ASSOCIATION FOR MOLECULAR PATHOLOGY
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October 6, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Comments re: Docket No. FDA-2015-N-1805, "Retrospective Review of Premarket Approval Application Devices; Striking the Right Balance Between Premarket and Postmarket Data Collection"

Submitted electronically at www.regulations.gov

To Whom It May Concern:

Thank you for the opportunity to submit comments to Docket No. FDA-2016-N-1805, "Retrospective Review of Premarket Approval Application Devices; Striking the Right Balance Between Premarket and Postmarket Data Collection." The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics (IVD) industry.

AMP is pleased that the FDA completed this retrospective review to determine if the data typically collected in premarket trials could be shifted to the postmarket setting and also, if some class III devices can be down classified as new information becomes available making it sufficient to use special controls. We are hopeful that this effort will continue to streamline the regulatory pathway for in vitro diagnostic (IVDs) test kit manufacturers and improve patient access to these important IVDs.

We write to you today to request additional transparency into the data, criteria, and process used by the FDA during this retrospective review. AMP had hoped to comment on whether or not the Association agreed with the reclassification of procodes for IVDs, however, we were unable to fully assess the agency's recommendation without further details about the review and analysis that led to the decision. AMP is interested in learning more about what specific data, publications, changes in risk determination, marketing or technology reports, personal interviews, advisory panels, proficiency testing reports, and other sources of information FDA considered for each procode decision during the retrospective review and encourages the FDA to make this information readily available on its website.

Thank you for the opportunity to provide these comments. If you have questions or if AMP may be of assistance, please contact Tara Burke at tburke@amp.org.

Sincerely,

Federico Monzon, MD
AMP President-Elect