BIO

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

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

Re: Docket No. 03D-0112, Federal Register: May 7, 2003 (Volume 68, Number 88, Page 24486-24487)

Dear Sir/Madam:

The following comments are provided by the Biotechnology Industry Organization (BIO). 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. BIO appreciates the opportunity to comment on the Food and Drug Administration's (FDA) Guidance for Industry: Independent Consultants for Biotechnology Clinical Protocols.

BIO commends the FDA for adopting this new program authorizing biotechnology product sponsors to request that the agency appoint an expert consultant to provide input during the review of proposed clinical trials. Because biotechnology products are often novel and complex, decisions on the appropriate design of clinical trials needed for product approval may be more difficult than for products with more well-understood science. This new, workable mechanism, enacted under the third reauthorization of the Prescription Drug User Fee Act (PDUFA III), enables the FDA and sponsors to obtain expert advice on medical and scientific issues related to cutting-edge biotechnology products.

BIO agrees that the guidance is consistent with the PDUFA III goals letter. However, we request that FDA provide additional clarity in a few areas.

1) In section IV, the guidance provides for a 60 day extension for the scheduling of a meeting that is subject to this guidance. This extension allows FDA time to consider and screen potential consultants and allows the consultant time to review the scientific issues.

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We request that FDA clearly state that 60 days is the maximum extension expected for any request. As worded, this section might be interpreted to allow up to 120 days (i.e. if there are scientific issues and special protocol questions assessments to be discussed at the same meeting).

2) In section VI, the guidance notes that FDA may decide not to select a consultant from the list suggested by the sponsor. If FDA does not consider any of the suggested consultants acceptable, we request that the guidance specify that FDA notify the sponsor of the potential consultants the agency is considering prior to finalizing the selection. We believe that it is important to provide the sponsor an opportunity to notify FDA of any known biases or conflicts an individual may have.

3) In section VII, please explain how the consultant's input will be shared with the sponsor. We request that the consultant provide a written assessment to FDA in advance of the meeting, and that the assessment be shared with the sponsor either before the meeting or by the time the meeting minutes are distributed.

4) In section VIII, please add a statement allowing for the use of dispute resolution if the sponsor does not agree with the rationale for denial.

It is our understanding that FDA will evaluate the effectiveness of this program prior to the next reauthorization of PDUFA. Assuming that the program is successful, we ask that FDA consider broadening the scope of products covered by the program, perhaps to include all biologics.

BIO looks forward to the final guidance from the FDA on the use of independent consultants. We believe that this program will help ensure that innovative, effective and safe biological products continue to be developed to meet serious, unmet medical needs.

Sincerely,

Wendy Taylor
Director of Regulatory
Affairs and Bioethics