



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1698]

Food and Drug Administration Activities for Patient Participation in Medical Product

Discussions; Report on Stakeholder Views; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is making available the summary report of the public comments received during the open period from November 4 to December 4, 2014, on FDA activities under the Food and Drug Administration Safety and Innovation Act (FDASIA), Patient Participation in Medical Product Discussions. The purpose of this notice is to announce the public availability of the report on stakeholder views based on the comments received in the docket.

ADDRESSES: An electronic copy of the summary report is available at

<http://www.fda.gov/ForPatients/About/ucm483931.htm>.

The summary report is also available in Docket No. FDA-2014-N-1698.

FOR FURTHER INFORMATION CONTACT: Andrea Furia-Helms, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5319, Silver Spring MD 20993-0002, [Andrea.Furia@fda.hhs.gov](mailto:Andrea.Furia@fda.hhs.gov).

## SUPPLEMENTARY INFORMATION:

## Background

On July 9, 2012, the President signed into law FDASIA (Pub. L. 112-144). FDASIA 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. Specifically, section 1137 of FDASIA 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, including by fostering participation of a patient representative who may serve as a special government employee in appropriate Agency meetings with medical product sponsors and investigators and exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

FDA formed an Agency-wide working group to explore approaches and procedures as well as to align strategies across the Agency for patient participation in accordance with the statute.

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-03479 Filed: 2/18/2016 8:45 am; Publication Date: 2/19/2016]