



Schering-Plough

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November 25, 2002

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

Re: Docket No. 02D-0320; Draft Guidance for Industry on the Use of Clinical Holds Following Clinical Investigator Misconduct

Dear Sir/Madam:

Schering-Plough has reviewed the Draft Guidance for Industry on the Use of Clinical Holds Following Clinical Investigator Misconduct, and we greatly appreciate and acknowledge the efforts that the Agency is putting into this guidance document. It is an important document that addresses an issue that is critical to Sponsors and to the adequate protection of human subjects participating in clinical trials. We offer the following comments for your consideration.

1. Our primary comment is that the guidance is lacking information as to how Sponsors (other than the Sponsor of the IND(s) in which the Investigator is involved) would be notified of the fact that a partial hold has been put on an investigator due to misconduct. If deficiencies in an investigator's application of Good Clinical Practice are serious enough to warrant a hold, this investigator should not be recruited for additional studies (at least until the hold has been lifted). Will this information be communicated publicly (similar to the list of disqualified investigators) so that Sponsors can refrain from selecting these investigators? If not, what mechanism does the Agency envisage to avoid the Sponsor's selection of investigators for their studies for whom a clinical hold has been implemented pursuant to this guidance document?
2. The current draft guidance does not contain the timeframe for specific steps (e.g., between when the hold is imposed and the NIDPOE letter is issued).
3. Guidance on the type of actions that Sponsors are expected to take in the event that a Sponsor finds serious Clinical Investigator misconduct during the monitoring of a trial is not provided in this document. Would the same criteria used by FDA to implement a hold apply to Sponsors (or be expected to apply to Sponsors) for a decision to stop (on their own) the participation of an Investigator in the trial?

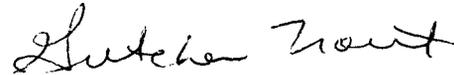
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4. Some of the examples in Section III. B. 1. would benefit from being rephrased or clarified. For example, "failure to report serious or life-threatening adverse events" - does this mean failing to report one SAE is cause to suspend a Clinical Investigator even in an early stage investigation, or does it mean a repeated or deliberate failure to report?

Schering-Plough appreciates the opportunity to comment on this guidance document and we look forward to clarifications that would address the above comments.

Sincerely,



Gretchen Trout
Director, Regulatory Relations and Policy
Worldwide Regulatory Affairs