BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

1225 Eye Street NW, Ste. 400
Washington, DC 20005

April 9th, 2007

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2006D-0526, Federal Register: January 8, 2007 (Volume 72, Pages 793-794)

Dear Sir/Madam:

The following comments are provided by the Biotechnology Industry Organization (BIO). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. We appreciate the opportunity to comment on the Food and Drug Administration's (FDA's) Draft Guidance for Industry on International Conference on Harmonisation; E15 Terminology in Pharmacogenomics.

General Comments

BIO fully supports harmonization in the area of genomics, and appreciates the work that FDA has done so far on this important issue. We also fully support the goal of this draft guidance, i.e. to establish common definitions for key genomics terminology as a necessary first step in developing harmonized approaches to pharmacogenomics. In our comments below, we address two specific minor concerns with the language of the guidance.

Specific Comments

Section 2.2.2: Additional Information

The first comment concerns the definitions for pharmacogenomics and pharmacogenetics. While we agree that drug response and drug effect include pharmacokinetics and pharmacodynamics as currently noted in the draft guideline (2.2.2.2), drug response and effect may also include the important aspects of efficacy and safety.

As such, we recommend that item 2 under this heading be replaced with the following underlined text: Drug response includes drug disposition and drug effects (such as, but not limited to, pharmacokinetics, pharmacodynamics, safety and efficacy).

Section 2.3.2.1, Section 2.3.2.2

BIO's second comment concerns the use of the term "personal identifiers" in sections 2.3.2.1 (Single coded data and samples) and 2.3.2.2 (Double-coded data and samples). We recognize the importance of not having any direct personal identifiers associated with coded data. However, it may be appropriate for coded samples to include certain general information related to individuals such as their ages or postal codes.

As such, we recommend that the following underlined statement be added to these two sections of the guidance: Coded data do not carry any direct personal identifiers but may include general information related to the individual, such as age or postal code.

In conclusion, we would like to reiterate our support for improving international harmonization through the establishment of key definitions in pharmacogenomics. We appreciate the opportunity to provide our comments to FDA on this important issue, and we look forward to the final guidance.

Sincerely,

/s/

Sara Radcliffe
Vice President
Science and Regulatory Affairs