

December 21, 1999

Alcon

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room IO-61
Rockville, Maryland 20852

6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

Re: Docket No. 99D-4396

Dear Sir or Madam:

Provided herewith are two (2) copies of Alcon's comments regarding the Draft Guidance for Industry on Financial Disclosure by Clinical Investigators.

If there are any questions regarding these comments, please contact me by telephone at (817) 551-6813 or Telefax at (817) 551-4630.

Sincerely,



Garry G. Heidel
Assistant Director
Regulatory Compliance

Attachments

99D-4396

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***Draft Guidance for Industry on
Financial Disclosure by Clinical Investigators***

Comments

8.Q: Does FDA have expectations about how the financial information should be collected? Will FDA consider it acceptable practice for a company to use a questionnaire to collect financial information from investigators rather than constructing an internal system to collect and report this information?

The FDA has not clearly indicated if questionnaires are acceptable for collecting financial information from clinical investigators. If questionnaires are considered unacceptable, then what forms of financial information collection documentation are considered satisfactory? For global companies, the ability to maintain detailed records essentially equates to “elaborate internal computerized tracking systems.”

12.Q: The rule requires that investigators are required to provide information on financial interests during the course of the study and for one year after completion of the study (see 54.4(b)). What does “completion of the study” mean?

FDA should clarify the following: If a sponsor completed a covered study prior to February 2, 1999 but the FDA asked the sponsor to do follow-up/extended studies after February 2, 1999, is the sponsor required to submit financial information on the investigator?

End of comments.

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