ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
EMS Professionals	Online survey	1,500	1	15/60
	Screening/Recruitment for Focus Groups	64	1	5/60
	Focus Groups	32	1	1

Dated: December 4, 2009.

Maryam Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–29435 Filed 12–9–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–0008]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Emergency Epidemic Investigations (0920–0008)—Extension—Office of Workforce and Career Development (OWCD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

One of the objectives of CDC's epidemic services is to provide for the prevention and control of epidemics, and protect the population from public health crises such as human-made or natural biological disasters and chemical emergencies. CDC meets this objective, in part, by training investigators, maintaining laboratory capabilities for identifying potential problems, collecting and analyzing data, and recommending appropriate actions to protect the public's health. When state, local, or foreign health authorities request help in controlling an epidemic or solving other health problems, CDC dispatches skilled epidemiologists from the Epidemic Intelligence Service (EIS) to investigate and resolve the problem. Resolving public health problems rapidly ensures cost-effective health care and enhances health promotion and disease prevention.

The purpose of the Emergency Epidemic Investigations data collection project is to collect data on the conditions surrounding and preceding the onset of a problem. The data must be collected in a timely fashion so that information can be used to develop prevention and control techniques, to interrupt disease transmission and to help identify the cause of an outbreak. Since the events necessitating the collections of information are of an emergency nature, most data collection is done by direct interview or written questionnaire and are one-time efforts related to a specific outbreak or circumstance. If during the emergency investigation, the need for further study is recognized, a project is designed and separate OMB clearance is required. Interviews are conducted to be as unobtrusive as possible and only the minimal information necessary is collected. The Emergency Epidemic Investigations data collection project is the principal source of data on outbreaks of infectious and noninfectious diseases, injuries, nutrition, environmental health, and occupational problems.

Each investigation contributes to the general knowledge about a particular type of problem or emergency, so that data collections are designed taking into account knowledge gained during similar situations in the past. Some questionnaires have been standardized, such as investigations of outbreaks aboard aircraft or cruise vessels.

The Emergency Epidemic Investigations data collection project provides a range of data on the characteristics of outbreaks and those affected by outbreaks. Data collected include demographic characteristics of the affected population, exposure to the causative agent(s), transmission patterns, and severity of the outbreak. These data, together with trend data, may be used to monitor the effects of change in the health care system, plan health services, improve the availability of medical services, and assess the health status of the population.

Users of the Emergency Epidemic Investigations data include, but are not limited to, Epidemic Intelligence Service (EIS) officers of the CDC, who investigate the patterns of disease or injury, the level of risky behaviors, causative agents, the transmission of the condition, and the impact of interventions. EIS is a two-year program of training and service in applied epidemiology through CDC, primarily for persons holding doctoral degrees.

There is no cost to the respondents other than their time for participation. Predicting the number of epidemic investigations that might occur in any given year is difficult. The previous three years' experience shows an annualized burden of 3,750 hours and respondent total of 15,000. Therefore, for this clearance, the annualized burden hours are estimated to be 3,750.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General public	Emergency Epidemic Investigations	15,000	1	15/60
State and local officials	Emergency Epidemic Investigations	100	1	15/60

Dated: December 3, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0025] (formerly Docket No. 1998D–0266)

Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''PET Drugs—Current Good Manufacturing Practice (CGMP).'' Elsewhere in this issue of the **Federal Register**, we are issuing final regulations on CGMPs for positron emission tomography (PET) drugs. We are issuing the guidance to help PET drug producers better understand FDA's thinking concerning compliance with the PET CGMP regulations.

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

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that 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: Brenda Uratani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–240–328–7621, e-mail: *Brenda.Uratani@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Public Law 105–115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of the drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

In accordance with section 121 of the Modernization Act, we have taken the following actions in developing the regulations on CGMP for PET drugs:

- *Regulations*. We made available preliminary draft regulations (64 FR 51274, September 22, 1999), and a preliminary draft proposed rule (67 FR 15344, April 1, 2002), and published a proposed rule on PET drug CGMP (70 FR 55038, September 20, 2005).
- *Public Meetings*. We held public meetings on February 19, 1999, September 28, 1999, and May 21, 2002, to discuss our tentative approach, preliminary draft regulations, and preliminary draft proposed rule. We responded to numerous questions and comments and made changes in our preliminary draft regulations and proposed rule in response to written and oral comments.
- *Guidance*. When we published the preliminary draft proposed rule, we published a draft guidance on CGMP for PET drugs (67 FR 15404, April 1, 2002). With the proposed rule, we published a revised draft guidance (70 FR 55145, September 20, 2005).

Elsewhere in this issue of the **Federal Register**, we are publishing a final rule on CGMP for PET drugs. We are making this guidance available so that PET drug producers can better understand our thinking on compliance with the PET CGMP regulations, including appropriate resources, procedures, and documentation for PET drug production facilities.

II. The Guidance

The guidance entitled ''PET Drugs—Current Good Manufacturing Practice (CGMP)'' provides recommended approaches for complying with the regulations on CGMP for PET drugs. In preparing the guidance, we considered all comments received on the revised draft guidance of the same name. The guidance includes revisions to coincide with the final rule on PET CGMP and clarifications in response to comments on the revised draft guidance.

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 compliance with CGMP for PET drugs. 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.

III. 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 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.

IV. Paperwork Reduction Act of 1995

The information collection resulting from this guidance is covered by the information collection provisions of the final rule entitled ''Current Good Manufacturing Practice for Positron Emission Tomography Drugs'' which is published elsewhere in this issue of the **Federal Register**. The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/*