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International Conference on Harmonisation; Draft Guidance on Q8 Pharmaceutical Development; Availability; Reopening of Comment Period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 In the notice, FDA announced the availability of a draft guidance entitled ''Q8 Pharmaceutical Development.''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DATES: Submit written or electronic comments on the draft guidance by June 11, 2005.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ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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