From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, February 24, 2005 9:43 AM
To: [redacted]
Subject: RE: Attention Pat Beersblock re: "mouse" signatures

Dear [redacted],

As we discussed yesterday, some key issues to keep in mind while considering the use of a software program that would permit the generation of a "handwritten" signature using a computer mouse (i.e., a free-lance, handwritten signature that is generated using features similar to "draw" features available in word processor and art-object software programs) include ensuring that features exist in the software that:

1) control user access. It would be especially important for each user to have an individual, password (or biometric) protected account that could only be accessed by th authorized user.

2) verify the authenticity of the "handwritten" (mouse-generated) signature.

I'm most interested in hearing about this technology. Please drop me a line, when you get the chance, after you learn more about this interesting technology.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

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, February 23, 2005 1:14 PM
To: 'gcpquestions@oc.fda.gov'
Subject: Attention Pat Beersblock re: "mouse" signatures

Hi Pat,

It was a pleasure speaking with you today regarding the "mouse" generated signature technology. [redacted]. I have no other information other than what we discussed. There isn't much on this [redacted], but it is a start. I look forward to discussing at length this technology with you and its applications for transmitting official documents used in clinical trials. Thank for your help and let me know what you think.

[redacted]

Regards,

[redacted]