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TO: Division of Dockets Management (HFA-305)
FROM: Paul B. Kurtz, Executive Director, CSIA
DATE: December 22, 2006
RE: RE: Docket No. 2006N-0464

On behalf of the members of the Cyber Security Industry Alliance (CSIA), I am submitting comments regarding Docket No. 2006N-0464, Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management. CSIA would like to speak specifically to ensuring the authenticity of transmitted documents through the use of trusted timestamp technology.

CSIA applauds the Food and Drug Administration (FDA) for taking steps over the past ten years to ensure a smooth transition to an electronic submission process. The FDA has taken great care to investigate the feasibility of the transition and the possible procedural concerns involved. The information transmitted often includes important product information promoting patient safety and new developments in medical technology. Providing a fast, convenient medium for all submissions is critical, but more important than the speed of submission is securing the content that is being transmitted.

In preparation for the upcoming hearing on electronic submission, the FDA asks in Question 1, "Transmission From Paper Submissions to Electronic Submissions," what are the major impediments to an all-electronic submission environment, and how can FDA address these impediments. CSIA believes the transition from paper records and documentation to electronic submission and storage presents the challenge of securing and verifying the documents. Trusted third-party time-stamping verifies the content and time integrity of the electronic document, proving it has never been tampered with over the course of the life of the document. We have submitted our fact sheet on data manipulation to provide background on the issue, as well as information on the benefits of timestamp technology.

With the ease, cost-savings, and speed at which information can be transmitted electronically, data and documents can easily be deleted, altered, or manipulated. In a sensitive environment such as premarket applications to the FDA, overseeing and controlling the life of a document is crucial. Other sectors, particularly the financial services sector, are taking measures to ensure secure and standardized methods are in place to verify when information is created, transmitted, or modified. International standards have been established that apply to trusted time-stamping, which ensures the validity of time-stamping. These standards are: the American National Standard X9.95-2005 Trusted Time Stamp Management and Security Standards (ANSI X9.95) and ISO/IEC 18014

As the FDA continues the transition to an all-electronic submission and storage system, CSIA strongly recommends the FDA to take into consideration the need to verify documents received and stored. Likewise, the FDA can encourage groups and individuals submitting information to use time-stamping to protect and maintain control of their works.

Please contact me if you have further questions about time stamping and data manipulation.

Thank you,

Paul B. Kurtz
Executive Director