



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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24 April 2008

Federico Goodsaid, Ph.D.
Associate Director for Operations in Genomics
Office of Clinical Pharmacology
Office of Translational Science
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Building 21, Room 4524
Silver Spring, MD 20903-0002

Comments Regarding FDA Guidance for Industry: E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories

Dear Dr. Goodsaid:

AMP is an international not-for-profit professional association representing over 1,500 physicians, doctoral scientists, and medical technologists who perform molecular diagnostic testing based on nucleic acid technology. AMP members practice their specialty in widely diverse settings: academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the in vitro diagnostic industry. In this capacity, AMP members are involved in every aspect of molecular diagnostic testing: administration and interpretation of molecular diagnostic tests, research and development, and education. As the only professional association dedicated solely to molecular pathology, AMP provides national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

We have reviewed and agreed with the definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories.

Thank you for the opportunity to comment on this very important document. Please do not hesitate to contact Vicky Pratt, PhD, Clinical Practice Committee Chair, at victoria.m.pratt@questdiagnostics.com if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gregory J. Tsongalis', written in a cursive style.

Gregory J. Tsongalis, PhD
President