



ASSOCIATION FOR MOLECULAR PATHOLOGY
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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD, 20852

Docket No. FDA-2016-D-1025-0002; Draft Guidance for Industry and Public Health Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities

Dear Sir/Madam:

On behalf of the Association for Molecular Pathology (AMP), I write to you today in support of the written comments submitted by our colleagues at the Infectious Diseases Society of America (IDSA) in regards to the Draft Guidance for Industry and Public Health Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities. 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.

Most infectious disease diagnostics are molecular-based and as such, our members are at the front lines of clinical care during an outbreak as they develop and validate laboratory developed testing procedures (LDPs) and in vitro diagnostic test kits (IVDs) to rapidly and accurately diagnose infectious disease. AMP is pleased that the draft guidance takes numerous steps to create flexibility for IVD sponsors to reduce delays in making these products available to patients. However, AMP shares the same concerns as the IDSA. Specifically, AMP requests:

1. The FDA modify the requirement to seek support from relevant government stakeholders to avoid delays in EUA submissions to allow flexibility if government officials are unavailable or non-responsive.
2. The agency should consider additional support for clinical laboratory sponsors who may have limited financial and administrative resources to complete the EUA process.

Thank you for the opportunity to submit this letter in support of the written comments submitted by the IDSA. If you have any questions or would like additional information, please contact Tara Burke, Policy Analyst, at tburke@amp.org.

Sincerely,

Charles E. Hill, MD, PhD
AMP President