ACTION: Notice of Non-competitive Replacement Award.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing a temporary non-competitive replacement award to the National Jewish Hospital and Research Center to avoid disruption and continue outreach, medical screening and referral services to former uranium mine workers and individuals in the states of Colorado, Wyoming and portions of Southeastern Utah exposed to radioactive fallout during prior testing of nuclear weapons.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: National Jewish Hospital and Research Center in Denver, Colorado.

Amount of the Award: $120,106.00 (an 8-month supplement, January 1, 2009, through August 31, 2009) to ensure ongoing services to the target populations.

Project Period: The period of supplemental support is from January 1, 2009, to August 31, 2009.

Authority: This activity is under the authority of the Public Health Service Act, Section 417C of Public Law 106–245.

Catalogue of Federal Domestic Assistance Number: 93.257

Justication for the Exception to Competition: Critical funding for outreach, medical screening and referral services to the target populations in Colorado, Wyoming and portions of Southeastern Utah will be continued through a temporary, non-competitive replacement award to the National Jewish Hospital and Research Center (NJHRC) as the new recipient. This temporary award is needed because the former grantee, St. Mary's Hospital and Medical Center, relinquished, effective December 31, 2008, the original award (project period September 1, 2008, through August 31, 2011). NJHRC, nationally known as the ''Center for Research and Treatment of Respiratory Conditions,'' is uniquely qualified to provide screening and diagnosis of occupationally related radiogenic diseases for the target populations. NJHRC has administered the HRSA-funded Black Lung Clinic Program (BLCP) grant for the past five years and is well suited to undertake operations of the Radiation Exposure Screening and Education Program under the previously approved scope of project. Additionally, this organization has a thorough understanding of the characteristics and needs of miners (both current and retired) as well as other workers at risk for occupational diseases. HRSA's Office of Rural Health Policy is not aware of any other organization that could provide such treatment and services to the impacted service populations without additional time and resources being devoted to bringing that organization's service capacity up to the level needed under the project scope of this award.

This temporary non-competitive replacement award will permit the new recipient to ensure continuity of services to the affected populations. The supplemental funding will provide support for 8 months. Further funding beyond August 31, 2009, for this service area will be provided through a limited service area competition to be announced in the near future.

FOR FURTHER INFORMATION CONTACT: Tom Morris, Associate Administrator, Office of Rural Health Policy, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857; phone 301–443–0835; *tmorris@hrsa.hhs.gov*.

Dated: April 9, 2009.

Marcia K. Brand,

Deputy Administrator.

[FR Doc. E9–8442 Filed 4–13–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences, Division of Extramural Research and Training; Proposed Collection; Comment Request Hazardous Waste Worker Training

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Hazardous Waste Worker Training—42 CFR part 65. *Type of Information Collection Request:* Revision of OMB No. 0925–0348 and 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) was 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(a) 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 should

address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

FOR FURTHER INFORMATION CONTACT: 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 Branch, 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 60-days of the date of this publication.

Dated: April 2, 2009.

Marc S. Hollander,

NIEHS Associate Director for Management.

[FR Doc. E9–8472 Filed 4–13–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–P–0250] (formerly Docket No. 2007P–0341)

Determination That ZOMETA (Zoledronic Acid for Injection), Equivalent to 4 Milligrams Base Per Vial, Lyophilized Powder for Injection, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ZOMETA (zoledronic acid for injection), equivalent to (EQ) 4 milligrams (mg) base/vial, lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for zoledronic acid lyophilized powder for injection, 4-mg base/vial.

FOR FURTHER INFORMATION CONTACT: Nancy Boocker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6244, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ZOMETA (zoledronic acid for injection), EQ 4-mg base/vial, lyophilized powder for injection, is the subject of approved NDA 21–223 held by Novartis Pharmaceuticals Corp. (Novartis). Zoledronic acid, lyophilized powder for injection, EQ 4-mg base/vial, is indicated for treatment of hypercalcemia of malignancy. It also is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Novartis ceased manufacturing ZOMETA (zoledronic acid for injection), EQ 4 mg-base/vial, lyophilized powder for injection, in May 2003. On September 13, 2007, Kendle International, on behalf of Sun Pharmaceutical Industries Ltd., submitted a citizen petition (Docket No. 2007P–0341/CP1), under 21 CFR 10.30, requesting that the agency determine whether zoledronic acid lyophilized powder for injection, EQ 4-mg base/vial, was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that ZOMETA (zoledronic acid for injection), EQ 4-mg base/vial, lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that zoledronic acid lyophilized powder for injection, 4-mg base/vial, was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant information has uncovered no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously, ZOMETA (zoledronic acid for injection), EQ 4-mg base/vial, lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZOMETA (zoledronic acid for injection), 4-mg base/vial, lyophilized powder for injection, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ZOMETA (zoledronic acid for injection), EQ 4-mg base/vial, lyophilized powder for injection, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that the labeling of this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.