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May 7, 2004

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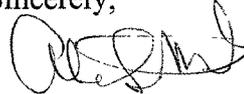
Re: Docket No. 2004N-0133 – 21 CFR Part 11 Electronic Records; Electronic Signatures

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to the Docket number 2004N-0133 requesting input on the Agency’s regulations on electronic records and electronic signatures in part 11 (21 CFR part 11).

AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

AHI commends the Agency for seeking public comment so that this rule can be re-evaluated for potential changes. We provide the following general and specific comments for your consideration prior.

Sincerely,



Alexander S. Mathews

Enclosure

2004N-0133

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Comment Form

				Date April 27, 2004	Document 21 CFR Part 11
Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
AHI		13	Delete "even if such records are not specifically identified in agency regulations"	In contradiction to recent guidance "Scope and Application"	
AHI		14	Delete "However, this part does not apply to paper records that are , or have been transmitted by electronic means."	Exceptions if they exist are best handled in guidance documents that may adapt to technological changes.	
AHI		70 & 87	Delete. The issue of	The issue of open and closed systems is confusing. Proper controls for systems when in place make this distinction irrelevant	
AHI		72	Digital Signature	Should be combined with definition of "Electronic Signature"	
AHI		75	Include distinction between data and documents	The requirements, and processes for data are different than those for documents. This distinction has significant impact on validation and audit trails.	
AHI	11.10	92	Delete	Part 11 Rule as stated is intended as a records rule. This (11.10) and Section 10.30 are focused on systems and applications. However, if retained the designation between "Open" and "Closed" systems should be eliminated. Security requirements for systems should be risk based, based on risk assessment, necessary access controls and security will be implemented to assure the authenticity, and integrity of the information.	
AHI	11.10a	100	Sentence ending "...and the ability to discern invalid or altered records" should be modified to read "...and the ability to discern invalid or altered data."	Systems that generate, record, analyse and maintain data should be validated to an appropriate level determined by risk and are identified in the predicate rule for that data. There are no predicate rule requirements for document management systems or their validation.	
AHI	11.10(a)	100	Delete	Not required, since this was a part of GXP requirements for many years before Part 11	
AHI	11.10e	110	Revise – Remove the requirement that the audit trail be computer generated from the rule. The audit trail requirement should be addressed in guidance.	The distinction between data and documents is critical to this concept. Data are distinct recordings of measurements, actions, results and as such once accurately recorded should not be changed and therefore audit trails are appropriate. Documents are assimilations of data and conclusion. Once a document is issued it is not altered but amended or superseded by another document. This process is tracked by version control, which is distinctly different than audit trails. The rule should not include a requirement that the audit trail be computer generated. The degree of audit trail should be risk-based and more clearly defined in guidance.	
AHI	11.10 f	116	Delete	This applies to a very limited class of applications/systems and is appropriately identified in the requirements for that system when appropriate.	
AHI	11.10g	118	Delete	This is redundant to 11.10d. It should be deleted entirely or combined with 11.10d	

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
AHI	11.10h	121	Delete	This applies to a very limited class of applications/systems and is appropriately identified in the requirements for that system when appropriate.
AHI	11.10k	129	Delete	Best handled in guidance.
AHI	11.10k 2	132	Delete	Best handled in guidance. Many systems that are either already in use or purchased off the shelf (COTS) do not provide the user the opportunity to develop documentation in strict sequence. It is more important that the documentation be developed.
AHI	11.30	136-144	Delete	This distinction has resulted in the unintended result that "open systems" are inherently bad and impeded the implementation of some areas of technology that might be interpreted as open
AHI	11.70	163-166	Delete	This discussion of electronic signature linking is confusing, especially as it related to the definition of electronic signature in Section 11.3.
AHI	11.100	168-190	Delete	Requirements for electronic signatures are best handled in guidance to retain consistence with other Federal requirements for electronic signatures and encourage development and implementation of technologies.
AHI	11.200	193-211	Delete	Requirements for electronic signatures are best handled in guidance to retain consistence with other Federal requirements for electronic signatures and encourage development and implementation of technologies.
AHI	11.300	214-237	Delete	Requirements for identification codes/passwords are best handled in guidance to retain consistence with other Federal requirements for electronic signatures and encourage development and implementation of technologies.
AHI	General			Legacy systems need to be addressed in the rule.