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July 25, 2003

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

MERCK
Research Laboratories

RE: Docket No. 03D-0112
Draft Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols

Merck & Co., Inc, is a leading worldwide, human health product company that has produced many of the most important pharmaceutical products on the market today. Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. It is incumbent upon regulators and upon industry to see that important therapeutic breakthroughs reach patients without unnecessary or unusual regulatory delays.

Merck's extensive experience in vaccine development has provided its scientists and regulatory affairs professionals with an important understanding of the laws and regulations governing biologics under the Federal Food, Drug, and Cosmetic (FD&C), and the Public Health Service (PHS) Acts, which are the subject of this notice. Therefore, Merck is well qualified to respond to this request for comments on the Draft Guidance, *Independent Consultants for Biotechnology Clinical Trial Protocols*, hereafter referred to as the Draft Guidance.

Merck supports the Agency's efforts to establish a program that allows sponsors of clinical trials for certain products to request that FDA engage an independent consultant to participate in the review of clinical protocols intended to serve as the primary basis for claims of efficacy. Both sponsors and FDA benefit from expertise that is not available within the pharmaceutical industry or the Agency. For example, within the area of HIV vaccine development, where there may be lack of consensus on the immune correlates of protection, an independent consultant could educate both parties on the state of the art. We offer three comments for your consideration:

1 This first comment is offered in the spirit of issuing a Guidance that clearly explains how a sponsor may take advantage of this program. Section III of this Guidance states, *We recommend that you submit a written request to us asking that we engage a consultant as part of your request for a formal meeting.* We suggest that you require that sponsors submit a written request to engage a consultant, making it mandatory to submit such requests in writing due to their importance.

Two additional comments related to how the FDA screens prospective consultants for potential conflicts of interest:

2 It would be helpful if the Guidance specified or referred to the criteria that will be used to screen a prospective consultant for potential conflicts of interest. This will assist sponsors when identifying candidates to recommend to FDA. For example, will candidates be screened according to the criteria described in *Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants, and Experts* (FDA Waiver Criteria 2000)?

3. The Guidance should address whether restrictions are/are NOT imposed on a consultant following a review of a clinical protocol. For example, after a consultant provides the FDA with advice on a clinical protocol, is the consultant restricted from serving on future Advisory Committees at the request of the Agency? Or representing the sponsor at future Advisory Committee meetings? When the same product is reviewed? When a related product/technology is reviewed?

We appreciate the opportunity to comment on this Guidance.

Sincerely,

Lauren M Hetrick

for David Blois, Ph.D.
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