Association for Molecular Pathology
Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology
9650 Rockville Pike, Bethesda, Maryland 20814
Tel: 301-634-7939 ▪ Fax: 301-634-7990 ▪ Email: amp@amp.org ▪ www.amp.org

March 1, 2013

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-1248

Thank you for the opportunity to submit written comments to the public hearing on "Creating an Alternative Approval Pathway for Certain Drugs Intended to Address Unmet Medical Need." The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,000 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 and the in vitro diagnostics industry.

AMP is pleased that the FDA held a public hearing to explore regulatory pathways for subpopulations of patients. Often times, these subpopulations are distinguished by genetic or molecular markers. While the FDA discusses the creation of such a pathway, AMP encourages the FDA to also consider how the information describing subpopulations of patients might be described in drug labels.

In 2009, the Center for Drug Evaluation and Research (CDER) changed the labels for two anti-EGFR monoclonal antibodies, cetuximab and panitumumab. As you may know, patients with mutations in the KRAS gene respond to these drugs and hence, reflect a subpopulation of patients. In a letter to Center Director Dr. Janet Woodcock,[1] AMP commended CDER on these changes. At that time, numerous CLIA certified laboratories were conducting KRAS testing as laboratory developed tests (LDTs) under the guidance of qualified laboratory directors. AMP was very pleased to see that the new labeling for these drugs referenced the biological description of the gene and mutation analysis for KRAS, and that it did not refer to market brand names for the assay(s) used in the studies.

When FDA includes a brand name of a diagnostic kit on a drug label, the medical community often views this as a tacit endorsement of that one company's test. Diagnostic companies sometimes lead physicians to believe that one FDA approved/cleared test is preferred over another FDA approved/cleared test or other validated test simply because it is included by name on the drug label. This effectively ties the hands of the pathologist and clinical laboratories, who should be free to choose the test that best suits the needs of their patients, physicians and laboratory environment, and is a disincentive for the development of alternative and possibly improved versions of assays for the same analyte.

[1] http://www.amp.org/publications_resources/position_statements_letters/WoodcockLtr_DxonRxLabels_082709.pdf

AMP commended the FDA and CDER for establishing this significant precedent of referencing the biological description of a diagnostic test in the labeling of a companion therapeutic. This ensured that laboratory directors are able to use their clinical judgment to select the most appropriate test method. We hope that as the Center contemplates regulatory pathways for drugs intended to meet an unmet need that you also consider how best to incorporate genetic subpopulations into a drug's label to ensure that patients receive high quality personalized healthcare. Thank you very much for considering these comments and please do not hesitate to call on AMP if we can provide assistance.

Sincerely,

Jennifer L. Hunt, MD, MEd
President