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AdvaMed

Advanced Medical Technology Association

June 26, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Docket #00D-154: Draft Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps

Dear Sir/Madam:

On behalf of the AdvaMed Part 11 Issue Working Group, I am pleased to submit the enclosed comments on the FDA Draft *Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures*. AdvaMed, the Advanced Medical Technology Association, (formerly the Health Industry Manufacturers Association) represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the \$68 billion health care technology products consumed annually in the United States, and nearly 50 percent of \$159 billion purchased around the world annually. We are pleased to have had the opportunity to comment on this document.

To facilitate your review of our comment, we have also attached a copy of the draft guidance with embedded line numbers. We have used this document as the reference point for our comments.

We compliment the agency on the work done on this document. We believe that it removes some ambiguities that have lingered since the publication of the rule. Most of our attached comments, rather than being technical in nature, are aimed at improving the clarity of the document.

We do, however, have one general comment. We believe that the language in the document would be more effective if moved from the first person to a more formal mode. It might be helpful to review some other FDA guidance documents and to bring the style into closer agreement with them.

00D-1538

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June 26,, 2002

If you have any questions regarding these comments, please fell free to contact me directly at 202.434.7230 or bliebler@AdvaMed.org

Sincerely,

A handwritten signature in black ink, appearing to read 'Bernie Liebler', written in a cursive style.

Bernie Liebler
Director
Technology and Regulatory Affairs