DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1540]

Withdrawal of Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records.''

DATES: [*Insert date of publication in the* **Federal Register**.]

FOR FURTHER INFORMATION CONTACT: Randall L. Woods, Center for Drug Evaluation and Research (HFD–324), Food and Drug Administration, Metro Park North I, 7520 Standish Pl., rm. 265, Rockville, MD 20855, 301–827–0065.

SUPPLEMENTARY INFORMATION:

I. Background

On August 21, 2002, FDA announced that it was undertaking a new initiative to enhance FDA's current good manufacturing practice program (the CGMP initiative). This new initiative will focus FDA's resources and regulatory attention on those aspects of manufacturing that pose the greatest risk, ensure that FDA's work does not impede innovation, and enhance the consistency of FDA's regulatory approach among the various components. More

information on FDA's announcement of this new initiative can be found on FDA's Web site at www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html, or a copy of the press release (Ref. 1) may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please reference the docket number found in brackets in the heading of this document.

Under the new initiative, primary responsibility for implementing part 11 (21 CFR Part 11); Electronic Records; Electronic Signatures has shifted to the Center for Drug Evaluation and Research, with continued involvement from other Centers and the Office of Regulatory Affairs.

On November 12, 2002 (67 FR 68674), the agency issued a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records.'' The agency wishes to limit the time spent by industry reviewing and commenting on the guidance, which may no longer represent FDA's approach under the CGMP initiative. The agency may decide to reissue the draft guidance once it has reviewed it under the CGMP initiative.

II. Reference

The following reference is on display at the Dockets Management Branch (see section I of this document) and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration press release, ‘‘FDA Unveils New Initiative To Enhance Pharmaceutical Good Manufacturing Practices,’’ August 21, 2002.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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