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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

[Docket No. 00D–1540]

Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records." This draft guidance describes the agency's current thinking on issues pertaining to furnishing FDA with electronic copies of electronic records that are subject to part 11. Part 11 requires persons to employ procedures and controls for records subject to part 11 that include the ability to generate electronic copies of electronic records that are accurate, complete, and suitable for FDA inspection, review, and copying. This requirement helps ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Information and Quality Assurance (HFC–240),

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Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive labels to assist that office in processing your requests.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Motise, Office of Enforcement (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0383, e-mail: pmotise@ora.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records." In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper ("part 11"). The preamble to part 11 (21 CFR part 11) stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance addresses issues pertaining to providing FDA with electronic copies of electronic records subject to part 11 that are accurate,

complete, and suitable for FDA inspection, review, and copying. Part 11 requires persons to be able to furnish FDA with electronic copies of electronic records that are subject to part 11. This draft guidance is intended to assist people who must meet this requirement; it may also assist FDA staff who apply part 11 to persons subject to the regulation. However, this draft guidance is not intended to address issues related to electronic records that are submitted to FDA but that are not required to be maintained.

The draft guidance provides specific information on key principles and practices on electronic copies of electronic records, and it addresses some frequently asked questions. However, it is not intended to cover every aspect of generating electronic copies of electronic records that are accurate, complete, and suitable for FDA inspection, review and copying.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on providing FDA with electronic copies of electronic records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any nonelectronic comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance

and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ohrms/dockets/dockets/dockets.htm.

Dated: 10/28/02

October 28, 2002.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

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