From: Lepay, David
Sent: Thursday, November 10, 2005 6:35 AM
To: [purged]
Subject: RE: FDA's position on the Helsinki Protocols for Clinical
Trials

Dear Dr. [purged]:
FDA last referred to the Declaration of Helsinki in two documents:

1) "Guidance for Industry, Acceptance of Foreign Clinical Studies", published in March 2001 (which can be accessed from FDA's GCP website www.fda.gov/oc/gcp through the link to "Guidances and Information Sheets";

2) A proposed regulation (that is currently in the process of finalization following a public comment period) entitled: "Human Subject Protection; Foreign Clinical Trials Not Conducted Under an Investigational New Drug Application", which published on June 10, 2004, and can be accessed from the same GCP website www.fda.gov/oc/gcp through the link to "Proposed Regulations and Draft Guidances".

To my knowledge FDA has not issued any further guidance or policy related to the Declaration of Helsinki since the two documents noted above.

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: Wednesday, November 09, 2005 1:12 PM
To: gcpquestions@oc.fda.gov
Subject: FDA's position on the Helsinki Protocols for Clinical Trials

Could you please provide information about the FDA's position on the Helsinki Protocols for Clinical Trials and recent amendments to the protocols and FDA Guidances?

Thank you

[purged]