MessageFrom: Lepay, David on behalf of OC GCP Questions
Sent: Friday, October 01, 2004 8:59 AM
To: [purged]
Subject: RE: question to dr. Lepay

Dear Dr. [purged]:
FDA GCP inspections (of clinical investigators, sponsors, or IRBs) generally last 3-5 working days (on occasion, they may extend longer if records need to be obtained from satellite sites, etc.). We don't cost out individual inspections (because these are funded by FDA --- not billed to the inspected party). Cost will vary depending on duration, location (travel expenses), size of the inspection team (usually one investigator with headquarters scientific support in the U.S. and one investigator plus one scientific expert for international inspections), and so forth. On average, I expect cost to be on the order of U.S. $5000.

I hope this answers your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Monday, September 27, 2004 3:05 AM
To: gcpquestions@oc.fda.gov
Subject: question to dr. Lepay

Dear dr. Lepay,

I enjoyed your presentation at the ACRP annual meeting in Brussels on September 16th and 17th very much. Your slide on international inspections shows that 16 CGP inspections were performed in Belgium. Could you give us

some more information on this procedure: how long does such an inspection take, how much does it cost etc.

Thank you very much for your help,

Sincerely,

[purged]