From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, April 30, 2003 8:36 AM
To: [redacted]
Subject: RE: Good Clinical Practices Traiining

Dear [redacted],

FDA does not offer Good Clinical Practices training, although we do co-sponsor and participate in conferences which may, in part, fulfill such a training requirement. I suggest that you go back to your IRB to determine the training they expect you to complete. If the IRB does not have specific suggestions, you should contact [redacted], in the [redacted]. I believe that [redacted] has developed specific training modules for this purpose. [redacted] email address is [redacted]. I hope this is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, HF-34, 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: [redacted]
Sent: Wednesday, April 23, 2003 4:32 PM
To: gcpquestions@oc.fda.gov
Cc: [redacted]
Subject: Good Clinical Practices Training
Importance: High

Dear Sir or Madam:

Our IRB at the [redacted] is requiring that we "complete Good Clinical Practices training". Does the FDA offer such training and if so how may we go about getting it? I would appreciate any assitance you could give with this question.

Sincerely,

[redacted]