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 (NOx), 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

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

Dated: January 4, 2008.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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

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/comments 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 guidelines 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,
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). This draft will be considered by FDA and the Quality Expert Working Group.