From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, November 16, 2005 4:59 PM
To: [purged]
Subject: RE: Question regarding FDA 1572

Dear Ms. [purged]:

Your e-mail was forwarded to me for a response. You asked if a 1572 must be completed by clinical investigators for studies involving products other than investigational drugs (e.g., medical devices or a nutritional product).

No. Under the regulations, a 1572 is only required for studies of investigational drugs and biologics conducted under an IND. It is not required for studies that are not done under an IND, and is not applicable to investigational device studies. Sponsors of device studies, however, must obtain a signed agreement (containing information similar to that requested on the 1572) from each participating investigator, per 21 CFR 812.43(c).

There are no specific regulatory requirements for the conduct of studies involving nutritional supplements, and no requirement that clinical investigators sign a 1572 or similar agreement.

I will also forward your e-mail to the Center for Food Safety and Applied Nutrition (CFSAN) regarding the regulatory requirements for testing and manufacturing of infant formula, as CFSAN may have developed additional guidance on this issue.

If you wish to look at FDA's regulations for the conduct of clinical trials, there is a link on FDA's good clinical practice website at http://www.fda.gov/oc/gcp.

I hope this is helpful.

Sincerely,
Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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-----Original Message-----
From: [purged]
Sent: Wednesday, November 16, 2005 4:14 PM
To: gcpquestions@oc.fda.gov
Subject: Question regarding FDA 1572

Hello,

I am having some difficulty locating the guidelines for which trials require the filing of a form 1572. I know that investigational drugs require this form, but I am unable to locate information regarding device trials or nutritional products (i.e. formula, vitamins).

Could you possibly send me a link to this information? Thank you!

[purged]

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