pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, The Superfund Amendments and Reauthorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment. The primary purpose of this activity, which ATSDR has supported since 1992, is to develop, implement, and maintain a state-based surveillance system for hazardous substances emergency events which can be used to (1) describe the distribution of the hazardous substances releases; (2) describe the public health consequences (morbidity, mortality, and evacuations) associated with the events; (3) develop strategies to reduce future public health consequences. The study population will consist of all hazardous substance non permitted acute releases within the 14 states (Colorado, Florida, Iowa, Louisiana, Michigan, Minnesota, New Jersey, New York, North Carolina, Oregon, Texas, Utah, Washington, and Wisconsin) participating in the surveillance system.

Until this system was developed and implemented, there was no national public health-based surveillance system to coordinate the collation, analysis, and distribution of hazardous substances emergency release data to public health practitioners. It was necessary to establish this national surveillance system which describes the public health impact of hazardous substances emergencies on the health of the population of the United States. The data collection form will be completed by the state health department Hazardous Substances Emergency Events Surveillance (HSEES) coordinator using a variety of sources including written and oral reports from environmental protection agencies, police, firefighters, emergency response personnel; or researched by the HSEES coordinator using material safety data sheets, and chemical handbooks. There is a reduction in the annual burden hours per response because of the reduction in number of states from 15 to 14 and because of a change in the case definition of an HSEES event in 2005, which excludes stack emissions of oxides of nitrogen (NO_X), oxides of sulfur (SOx), and carbon monoxide (CO) when they are not mixed with another hazardous substance.

The HSEES public use data set is available on the ATSDR HSEES Web site. Interested parties complete a brief description of who will be using the data and for what purpose in order to download the data. This allows ATSDR to widely distribute the data and track its usefulness.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Participating State Health Department HSEES Coordinators	14	536	45/60	5,628
Persons interested in HSEES data through Web site	500	1	6/60	50
Total	514			5,678

Dated: January 4, 2008.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–270 Filed 1–9–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0493]

International Conference on Harmonisation; Draft Guidance on Q8(R1) Pharmaceutical Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q8(R1) Pharmaceutical Development Revision 1.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance is an annex to the parent ICH guidance entitled ''Q8 Pharmaceutical Development'' (71 FR 29344, May 22, 2006) (ICH Q8). It provides further clarification of key concepts outlined in ICH Q8 and describes the principles of quality by design (QbD). The draft guidance is intended to show how concepts and tools (e.g., design space) outlined in ICH Q8 could be put into practice by the applicant for all dosage forms.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 9, 2008.

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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. 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. The draft 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance and other guidances mentioned in this document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance*: Moheb Nasr, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 21, rm. 2630, 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 20852–1448, 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 IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In November 2007, the ICH steering committee agreed that a draft guidance entitled ''Q8(R1) Pharmaceutical Development Revision 1'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft guidance is an annex to the parent guidance ICH Q8. It provides further clarification of key concepts outlined in ICH Q8 and describes the principles of QbD. The annex is not intended to establish new standards or increase regulatory expectations. It is intended to show how concepts and tools (e.g., design space) outlined in ICH Q8 could be put into practice by the applicant for all dosage forms. Where a company chooses to apply QbD and quality risk management (see ICH ''Q9 Quality Risk Management''), linked to an appropriate pharmaceutical quality system (see ICH ''Q10 Pharmaceutical Quality Systems''), then opportunities arise to enhance science- and risk-based regulatory approaches.

The draft guidance outlines the elements that should be included in pharmaceutical development and additional elements when QbD principles are applied. It elaborates, by means of description and example, possible approaches to gaining a more systematic, enhanced understanding of the product and process under development. The draft guidance also provides recommendations on the placement of pharmaceutical development and other related information in module 3 of a regulatory submission in the common technical document format.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft guidance. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

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: January 2, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–213 Filed 1–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2007–29070]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number 1625–0108

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) requesting an extension of their approval for the following collection of information: 1625–0108, Standard Numbering System for Undocumented Vessels. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before February 11, 2008.

ADDRESSES: To make sure your comments and related material do not enter the Coast Guard docket [USCG–2007–29070] or are received by OIRA more than once, please submit them by only one of the following means:

(1) *Electronic submission.* (a) To Coast Guard docket at *http://www.regulations.gov*. (b) To OIRA by e-mail to: *nlesser@omb.eop.gov*.