From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, February 24, 2005 2:54 PM
To: [purged]
Subject: RE: Declaration of Helsinki

Dear Mr.. [purged],

You can find FDA's current thinking on the use of the Declaration of Helsinki in our guidance document entitled "Guidance for Industry: Acceptance of Foreign Clinical Studies" [see http://www.fda.gov/oc/gcp/guidance.html for an e-copy of this guidance document]. Essentially this document clarifies the version of the Declaration of Helsinki that apply to FDA's acceptance of foreign clinical studies not conducted under an investigational new drug application (IND). This guidance also notes that FDA is currently reviewing its regulations pertaining to the acceptance of foreign clinical studies to determine if it should revise those regulations to incorporate new or modified standard or requirements.

In June 2004, FDA did, indeed, publish in the Federal Register a proposed rule to revise its regulations on its acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. FDA proposed to replace the requirement that such studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki (Declaration) with a requirement that the studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee (IEC). The proposed rule is intended to update the standards for the acceptance of nonIND foreign studies and to help ensure the quality and integrity of data obtained from such studies.(see http://www.fda.gov/OHRMS/DOCKETS/98fr/04-13063.htm for an e-copy of this proposed rule).

The comment period for this propose rule closed on September 8, 2004. FDA received a number of comments on the proposed rule that are currently being evaluated within FDA. Once these comments have been fully evaluated, the rule will be published again in the Federal Register for public comment.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director

Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340
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: Thursday, February 24, 2005 10:04 AM
To: gcpquestions@oc.fda.gov
Subject: Declaration of Helsinki

I have a question in regard to the Declaration of Helsinki and 21 CFR Part 312. Can you tell me what year of the Declaration is Part 312 aligned too? I can't seem to find that information when reading Part 312, subsection C.

Thanks,
Mike

[purged]