From: Toth-Allen, Jean
Sent: Tuesday, August 01, 2006 10:53 AM
To: [purged]
Subject: Timeframe for study reports

Dear [purged]:

Your inquiry was forwarded to us from CDER DRUG information. Please excuse the previous message, it sent prematurely and so was incomplete.

FDA regulations governing the conduct of both pharmaceutical and device clinical studies require annual progress reports for studies done via an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE) respectively. These reports are required for drug studies at 21 CFR 312.33 and for device studies at 812.150(b)(5). Device regulations also specify the need for a final report (812.150(b)(7)) which, for drugs, was undoubtedly intended to be the annual report following the close of the study.

The ICH guidance document has been adopted by many countries besides the U.S. and so many of the areas covered in it are not specific but instead refer to what is required under applicable regulations. This is the case for study progress reports, which are discussed at 4.10.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
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: Tuesday, July 25, 2006 11:38 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Hello,
I have a question regarding the time frame for submitting Clinical Study Reports to the FDA. I can not find anything specifically stated in CFRs or in ICH E3. Can you give me guidance on this?
Thanks so much!
[purged]