ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
6120 Executive Blvd., Suite 700, Rockville, MD 20852
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

February 5, 2019

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

Re: Docket No. FDA-2018-D-3380, "Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products Guidance for Industry"

Comments submitted electronically at www.regulations.gov

To Whom It May Concern:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit written comments on the draft guidance titled, "Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products Guidance for Industry". AMP is an international medical and professional association representing over 2,500 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 academic medicine, hospital-based and private clinical laboratories, the government and the in vitro diagnostics industry.

Advances in precision medicine, especially in the field of oncology, have demonstrated that the single test, single drug paradigm is becoming increasingly obsolete as multiple therapies are developed to target a specific biomarker.[1] AMP is pleased that the Food and Drug Administration (FDA) recognizes this evolution in its draft guidance currently open for comment. We support the creation of a class of therapeutic products and the policy outlined in the draft guidance that would allow an in vitro diagnostic (IVD) test kit's label to reference a class instead of a product by name. AMP believes this will increase patients' access to targeted therapies by removing unnecessary barriers, avoiding additional burdens to the patient, and reducing healthcare costs stemming from collection of subsequent samples, duplicate test orders, delays in treatment, and more.

In our comments to the FDA in 2016[2], AMP recommended that the term "companion diagnostic" not be used in any regulatory policy and that instead, the Agency use "targeted biomarkers" to more accurately reflect the current standard of care. While the draft guidance takes significant steps forward to align with the current state of medical practice, it still refers to this outdated term. With the creation of classes of products to reference in labeling, we request again that the Agency move away from the notion of

[1] http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_2017_Progress_Report.pdf
[2] https://www.amp.org/AMP/assets/File/position-statements/2016/AMPComments-FDA-2016-D-1703-0001-CompanionDx-FINAL.pdf

companion diagnostic and embrace terminology that acknowledges that many clinically validated tests enable physicians to make decisions regarding the most appropriate treatment for a patient.

While the draft guidance document focuses on diagnostic labeling, we would also like to note that drug labeling often creates unreasonable restrictions on patient access to molecular testing. AMP has a position statement called "Reference to Diagnostic Tests in Drug Labels," which we encourage you to review.[3] To promote patient safety and high quality care, AMP believes that diagnostics described in drug labels should be described by the biological description of the gene or mutation using standard HUGO nomenclature. Further, AMP believes that tests should only be referenced by brand name in a drug's label as part of a description of relevant clinical studies. Recognizing the need for classes of therapeutic products based on biomarkers acknowledges this paradigm shift and we respectfully request that the FDA update its policy regarding the description of the biomarker described in drug labels in the final guidance.

Thank you again for the opportunity to provide comment on this draft guidance. AMP supports efforts to move away from the single test, single drug paradigm and we hope that the FDA will continue in that direction by both updating the terminology used and the way in which diagnostics are described in the drug's label. If we can provide additional assistance, please direct your correspondence to Tara Burke, AMP Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Victoria M. Pratt, PhD, FACMG
President

[3] https://www.amp.org/AMP/assets/File/position-statements/2011/PositionStatement_DrugLabelingCompanionDx_Final051611.pdf