For scientific/research issues, contact: Susan Chu, PhD, MSPH, Extramural Program Official, National Immunization Program, Centers for Disease Control and Prevention, National Immunization Program, MS E–05, 1600 Clifton Road NE, Atlanta, GA 30333. Telephone: 404–639–8727. E-mail: *SChu@cdc.gov.*

For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72. Telephone: 404–371–5277. Fax: 404–371–5215. E-mail: *MLerchen@cdc.gov.*

For financial, grants management, or budget assistance, contact: Yolanda Ingram-Sledge, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2787. E-mail: *Ysledge@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: May 5, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–9371 Filed 5–10–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0045]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 10, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Records; Electronic Signatures—(21 CFR Part 11) (OMB Control Number 0910–0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records; electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated our ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures (SOPs) to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) Section 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) section 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) section 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) section 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provisions (§ 11.100) require persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of SOPs, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents are businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

In the **Federal Register** of February 7, 2005 (70 FR 6447), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
11.10	2,500	1	2,500	20	45,000
11.30	2,500	1	2,500	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9370 Filed 5–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0021]

International Conference on Harmonisation; Draft Guidance on Q8 Pharmaceutical Development; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 11, 2005, the comment period for the notice, published in the **Federal Register** of February 9, 2005 (70 FR 6888). In the notice, FDA announced the availability of a draft guidance entitled ''Q8 Pharmaceutical Development.'' FDA is reopening the comment period to provide additional time for public comment consistent with the time for comment provided by other ICH regulatory entities.

DATES: Submit written or electronic comments on the draft guidance by June 11, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Ajaz Hussain, Center for Drug Evaluation and Research (HFD–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2847; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 9, 2004 (70 FR 6888), FDA announced the availability of a draft guidance entitled ''Q8 Pharmaceutical Development,'' prepared under the auspices of the ICH. The draft guidance provides recommendations to sponsors concerning pharmaceutical studies as defined in section 3.2.P.2 of module 3 of the Common Technical Document (CTD).

Interested persons were given until April 11, 2005, to submit comments on the draft guidance.

FDA has decided to reopen the comment period on the draft guidance until June 11, 2005, to allow the public additional time to review and comment on the contents and to be consistent with the time for comment provided by other ICH regulatory entities.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9369 Filed 5–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: April 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of April 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is