

Question:

From: Mollie.Shields.Uehling@SAFE-BioPharma.org

Sent: Sunday, September 24, 2006 6:21 PM

To: CDER DRUG INFO

Subject: DrugInfo Comment Form FDA/CDER Site

Name: Mollie Shields Uehling, CEO, SAFE-BioPharma Association

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Comments: At the 2006 annual DIA meeting in Philadelphia, Mr. Mark Gray, Office of the CIO, made a statement regarding FDA acceptance of scanned facsimiles of documents containing handwritten signatures as part of an electronic submission across the FDA E-Submissions Gateway. Would you please clarify the Agency's policies and objectives regarding the use of scanned and/or digital signatures for electronic submissions?

Thank you.

Mollie Shields Uehling

Answer:

From: Gray, Mark

Sent: Wednesday, October 04, 2006 1:14 PM

To: CDER DRUG INFO

Subject: RE: DrugInfo Comment Form FDA/CDER Site

An overall PDUFA objective for the FDA and Industry is to increase the number of electronic submissions, to eliminate paper from the application receipt and review processes. A completely paperless application receipt and review process is supported by the implementation of regulatory compliant electronic signatures.

At the 2006 DIA Annual Meeting in Philadelphia, the FDA speaker acknowledged that the agency will accept scanned facsimiles of documents containing handwritten signatures as part of an electronic submission across the FDA Electronic Submissions Gateway. The purpose of allowing scanned signatures is to provide flexibility as companies' transition to digital signatures. Submissions with scanned handwritten signatures remain hybrid in nature; while they may be submitted electronically, they are not full electronic submissions because the submitting organization must still handle and maintain the paper originals of signed documents. An electronic submission that includes digital or electronic signatures allows the Sponsor and the FDA to eliminate paper and move to fully electronic records.

The FDA does not endorse any particular electronic signature solution. The Agency has, however, worked with the biopharmaceutical community over the past two and one-half years to help ensure that the Signatures and Authentication for Everyone (SAFE) Standard: 1) complies with appropriate guidance, especially as related to 21CFR11; and (2) when used as the basis for implementation of a digital signature capability, the SAFE standard facilitates user compliance with 21CFR11.

Thanks,

Mark Gray

Division of Drug Information

Center for Drug Evaluation and Research

Food and Drug Administration

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute and

advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.