



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

October 28, 2004

Re: Docket No. 03D-0112

Dear Sir/Madam:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to support the Food and Drug Administration's (FDA) efforts in adopting the Independent Consultants guidance for biotechnology clinical protocols. 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.

Enacted under the reauthorization of the Prescription Drug User Fee Act (PDUFAIII), this program allows both the FDA and sponsors to obtain expert advice on medical and scientific issues related to sophisticated biotechnology products. Due to the innovative and complicated nature of many such products, designing appropriate clinical trials necessary for product approval is often a complex matter. BIO believes that allowing biotechnology product sponsors to request that the FDA appoint an expert consultant in the matter will, in appropriate circumstances, greatly facilitate agreement on clinical trial design.

BIO expresses appreciation to the agency for its efforts in adopting this guidance. It is our belief that the Independent Consultants program will be of significant benefit to the agency, the biotechnology industry and, ultimately the patients.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephan E. Lawton". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Stephan E. Lawton  
Vice President & General Counsel

1225 EYE STREET, N.W., SUITE 400  
WASHINGTON, D.C. 20005-5958

202-962-9200  
FAX 202-962-9201  
<http://www.bio.org>