From: Tech-Kles, Jean
Sent: Wednesday, August 09, 2006 11:20 AM
To: [snipped]
Subject: Clinical trial information

Dear [snipped]:

Your inquiry was forwarded to us for response.

Since your inquiry was originally made to CDER DRUG INFO, I am assuming your study involves a pharmaceutical product. Requirements for sharing information about clinical trials were included in the Food and Drug Administration Modernization Act (FDAMA) of 1997. The most recent guidance document available regarding these requirements is found at http://www.fda.gov/cder/guidance/4859FNL.PDF. This guidance notes that only information about effectiveness studies of pharmaceuticals intended to treat serious or life-threatening diseases or conditions are required to be submitted, though non-effectiveness studies and studies for products to treat conditions that are not serious or life-threatening may also be reported. This guidance provides the details about the information that needs to be provided as well as the timing for submitting such information. While the main purpose of this requirement was to provide information to the general public about on-going studies, as the guidance describes, the database will retain information about all studies entered, even after the completion of those studies. It also has provisions for providing links to articles in the published literature regarding trial outcomes. (See section IV. 3. for information on publications regarding outcomes.)

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 Tech-Kles, Ph.D.
Good Clinical Practices Program
OSRS, 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 judgement 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: Jack-jeether@pipsgroup.com [mailto:jack-jeether@pipsgroup.com]
Sent: Wednesday, August 09, 2006 12:19 PM
To: CDER DRUG INFO
Subject: Drugfacts Comment Form FDA/CDER Site

Name: [snipped]

E-Mail: [snipped]

Comments: To Whom it May Concern,

I understand that there are new guidelines and timeframes in which data
from clinical trials need to be posted or published. Can you please
provide me with some more information?

I need to know the timeframe, which types of trials it refers to (early
phase, Phase III, Phase IV, observational, etc.) and what exactly are
the parameters are (from from data lock to submission of data manuscript
or publication of manuscript).

Thank you very much for your time.

[snipped]