

Memorandum of Meeting

Date: July 25, 2002

Site: 1350 Piccard Dr., Rockville, MD 20850

Firm: IMAGE-X,
E-Filing.Com, Inc.,
30 S. La Patera Lane,
Santa Barbara, CA 93117

Participants, IMAGE-X, E-Filing.Com, Inc.

Dr. Mohammed Shaikh, Chairman

Participants, FDA:

Charles A. Snipes, Ph.D., Compliance Officer, CDER, Div. of Scientific Investigations

Jonathan Cook, Operations Research Analyst, CDER, Office of Pharmaceutical Sciences

Tom M. Chin, CSO, ORA, Office of Enforcement

The meeting was convened at the request of IMAX/E-Filing.com to discuss the firm's approach to filing, storage, and access to electronic records through the internet.

Following introductions, Dr. Shaikh was advised that discussions at this meeting may not be construed as FDA endorsement of the design, the product, or use of the product complies with the regulations. Dr. Shaikh was asked to identify trade secret or confidential commercial information shared at this meeting that may be exempt from public disclosure under the Freedom of Information Act.

Dr. Shaikh reported that the system was developed to allow the filing of court documents via the internet. The enrolled filer logs in with user name password, fills out a template and submits the e-files. The filing may include forms, electronic attachments, and physical papers that can be transmitted to the repository via fax.

Documents are converted to Adobe Acrobat file format, and a copy of the set is accessed outside the firewall by the filer or authorized viewer. The firm customizes installation to suit the host. Dr. Shaikh stated that the firm would cooperate with any request for an audit of its system.

Dr. Shaikhe provided a copy of the firm's tri-fold descriptive pamphlet identifiable as "Internet Legal Document Filing." The pamphlet was scanned in Adobe Acrobat 4.0 for inclusion in the FDA dockets along with a copy of this memorandum of meeting.

Prepared by: Tom M. Chin

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FDA Attendees

Part 11 Dockets:

Validation 00D-1538

Glossary 00D-1543

Archiving 00D-1539

Time stamps 00D-1542

E-copies 00D-1540

Audit trails 00D-1541

HFC-230 (r/f, chron, File: Electronic Records-Electronic Signatures)

HFA-224

Draft: Tchin: Image-xMOM.doc 07/30/2002

Edit: Jcook: 07/30/2002

Final: Tchin: 07/30/2002

Handout saved as: Imagex.pdf

Image-xMOM.doc