BIOTECHNOLOGY INDUSTRY ORGANIZATION

1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

July 23, 2011

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

RE: Comments Following the Public Meeting: Ultra High Throughput Sequencing for Clinical Diagnostic Applications - Approaches to Assess Analytical Validity; FDA-2011-N-0301

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit comments in association with FDA's public meeting entitled *Ultra High Throughput Sequencing for Clinical Diagnostic Applications - Approaches to Assess Analytical Validity*. BIO recognizes the complexities of developing appropriate, practical standards and methodologies for the assessment of analytical validity of ultra high throughput sequencing. BIO commends the FDA for prospectively seeking input from industry to ensure that the regulatory environment is supportive of the rapid technological advancement of technology in this area.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnologies, thereby expanding the boundaries of science to benefit society by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. Specifically related to next generation sequencing, BIO represents companies that develop and market these technologies. For this reason, BIO companies welcome the opportunity to work with the FDA on the development of policy in this area.

The accumulation of scientific knowledge and capabilities in the area of genomics and the genetic basis for disease is increasing rapidly. The current regulatory pathways administered by the FDA are not well suited to assess these technologies at the current state of the art, and will certainly be further challenged as the pace of development continues to rise. The approach to assessing the analytical validity of next generation sequencing clinical diagnostic applications must be both clear and flexible enough to allow for the variability among the platforms. Further, assessment of the analytical validity and clearance of this technology should focus on the individual platform, rather than proceeding on a gene-by-gene basis.

BIO agrees that the development of standards or standardized methodologies is critical to ensuring the accuracy of the results of next generation sequencing. FDA should work closely with industry to develop these standards or standardized methodologies to ensure that they are accurate and reliable, but also clear and flexible enough to ensure that innovation in this area is not inhibited. In addition to collaboration with industry, FDA should recognize the existing collaborative efforts formed amongst stakeholders to develop consensus standards on various topics, and ensure that the agency works closely with these groups to ensure the efficient and consistent development of policy in this area.

Respectfully submitted,

Paul Sheives, JD
Director, Diagnostics and Personalized Medicine
Biotechnology Industry Organization