



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2017-N-0455]

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 [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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