= 200). FDA estimates that cost of developing standard operating procedures for each data collection is $350 (10 hours of work at $35/hour). This results in a total cost to industry of $3,500 ($350 x 10 respondents).

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7708 Filed 5–19–06; 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; Guidance on Q8 Pharmaceutical Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q8 Pharmaceutical Development.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes the suggested contents for the pharmaceutical development section of a regulatory submission in the ICH M4 Common Technical Document (CTD) format. The guidance also indicates areas where the provision of greater understanding of pharmaceutical and manufacturing sciences can create a basis for flexible regulatory approaches.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written comments on the 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 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Moheb Nasr, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, Bldg. 21, rm. 2630, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1900; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), 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 recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research; FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 9, 2005 (70 FR 6888), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q8: Pharmaceutical Development.'' The notice gave interested persons an opportunity to submit comments by April 11, 2005. To provide additional time for public comment consistent with the time for comment provided by other ICH regulatory agencies, FDA reopened the comment period until June 11, 2005 (70 FR 24819, May 11, 2005).

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2005.

The guidance describes the suggested contents for the pharmaceutical development section (section 3.2.P.2) of a regulatory submission in the CTD format for drug products as defined in the scope of module 3 of the CTD. The information and knowledge gained from pharmaceutical development studies provide scientific understanding to support the establishment of specifications and manufacturing controls. The guidance also indicates areas where the provision of greater understanding of pharmaceutical and manufacturing sciences can create a basis for flexible regulatory approaches.

This guidance applies to pharmaceutical studies as defined in section 3.2.P.2 of module 3 of the CTD. The guidance does not apply to submissions for drug products during the clinical research stages. However, the principles described in the guidance are important to consider during product development.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen 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 document 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 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7727 Filed 5–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information ; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques of other forms of information technology.

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB No. 0915–0174)—Extension

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under section 621 of Title VI and section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the Section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to capital through the assumption of the mortgage credit risk by the Federal Government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are insured under these programs. The information is used to monitor the financial stability of the hospitals to protect the Federal investment in these facilities. The form used for the data collection is the Hospital Facility Data Abstract. No changes in the form are proposed.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Hospital Facility Data Abstract	80	1	1	80

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received with 60 days of this notice.

Dated: May 16, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–7726 Filed 5–19–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Bureau Of Customs And Border Protection

Notice of Cancellation of Customs Broker License Due to Death of the License Holder

AGENCY: Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General notice.

SUMMARY: Notice is hereby given that, pursuant to Title 19 of the Code of Federal Regulations 111.51(a), the following individual Customs broker licenses and any and all permits have been cancelled due to the death of the broker:

Name;	License #	*Port Name*
Peter Gawi	10645	New York.
Kirk K. Lakis	6361	Dallas.
George J. Young	02612	Los Angeles.
Daniel J. Hayes, Sr.	3758	Los Angeles.
James J. Rea	5498	New York.
Eugenio D. Santana	6864	New York.
Dennis Nowakowski	20659	Buffalo.