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December 22, 1999

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane (HFA-305)
Room 1 O-61
Rockville, MD 20852

RE: Comments on the FDA's Draft Guidance for Industry on Financial Disclosure by Clinical Investigators
[Docket No. 99D-4396]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

I. GENERAL COMMENT

Abbott supports the letter from the Health Industry Manufacturers Association (HIMA) on this same subject authored by Dr. Marlene Tandy. We also appreciate the Agency's ongoing efforts to provide additional help and guidance to comply with this final rule. As the FDA has noted in its comments on this subject, it has received a large number of questions about its proper implementation.

II. SPECIFIC REMARKS

- a. Timing. Section II. For items A, B, and C the Agency should highlight that financial disclosure is required only for those studies used to support applications that are submitted to FDA on or after February 2, 1999.

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- b. Definition of ‘Sponsor.’ Question No. 5. The guidance document should provide additional details regarding the definition of a sponsor. Instances where questions may arise include multiple sponsors and studies where government bodies might be viewed as the sponsor. Should sponsors identify the percentage of their sponsorship? Regarding trials sponsored through government bodies, examples include the many departments under the oversight of the National Institutes of Health, Department of Defense and the Environmental Protection Agency.
- c. Recordkeeping Requirements. Question Nos. 8, 13 and 28. Confirming what HIMA has detailed in its letter, it should be acceptable to the Agency that a manufacturer is entitled to rely on financial information provided by the investigator to the company (e.g., in response to a company questionnaire or recorded in the company files after contact with the investigator) as sufficient recordkeeping to comply with the financial disclosure requirements as long as the information from the investigator contains adequate detail, is properly updated and is stored for the appropriate length of time.
- d. Completion of the Study. Question No. 12. An end point which can be more clearly defined should be the goal for the final version of the guidance document. The Agency should consider the following alternative:
“Completion of the study should be defined as that point at which the last subject has his or her last visit for evaluation of the primary endpoint at the last trial site.”
- e. Applicability to *In Vitro* Diagnostic Products. Question No. 22. The guidance document should specify that the testing of *in vitro* products at a clinical site is considered a “covered clinical study,” but testing of *in vitro* products performed by a manufacturer’s employee(s) within the company’s facilities is not a “covered clinical study.” The guidance document should also specify that studies of *in vitro* products involving blood and blood components collected from routine volunteer blood donors are not “covered clinical studies” for the purpose of financial disclosure.

III. Closing Remarks

Because the guidance document has a broad scope and a large potential impact on the design of clinical trials, we believe that the Agency should continue to conduct questions and answer sessions in various public forums. Specifically, we recommend that the FDA present and review both the rule and guidance document at the annual meeting of the Drug Information Association (DIA) being held in June of 2000.

The rationale for this comment is based on:

- A. General educational purposes.
- B. Publicity. The impact of the final rule and guidance document has an ongoing effect on regulatory practices and expectations of manufacturers and the many parties associated with clinical trials. By carrying out these seminars, the Agency can publicize the new requirements and expectations for both the final rule and the guidance document currently under revision.
- C. Clarity. Finally, public seminars will serve to clarify regulatory expectations and interpretations.

Thank you for the opportunity to comment.

Yours truly,



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cc: Joseph R. Assenzo, PhD, DIA
Mary C. Gross, FDA (HF-24)
Dr. Marlene Tandy, HIMA
FDA Docket No. 93N-0445



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