From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, August 10, 2005 3:09 PM
To: [redacted]
Subject: RE: Question Concerning 21CFR11

Dear [redacted],

Please accept my apologies for the delay in this reply. I was on vacation and am just getting caught up with things.

There is no form that you need to complete when preparing the certification required by 21 CFR 11.100. You simply need to state in a letter addressed to the Office of Regional Operations that electronic signatures used in your system are intended to be the legally binding equivalent of traditional handwritten signatures.

If you have specific questions, you might want to contact the ORA's Division of Field Operations (the organization responsible for managing this certification program) by calling 301-827-5655.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857
Telephone: 301-827-3340

-----Original Message-----
From: [redacted]
Sent: Monday, July 25, 2005 9:31 AM
To: gcpquestions@oc.fda.gov
Subject: Question Concerning 21CFR11

Good Morning,

My question concerns section 11.100 of 21cfr11, specifically submitting the paper certifcation to the Office of Regional Operations. Is there a form to be filled out that must accompany this letter? What information must accompany this form to be certain it is processed correctly?

Thank you,

[redacted]