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 or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Survey of Residential Care Facilities (NSRCF), (OMB No. 0920–0780)—Revision— National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, ''shall collect statistics on health resources * * * [and] utilization of health care, including extended care facilities, and other institutions.''

In 2008, NCHS sought approval for a pretest and full survey of The National Survey of Residential Care Facilities (NSRCF). OMB approved only the pretest which has been completed. NCHS now seeks approval to collect the full survey. The survey is designed to complement data collected by other federal surveys and to fill a significant data gap about a major portion of the long-term care population. Data from NSRCF will provide information on residential care facilities that policymakers, providers, and researchers can use to address a wide array of policy and research questions. The survey will utilize a computer-assisted personal interviewing (CAPI) system to collect information about facility and resident characteristics. This computerized system speeds the flow of data and makes it possible to release information on a timelier basis and easier for respondents to participate in the survey. The CAPI system may also enhance data quality. Clearance for two years is requested.

A stratified random sample of residential care facilities across four strata (small, medium, large and very large) will be selected to participate in NSRCF. Within each facility a random sample of residents will be selected. To be eligible a facility must be licensed, registered, listed, certified, or otherwise regulated by the State; provide room and board with at least two meals a day; provide around-the-clock on-site supervision; help with activities of daily living (*e.g.,* bathing, eating, or dressing) or medication supervision; serve primarily an adult population; and have at least four beds.

The facility questionnaire will collect data about facility characteristics (*e.g.,* size, age, types of rooms), services offered, characteristics of the resident population, facility policies and services, charges for services, and background of the director. The resident questionnaire collects information on resident demographics, current living arrangements within the facility, involvement in activities, use of services, charges for care, health status, and cognitive and physical functioning. For the national survey, approximately 2,250 facilities will be surveyed for an annual average of 1,125 facilities. Information on an average of 4 residents will be collected from an annual average of 1,125 facility staff. Residents themselves will not be interviewed.

Users of NSRCF data include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation and the Agency for Healthcare Research and Quality; and associations, such as the American Association of Homes and Services for the Aging, National Center for Assisted Living, American Seniors Housing Association, Assisted Living Federation of America; universities; foundations; and other private sector organizations. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Name of form	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Response burden in hours
Facility Director	Facility Screener	1125	1	10/60	188
Facility Director	Resident Selection	1125	1	10/60	188
Facility Director	Pre-Interview Worksheet	1125	1	15/60	281
Facility Director	Facility Questionnaire	1125	1	1.25	1,406
Facility Director or Staff Member	Resident Questionnaire	1125	4	20/60	1,500
Total					3,563

Dated: June 3, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–13409 Filed 6–8–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0148] (formerly Docket No. 2007D–0493)

International Conference on Harmonisation; Guidance on Q8(R1) Pharmaceutical Development; Addition of Annex; 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(R1) 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 ICH Q8(R1) guidance includes the previously published parent guidance entitled ''Q8 Pharmaceutical Development'' (Q8 parent guidance) (71 FR 29344; May 22, 2006) and a newly added annex. The annex provides

further clarification of key concepts outlined in the Q8 parent guidance and describes the principles of quality by design (QbD). The annex is intended to show how concepts and tools (e.g., design space) outlined in the Q8 parent guidance could be put into practice by the applicant for all dosage forms.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, 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. 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.regulations.gov*. 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, 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–25), Food and Drug Administration, 1401 Rockville Pike, suite 200, Rockville, MD 20852–1448, 301–827–0373.

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 January 10, 2008 (73 FR 1890), FDA published a notice announcing the availability of a draft guidance entitled ''Q8(R1) Pharmaceutical Development Revision 1.'' The notice gave interested persons an opportunity to submit comments by April 9, 2008.

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 2008. Revisions were made in response to comments received by the three ICH regions to better express the original intent of the draft.

The annex added to the Q8 parent guidance provides further clarification of key concepts outlined in the Q8 parent guidance 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 the Q8 parent guidance could be put into practice by the applicant for all dosage forms. Following the addition of the annex to the Q8 parent guidance, ICH recoded the parent guidance Q8(R1).

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 comments on the 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*, *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: May 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–13374 Filed 6–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration