



DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

2177 '03 APR 25 A8:59

VIA FEDERAL EXPRESS

April 24, 2003

Dockets Management Branch (HFA-305)
Docket # 03D-0060
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: DuPont Comments/Draft Guidance for Industry Part 11, Docket No. 03D-0060

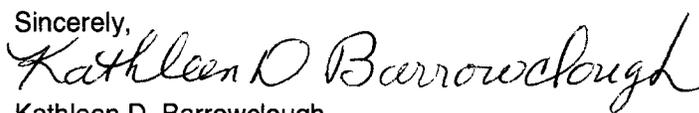
Dear Sir/Madam:

E. I. du Pont de Nemours and Company (DuPont) is pleased to comment on the Draft Guidance for Industry, Part 11, Electronic Records; Electronic Signatures - Scope and Application, as referenced in Vol. 68 No. 37, Federal Register (February 25, 2003) 8775-8776.

DuPont is a science company, delivering science-based solutions that make a difference in people's lives in food and nutrition; health care; apparel; home and construction; electronics; and transportation. Because DuPont has operations regulated by U.S. FDA, changes in scope and enforcement of 21 CFR Part 11 (Part 11) will directly impact DuPont.

DuPont welcomes the Agency's flexibility and re-examination of Part 11, as well as the proposed intention to narrowly interpret the scope of the Rule during this re-examination.

Enclosed with this letter is the summary and discussion that DuPont has respectfully submitted to Docket No. 03D-0060.

Sincerely,

Kathleen D. Barrowclough,
Quality Programs Manager
(302) 366-5344

03D-0060

C12

SUMMARY

DuPont appreciates the measures being taken by FDA to re-examine 21 CFR Part 11 (Part 11)¹ and the reasonable approach the Agency has expressed in interpreting a narrower scope of the Rule during re-examination.

While Part 11 has certainly played a role in improving practices associated with acquiring, implementing and managing electronic systems, there have been both technical and financial difficulties experienced by regulated industry, as they have struggled to achieve compliance.

In particular, there have been occasions where technology for achieving compliance with the audit trail requirements has not been available for the systems needed to conduct routine business. Additionally, rapid advances in technology have produced barriers to long-term archiving by making it financially burdensome to take advantage of new technology because of the huge cost involved in migrating data with meta data and retaining processing capability for archived data.

DuPont encourages FDA to use this re-examination of Part 11 as an opportunity to engage regulated facilities and other technical experts in an effort to achieve reliability and trustworthiness of electronic records without undue restriction of electronic technology or significantly increased costs of compliance to an extent that was not contemplated at the time the rule was drafted².

DISCUSSION

DuPont believes there are varying levels of security and system controls for electronic record-keeping systems based on the type of data being collected and maintained; the reason for keeping the data; the critical impact on health, health products and the environment; cost and quality benefits; and the acceptability of procedural controls in managing the data. DuPont, therefore, agrees with FDA's recommendation that a decision on whether to apply audit trails, or other appropriate measures, be based on the need to comply with predicate rule requirements, a justified and documented risk assessment, and a determination of the potential impact on product quality and safety and record integrity³.

DuPont agrees that a risk-based approach can be used in validation efforts as well. For example, FDA Good Laboratory Practice for Nonclinical Laboratory Studies (GLP)⁴ requires that data be archived and indexed to permit expedient retrieval. If the index were electronic, it would seem appropriate for a facility to use a risk-based approach in determining the extent of validation and need for audit trails. The ultimate goal in this case is to readily produce the data for FDA review or for other business purposes. If the data were consistently produced on request, the system would be considered GLP compliant.

DuPont commends FDA's recognition that while many documents are created electronically, some are legitimized only when the signed hard copy is executed. In such instances, DuPont believes the electronic tool used to create the executed paper document should not be within the

¹ FDA, 21 CFR Part 11, electronic Records; Electronic Signatures; Final Rule, Vol. 62, No. 54, 13430, 1997.

² FDA, Draft Guidance for Industry, Part 11, Electronic Records; Electronic Signatures - Scope and Application; Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide, Vol. 68 No. 37, Federal Register (February 25, 2003) 8776.

³ FDA, Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application (Draft Guidance), February 2003, Lines 227-230.

⁴ FDA GLP Regulations; Final Rule, 21 CFR Part 58, 33768, 1987.

scope of Part 11. DuPont includes draft reports and protocols in this category of documents. By following good records management practices, DuPont considers the final signed document to be the official document. Therefore, draft documents are destroyed when the final has issued.

In the case of SOPs, DuPont Haskell Laboratory currently has a hybrid system, one where the signed hard copy SOP is the official document, while the electronic PDF version is available for laboratory personnel to view. DuPont encourages FDA to continue along the lines expressed in the Draft Guidance, whereby hybrid systems will be acceptable.

Additionally, DuPont urges the Agency, when considering a more narrow scope of covered records, to consider excluding those electronic records that are merely transient views of data. For example, while data may be captured in a data collection system that has all the security and audit trail capabilities suitable for a data collection system, there may be situations where data is exported from that system to a less secure area (managed by applying risk-based controls) and used as input into a statistical program that also has security and audit trail capabilities. Any data inputs and exports from the statistical program can be traced back to the data in the original data collection system, thus assuring no data loss or transcription errors during the process.

The Agency intends to "exercise enforcement discretion"⁵ in applying Part 11 to legacy systems that were operational prior to August 1997. Please clarify whether this includes legacy systems that may have undergone upgrades since 1997.

It appears FDA recognizes that technology is not always available to provide the same processing capability to FDA in copies of records that is available within the system at the facility. If so, this recognition is welcome, as it will reduce unwarranted citations and allow facilities greater flexibility in conducting business. The additional implication that inspection, review and copying of records in a human readable form may be feasible on our site seems to take into account the fact that providing for that capability external to the facility is not always a reasonable expectation. DuPont appreciates this sensible approach to meeting inspectional needs.

Finally, DuPont commends the Agency for allowing archival of electronic records to non-electronic media such as microfilm, microfiche, and paper, or to a standard electronic file format, such as PDF. Long-term electronic archival has been one of the most problematic areas of Part 11, both from a technological and financial perspective.

⁵ FDA, Draft Guidance for Industry, Part 11, Electronic Records; Electronic Signatures - Scope and Application; Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide, Vol. 68 No. 37, Federal Register (February 25, 2003) 8775.