23	Straw Dust	NA.
k33	Oak	NA.
k70	Green coffee bean	*Coffea* spp.
k71	Castor bean	*Ricinus communis*.
k72	Ispaghula	*Plantago psyllium/Plantago ovata*.
k73	Silk waste	NA.
k74	Silk	*Bombyx mori*.
k75	Isocyanate TDI (Toluene diisocyanate)	NA.
k76	Isocyanate MDI (Diphenylmethane diisocyanate)	NA.
k77	Isocyanate HDI (Hexamethylen diisocyanate)	NA.
k78	Ethylene oxide	NA.
k79	Phthalic anhydride	NA.
k80	Formaldehyde/Formalin	NA.
k81	Ficus	*Ficus benjamina* (*Ficus* spp.).
k83	Cotton seed	*Gossypium hirsutum*.
k84	Sunflower seed	*Helianthus annuus*.
k85	Chloramin T	NA.
k86	Trimellitic anhydride, TMA	NA.
k87	Asp o 21, alpha-amylase	*Aspergillus oryzae*.
k89	Orris root	*Iris florentina*.
k99	HSA (Human Serum Albumin) (Hom s HSA)	*Homo sapiens*.
k201	Car p 1, Papain	*Carica papaya*.
k202	Ana c 2, Bromelain	*Ananas comosus*.
k204	Maxatase	*Bacillus licheniformis*.
k205	Alcalase	*Bacillus* spp.
k206	Savinase, Protease 1 (Bac l Subtilisin)	*Bacillus* spp.
k208	Gal d 4, Lysozyme	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
k209	Hexahydrophtalic anhydrid	NA.
k210	Maleic anhydride	NA.
k211	Methyltetrahydrophtalic anhydrid	NA.
k212	Abachi wood dust	*Triplochiton scleroxylon*.
k213	Pepsin (Sus s Pepsin)	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
k213	TCPA	NA.
k214	Bougainvillea	*Bougainvillea* spp.
k225	Horse radish peroxidase (Arm r HRP)	*Armoracia rusticana*.
k226	Ascorbate oxidase (Cuc p ascorbate oxidase)	*Cucurbita pepo*.
k301	Flour dust	*Triticum* spp.
k501	Savinase customer specific	Proprietary knowledge of customer.
k502	Lipolase customer specific	Proprietary knowledge of customer.
k503	Termamyl customer specific	Proprietary knowledge of customer.
k504	Clazinase customer specific	Proprietary knowledge of customer.

V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov*. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf*.

Dated: March 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04938 Filed 3–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0455]

Enhancing Patient Engagement Efforts Across the Food and Drug Administration; Establishment of a Public Docket; Request for Comments

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to solicit input on ongoing efforts to enhance mechanisms for patient engagement at the Agency. Engaging with patients, their caregivers, and advocates has long been a priority of the Agency. In this tradition, FDA intends to enhance future patient engagement by providing a more transparent, accessible, and robust experience for patient communities. To achieve these goals, FDA is considering establishing a new Office of Patient Affairs. This concept was directly informed by the public feedback solicited through the prior public docket regarding FDA's stakeholder engagement responsibilities outlined by the Food and Drug Administration Safety and Innovation Act (FDASIA). The purpose of this notice is to outline FDA's proposal for the future of patient engagement at the Agency so that the perspectives of

patient communities can be better captured.

DATES: Submit either electronic or written comments by June 12, 2017.

ADDRESSES: You may submit comments as follows:

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):* 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–2017–N–0455 for '' Enhancing Patient Engagement Efforts Across FDA; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sharnell Ligon, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6125, Silver Spring, MD 20993, 301–796–5253, FAX: 301–847–3532.

SUPPLEMENTARY INFORMATION: FDA has long recognized the importance of engaging with patients, caregivers, and their advocates in the medical product development process. On July 9, 2012, the President signed into law FDASIA (Pub. L. 112–144), which expands FDA's authorities and strengthens the Agency's ability to safeguard and advance public health in several areas, including increasing stakeholder involvement in FDA regulatory processes. Section 1137 of FDASIA, Patient Participation in Medical Product Discussions, codified in section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c), directs the Secretary of Health and Human Services to ''develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions.''

On November 4, 2014, FDA issued a **Federal Register** notice establishing a docket (FDA–2014–N–1698) for public commenters to submit information related to FDA's implementation of FDASIA's Patient Participation in Medical Product Discussions under FDASIA section 1137 (79 FR 65410). In response to public comments, and recognizing a need for improved coordination and support for patient engagement across medical product centers, the Office of the Commissioner launched an effort to enhance mechanisms for patient engagement at FDA.

As part of this effort, the Agency has identified the following objectives for its patient engagement activities:

- Develop a nuanced understanding of the patient experience of disease by:
  - Gathering patient perspective on what is clinically meaningful,
  - assessing attitudes towards benefit-risk and tolerance of uncertainty, and
  - enhancing the science of eliciting and integrating patient input.
- Support patients and their advocates in understanding regulatory processes and navigating the FDA by:
  - Communicating relevant FDA positions, procedures, and activities,
  - connecting patients and their advocates with the appropriate resources, and
  - resolving discrete challenges and needs.

To achieve these objectives, the Agency is considering establishing a central ''Office of Patient Affairs'' which will be tasked with supporting and coordinating patient engagement activities across medical product centers and other offices that engage with patients and their advocates on matters pertaining to medical products. In order to improve the transparency, coordination, and implementation of FDA's patient engagement activities, the responsibilities of this central office would include:

- Offering a single, central entry point to the Agency for the patient community,
- providing triage and navigation services for inbound inquiries from patient stakeholders,
- hosting and maintaining robust data management systems that would

incorporate and formalize knowledge shared with FDA by patient stakeholders and FDA's relationships with patient communities, and

• developing a scalable and forward-looking platform for communicating with patient stakeholders, particularly online channels.

Under this proposal to enhance mechanisms for patient engagement at FDA, a new ''Office of Patient Affairs'' would be directly accountable to the medical product Centers through clear governance structures. In addition, a regular evaluation of this central office and of FDA's overall patient engagement efforts is proposed. This evaluation will include feedback from external stakeholders (including patients and their advocates) on a biennial basis to best ensure the Agency's ongoing responsiveness to the needs of patient communities.

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04982 Filed 3–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0402]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives.'' The topics to be discussed will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing the fiscal year (FY) 2018 Regulatory Science Plan.

DATES: The public workshop will be held on May 3, 2017, from 8:30 a.m. to 4:30 p.m. The registration deadline to attend either in person, or virtually via web cast, is April 5, 2017. Comments regarding this public workshop may be submitted March 2, 2017, through June 2, 2017.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

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.*

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• 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–2013–N–0402 for ''Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Workshop; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephanie Choi, Center for Drug