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FDA to Convene Metal-Containing Implants and Dental Amalgams Panel, Nov. 13-14, 2019

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FDA announced it will open a public docket and hold an Immunology Devices Panel meeting to deliberate the potential for patients who receive medical device implants that contain select metal or metal alloys to develop immune and inflammatory reactions. The panel may provide input on scientific information the FDA should consider as part of premarket review and postmarket surveillance of metal-containing implants and dental amalgams.

Last March, FDA announced an ongoing evaluation of the growing body of evidence that suggests a small number of patients who receive medical device implants may have biological responses, such as tissue changes and inflammatory reactions that cause pain and fatigue. According to a press release issued Sept. 30 by the director of the Center for Devices and Radiological Health, Dr. Jeffrey E. Shuren, M.D., J.D., the agency will specifically consider how patients respond to select metal or metal alloys used in medical device implants to continue FDA's efforts to determine how to better identify patients who may have an increased risk of a hypersensitivity response before they receive a metal-containing implant.

Two publications authored by FDA staff were posted as background material ahead of the November meeting. One was a scientific review summarizing the current knowledge regarding different aspects of metal implants, and the other was a literature review of the latest risk-assessment data evaluating potential risks reported to be associated with dental amalgam.

Metal-containing implants and dental amalgams are commonly used in cardiology, orthopedics, dentistry, gastroenterology, neurology, and neurosurgery. FDA has opened a docket for public comment and seeks input specifically from health care providers, scientists, and patients—as well as industry stakeholders. The panel will meet on Nov. 13-14, 2019 in Gaithersburg, Maryland to discuss the current advances and potential gaps in the scientific community's understanding of immunology. The panel will provide recommendations for future approaches and standards for biocompatibility, including:

- The extent immunological responses to certain metals may cause or contribute to device-related local and systemic adverse effects as well as the potential underlying mechanism(s) involved and corresponding clinical manifestations;

- Patient characteristics, metal types, and/or anatomical considerations that may put an individual at higher risk for a heightened immunological response to a metal-containing implant, and methods that may assist in their identification;

- Mitigations that may reduce the risk for unintended immunological responses, including changes to device composition and design;

- The evidentiary gaps in biomedical research and clinical/diagnostic management associated with immunological responses to metal implants; and

- The adequacy, conclusions, and evidence gaps identified by a systemic literature review aimed to assess the recent epidemiologic and clinical evidence on adverse health effects reported in relation to occupational or non-occupational exposure to dental amalgam.

Members of the public who wish to present data, information, or views (orally or in writing) on issues pending before the panel should submit all written and electronic comments on or before Oct. 28, 2019. Oral presentations from the public will be scheduled during the panel meeting in Maryland. Those individuals or groups interested in making formal oral presentations at the meeting must submit a brief statement of the general nature of their evidence and arguments on or before Oct. 16, 2019.

FDA will accept written comments after the Immunology Devices Panel meeting until Dec. 16, 2019.

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