

FDA COMPLIANCE CORNER

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This column provides a concise update each quarter on computer validation subject matter. The goal of this column is to provide valuable information to Software Division members employed in FDA-regulated industries such as medical devices, laboratories, clinical research and development, and manufacturing of food, drugs, and cosmetics.

On September 17, 2004, a citizen's petition was delivered to the U.S. Food and Drug Administration. The petition requests that the FDA revoke 21 CFR Part 11 in its entirety.

Furthermore, it urges FDA to "pursue implementation of electronic record and signature systems through the application of Government Paperwork Elimination Act ("GPEA") standards and the enforcement of predicate rules."

The 16-page formal petition was submitted by the Industry Coalition on 21 CFR Part 11:

http://www.chpa-info.org/web/advocacy/submissions/09_17_04_Coalition_Cit_Petition.pdf

The coalition believes that recently passed Federal laws should be used to support this rather than the prescriptive regulation.

Great Sites:

FDA Center for Radiological Health Searchable Recognized Consensus Standards:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

NIST Information Technology Laboratory, Computer Security stuff:

<http://www.itl.nist.gov/>

Validation of computers, methods and data in analytical laboratories:

<http://www.labcompliance.com/index.htm>

Please send me more great stuff to share in this column: walkercsqe@juno.com