Number of Respondents: 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 100,000. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways November 17, 2009:

1. *Electronically*. You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 11, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–22561 Filed 9–17–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Division of Extramural Research and Training; Submission for OMB Review; Comment Request; Hazardous Waste Worker Training—42 CFR Part 65

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 14, 2009, pages 17195–17196, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995 unless it displays a currently valid OMB control number.

Proposed Collection: Title: Hazardous Waste Worker Training—42 CFR Part 65. *Type of Information Collection Request:* Revision of OMB No. 0925–0348, expiration date September 30, 2009. *Need and Use of Information Collection:* This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) has been given major responsibility for initiating a worker safety and health training program under Section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In twenty-one years (FY 1987–2008), the NIEHS Worker Training program has successfully supported 20 primary grantees that have trained more than 2.2 million workers across the country and presented over 130,250 classroom and hands-on training courses, which have accounted for nearly 30 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4(a), (b), (c) and 65.6(b) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources, including budget and curriculum, and response to meeting training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to provide their information in hard copy as well as enter information into the WETP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards. *Frequency of Response:* Biannual. *Affected Public:* Non-profit organizations. *Type of Respondents:* Grantees. The annual reporting burden is as follows*: Estimated Number of Respondents:* 18; *Estimated Number of Responses per Respondent:* 2; *Average Burden Hours Per Response:* 14; and *Estimated Total Annual Burden Hours Requested:* 504. The annualized cost to respondents is estimated at: $16,380. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Joseph T. Hughes, Jr., Director, Worker Education and Training Program, Division of Extramural Research and

Training, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–0217 or E-mail your request, including your address to *wetp@niehs.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: September 9, 2009.

Christopher W. Long,

NIEHS Deputy Associate Director for Management.

[FR Doc. E9–22567 Filed 9–17–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: This is a Notice of Availability and request for comments on a draft Agency Guidance (''Policy Information Notices'' (PINs)) to convey and clarify statutory and regulatory governance requirements for federally-funded health centers and Federally Qualified Health Center (FQHC) Look-Alikes. The PIN, ''Health Center Governance Requirements and Expectations'' is available on the Internet at http://bphc.hrsa.gov/draftsforcomment/governance/draftgovernancepin.htm.

DATES: Comments must be received by October 26, 2009.

ADDRESSES: Comments should be submitted to <*OPPDGeneral@hrsa.gov*> by close of business October 26, 2009.

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PIN referenced above. Comments will be reviewed and analyzed, and a summary and general response will be published as soon as possible after the deadline for receipt of comments.

Background: HRSA administers the Health Center Program, which supports more than 7,500 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve medically underserved communities, delivering preventive and primary care services to patients regardless of their ability to pay. The purpose of the recently published draft PIN is (a) To convey and clarify HRSA's policy regarding Health Center Program statutory and regulatory governance requirements for all Health Center Program grantees (*e.g.,* health centers funded under section 330(e), (g), (h) and (i) of the Public Health Service (PHS) Act, as amended) and FQHC Look-Alikes (per section 1905(l)(2)(B) and section 1861(aa)(4) of the Social Security Act.); (b) provide clarification regarding board requirements for public centers under co-applicant arrangements, including public centers funded or designated solely under sections 330(g), 330(h) and/or 330(i) of the PHS Act, as amended to serve special populations; and (c) outline the eligibility and qualifying expectations for HRSA approval of a governance waiver for the fifty-one percent consumer/patient majority governance requirement for eligible section 330 grantees and FQHC Look-Alikes. The PIN eliminates the monthly meeting requirement from waiver consideration.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301–594–4300.

Dated: September 11, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–22444 Filed 9–17–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0427]

Draft Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines'' dated September 2009. The draft guidance document provides recommendations to sponsors who wish to submit an Investigational New Drug application (IND) for a therapeutic cancer vaccine on critical clinical considerations for investigational studies of these products. The draft guidance applies to therapeutic cancer vaccines that are intended to be administered to patients with an existing cancer for the purpose of treatment. The draft guidance does not apply to products intended to be administered to patients to prevent or decrease the incidence of cancer and does not apply to adoptive immunotherapeutic products such as T cell or NK cell products.

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 December 17, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to 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. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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 *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines'' dated September 2009. The draft guidance document provides recommendations to sponsors who wish to submit an IND for a therapeutic cancer vaccine on critical clinical considerations for early and late phase investigational studies intended to support a biologics license application. Development of a therapeutic cancer vaccine can present different considerations for clinical trial design than development of a traditional cytotoxic drug or biological product, due to differences in the proposed