MessageFrom: Lepay, David on behalf of OC GCP Questions
Sent: Tuesday, June 14, 2005 1:08 PM
To: [purged]
Subject: RE: Quick Question

Dear [purged]:

FDA's Bioresearch Monitoring (BIMO) program is an agency-wide program: each of FDA's five Centers (Drugs, Biologics, Devices, Veterinary Medicines, and Food Safety), FDA's Office of Regulatory Affairs (field inspection force), and our Good Clinical Practice Program office are part of this program.

DSI (the Division of Scientific Investigations) is the component of the BIMO program in FDA's Center for Drug Evaluation and Research --- similar to the parallel Division of Bioresearch Monitoring in FDA's Center for Devices, and so forth. The Center components of the program (including DSI) are responsible for working with review divisions within that Center to develop inspections assignments, to convey assignment information to the Office of Regulatory Affairs (which conducts the inspection or leads the inspection team from its district offices), to evaluate the results of the inspection, and to initiate any necessary enforcement actions related to inspections assigned by that Center.

As noted, it is FDA's Office of Regulatory Affairs which administers FDA's district and regional offices across the United States and is responsible for conducting BIMO inspections (based on assignments from the Centers) or leading the inspection team.

Our Good Clinical Practice Program office in the Office of the Commissioner is responsible for coordination of the agency BIMO program, coordinating cross-cutting policy and operational issues for the program as a whole where it relates to human (vs. veterinary) clinical studies.

I hope this information answers your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, GCP 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, June 13, 2005 2:19 PM
To: gcpquestions@oc.fda.gov
Subject: Quick Question

Hi -

I was reviewing some FDA slides from a presentation delivered at the recent ACRP meeting in Orlando and had a quick question.
I was wondering if I could get a brief explanation about the relationship (if any) between the DSI within CDER and the ORA/BIMO programs. I understand that there is a coordination aspect to inspection activity. So, is it a fair characterization if I say that the DSI activities within CDER are a component of the larger BIMO program with respect to drugs? Or are these completely independent of each other?
Thanks.
[purged]

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