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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ref: Docket No. 02D-0320, OC 2002121. Draft Guidance for Industry and Clinical Investigators on The Use of Clinical Holds Following Clinical Investigator Misconduct."

Abbott Laboratories commends the Agency on their efforts to provide guidance to industry and clinical investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct, published in the Federal Register on August 27, 2002.

We are very pleased to have the opportunity to comment on this draft guidance and thank the Agency for your consideration of our attached comments. Should you have any questions, please contact Ivone Takenaka, Ph.D. at (847) 935-9011 or by FAX at (847) 938-3106.

Sincerely,

Douglas L. Sporn
Divisional Vice-President
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02D-0320

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**Comments on
Guidance for Industry and Clinical Investigators on
The Use of Clinical Holds Following Clinical Investigator Misconduct**

Docket No. 02D-0320

GENERAL COMMENTS

Abbott commends the Agency on their efforts to provide guidance to industry and clinical investigators on the “The Use of Clinical Holds Following Clinical Investigator Misconduct”. Furthermore, we appreciate the requirements set out in the ICH E6-Good Clinical Practice Guidance and in the 21 CFR Parts 312.42, 50, 56 and 60. However, we would like the agency to consider the following comments.

We recommend the Agency to expand Section I in the guidance to include guidelines on the responsibilities of the sponsor in the case of a clinical hold due to an investigator’s misconduct.

SPECIFIC COMMENTS

I. PURPOSE

The guidance states in the 3rd sentence: “*Such a clinical hold may be imposed on the study in which the misconduct occurred or on other studies of drugs or biological products in which the clinical investigator is directly involved or proposed to be involved.*”

Comment:

In regards to multi center studies, we recommend rewording the sentence to the following: “Such a clinical hold may be imposed on the **study site where** the misconduct occurred...etc.”

II. BACKGROUND

B. What Actions Can FDA Take to Address Clinical Investigator Misconduct?

¶2. The guidance states : “*Where FDA finds that there have been serious violations... . Such actions can take several months and frequently years to complete*” and reiterate in ¶3 that “[a] *disqualification proceeding generally takes many months or years to complete*”. Furthermore, under section **IIC. ¶1**, the guidance states that “[i]nitiation of an enforcement action in federal court or disqualification proceeding does not by itself halt an investigator’s participation in clinical trials.”

Docket No. 02D-0320

Comment:

Since an investigator under an enforcement action or disqualification proceedings can still participate in other studies, we request the Agency to clarify how sponsors will be made aware of an investigator being on hold or under investigation so additional subjects are not placed at risk.

III. USE OF CLINICAL HOLDS TO PROTECT HUMAN SUBJECTS

B. 1. Before an enforcement action is initiated.

Last ¶, 4th sentence. The guidance states “*Nonetheless, protecting the safety of patients at imminent risk is of great importance, and even preliminary (e.g. pre-inspectional), but credible evidence raising concerns that patients may be placed at substantial risk may warrant a hold while further information is being obtained.*”

Comment:

As stated, it appears that an investigator can be placed on hold if some type of preliminary (e.g., pre-inspectional) but credible evidence against the investigator’s practices has raised a concern. We would like the Agency to clarify in the guidance what would constitute credible evidence in the absence of an inspection other than a report of non-compliance or fraud initiated by a sponsor.