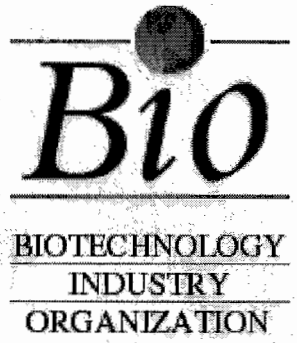

November 21, 2005

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

Re: Docket No. 2005D-0310, CBER 200523.
Draft Guidance for Industry on Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) "Draft Guidance for Industry on Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events." BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Reference is made to FDA's Draft Guidance for Industry on *Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events*, published August 23, 2005 (Docket No. 2005D-0310, CBER 200523).

This draft guidance on long-term follow up (LTFU) of gene transfer recipients has been under development as of the Biological Response Modifiers Advisory Committee (BRMAC) meeting on October 24, 2001, in which BRMAC proposed that FDA require sponsors to follow all gene transfer patients for at least 15 years, regardless of vector type. Since that time, many deliberations have occurred, including an especially fruitful meeting in June 2004, immediately prior to the American Society of Gene Therapy annual meeting. Furthermore, the recommendations for LTFU of gene transfer investigational products have evolved significantly.

BIO commends FDA for its continued and active role in gathering investigator, industry, and public comments on the proposed LTFU initiative. We feel the draft guideline

released on August 23, 2005 offers thoughtful, reasonable, and detailed recommendations to sponsors of gene transfer clinical studies.

However, BIO would like to offer the following points for consideration:

1. LTFU is a global issue affecting clinical trials worldwide and, as such, BIO strongly recommends collaboration with international health and regulatory bodies (e.g., ICH). Global collaboration should be undertaken to ensure that data obtained is scientifically valid.

2. BIO believes it is imperative that adequate funding be made available to support the infrastructure and resources required for LTFU. Lack of funding could discourage research and development efforts in the gene transfer field. Without adequate and consistent funding, academic sponsors (which typically have limited funding for 3-5 years) and many biotechnology companies may not be able to afford to develop new therapies at all.

3. The draft guidance does not contain any provisions for LTFU of marketed gene transfer products. BIO suggests that FDA consider future discussions with stakeholders to obtain input regarding appropriate approaches for post-marketing LTFU including consideration of the establishment and use of an international registry for collecting LTFU data, where required.

We again thank FDA for the opportunity to provide our comments on this draft guidance and look forward to continuing work with the agency as it proceeds toward publication of a final guidance. If we may be of further assistance on any of the topics addressed above, please do not hesitate to contact us.

Sincerely,

/s/

Sara Radcliffe
Managing Director
Science and Regulatory Affairs