appropriately evaluated, (c) designing an OBCQI approach to improve quality in a systematic, evolutionary manner, and (d) testing the usefulness of the data items for assessment and care planning. A three-phase field test will result in the refinement of the draft COCOA data items and protocols as needed. Findings from the project are intended to guide the possible implementation of a national approach for OBCQI and core comprehensive assessment for PACE.

Frequency: On Occasion.

Affected Public: Not-for-profit institutions and individuals or households.

Number of Respondents: 8,298.

Total Annual Responses: 90,070.

Total Annual Hours: 22,503.77.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 12, 2002.

John P. Burke, III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 02–6756 Filed 3–19–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1542]

Draft Guidance for Industry on Electronic Records; Electronic Signatures, Time Stamps; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps.'' The draft guidance describes the agency's current thinking on issues pertaining to the use of computer generated time stamps in computer systems subject to part 11 (21 CFR part 11) requirements, to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities. The use of the computer generated time stamps is a requirement of part 11 of title 21 of the Code of Federal Regulations.

DATES: Submit written or electronic comments on the draft guidance by June 18, 2002. 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), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label 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, rm. 1060, 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, Time Stamps.'' 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 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents.

The draft guidance addresses issues pertaining to computer generated time stamps in computer systems used to create, modify, maintain, archive, retrieve, or transmit electronic records and electronic signatures subject to part 11. Part 11 requires persons subject to the regulation to implement time stamps in audit trails and signature manifestations, and the 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.

The draft guidance provides specific information on key principles and practices, and it addresses some frequently asked questions. However, it is not intended to cover every aspect of time stamps.

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 computer generated time stamps used in computer systems subject to part 11. 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 (address above) written or electronic comments on the draft guidance. Two copies of any 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/ora/compliance_ref/Part11/default.htm.

Dated: March 12, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–6623 Filed 3–19–02; 8:45 am]

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