From: Lepay, David
Sent: Monday, May 16, 2005 4:29 PM
To: [purged]
Subject: RE: Query re Declaration of Helsinki

Dear Mr. [purged]:
FDA is currently in the process of updating our regulations for accepting non-U.S., non-IND studies in support of an application (e.g., NDA) to FDA. The proposed rule has completed its public comment period, but does not become effective until a final rule publishes. We hope this will take place by the end of 2005. I might suggest that you review this proposed rule (which does not reference the Declaration of Helsinki [DOH] directly, but rather makes reference to GCP standards); this can be accessed from FDA's GCP website at www.fda.gov/oc/gcp through the link to "Proposed Regulations and Draft Guidances" and hence to the pertinent entry (with its publication date of 6/10/04).

Until an updated final rule issues, FDA guidance (accessible at the same GCP website through the link to "Guidances" and hence to the pertinent entry: "Guidance for Industry ---
Acceptance of Foreign Clinical Studies", published in March 2001) provides more detailed information on current FDA requirements and expectations, particularly as these cite earlier versions of DOH.

I hope that this information is helpful in addressing your query. If you have any specific concerns about provisions of the 1996 version of the Declaration of Helsinki (DOH) that may be in conflict (that is, lead to noncompliance) with the earlier versions of DOH still cited in FDA regulations (until our updated rule finalizes), please do bring these to my attention.

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: Wednesday, May 11, 2005 9:48 AM
To: 'david.lepay@fda.hhs.gov'
Subject: Query re Declaration of Helsinki

Dear Dr Lepay,

You are probably aware that the European Union published a new directive
(2005/28/EC) on good clinical practice last month. Article 3 includes the text "Clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996)", thus establishing the 1996 version of the Declaration as the required standard for compliance with EU law.

My understanding of US regulations is that it is the 1989 version of the Helsinki Declaration that is specifically referenced. We are currently trying to reconcile our advice to sponsors to ensure that studies are conducted to the appropriate standards for acceptance by both the FDA and European regulatory agencies. Consequently, I would be grateful for your confirmation that compliance with the 1996 version is acceptable to FDA, or for an alternative comment concerning FDA's position.

Thank you very much for your help.

Best wishes,

[purged]

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