**Attachment 3**

*Guam*

Agana Power Plant—(PB2004–100066).

*Illinois*

Bordner Manufacturing Company—(PB2005–100067).

*Northern Mariana Islands, Commonwealth of the*

Saipan Capacitors [a/k/a Tanapag Village (Saipan)]—(PB2005–100063).

*Ohio*

Gentile Air Force Station (a/k/a USDOD Defense Electronics Supply Center)—(PB2004–107098).

*Tennessee*

Volunteer Army Ammunition Plant—(PB2005–100065).

*Texas*

Kelly Air Force Base—(PB2004–106801).

Dated: November 19, 2004.

**Georgi Jones,**

*Director, Office of Policy, Planning, and Evaluation, National Center for Environmental Health, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 04–26318 Filed 11–26–04; 8:45 am]

BILLING CODE 4163–70–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day–05AJ]

### Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 498–1210 or send comments to Sandi Cambercia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including 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 Surveillance for Severe Adverse Events (Hospitalization or Death) Associated with Treatment of Latent Tuberculosis Infection (LTBI)—New—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

The Centers for Disease Control and Prevention proposes to collect data for the National Surveillance for Severe Adverse Events (Hospitalization or Death) Associated with Treatment of Latent Tuberculosis Infections. CDC is requesting OMB approval for three years for this proposed data collection.

As part of the national TB elimination strategy, the American Thoracic Society and CDC have published recommendations for targeted testing for TB and treatment for latent TB infection (LTBI). However, between October 2000 and September 2004, the CDC received reports of 50 patients with severe adverse events associated with the use of the two or three-month regimen of rifampin and pyrazinamide (RZ) for the treatment of LTBI; 12 (24%) patients died (Morbidity and Mortality Weekly Report 2003;52[31]:735–9). A severe adverse event is defined as hospitalization or death of a person receiving treatment for LTBI. On the basis of these data, the American Thoracic Society and CDC recommended that RZ should generally not be offered for treatment of persons with LTBI, regardless of HIV status. Rifampin and pyrazinamide should continue to be administered in multidrug regimens for the treatment of persons with active TB disease.

Reports of severe adverse events related to RZ and other older LTBI regimens have prompted a need for this project—a national surveillance system of such events. The objective of the project is to determine the annual number and temporal trends of severe adverse events (hospitalization or death) associated with any treatment for LTBI in the United States. Surveillance of such events will provide data to support periodic evaluation of guidelines for treatment of persons with LTBI and revision, as needed.

This project will set up a passive reporting system for severe adverse events (death or hospitalization) to therapy for LTBI. The system will rely on medical chart review of already existing data by TB control staff.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, and 8 jurisdictions in the Pacific and Caribbean). Data will be collected using the data collection form for adverse events associated with LTBI treatment (AELT). Based on previous reporting, CDC anticipates receiving an average of 12 responses per year from the 60 reporting areas. The AELT form will be completed for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information. CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and also will conduct special analyses for publication in peer-reviewed scientific journals to further describe and interpret these data.

The Food and Drug Administration (FDA) collects data on adverse events related to drugs through the FDA MedWatch Program. CDC is planning to collaborate with FDA in developing the national surveillance system for adverse events associated with LTBI. Reporting will be conducted through telephone, e-mail, or during CDC site visits. The only cost to respondents is their time to complete the form.

| Respondents | Number of respondents | Responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|
| Health Departments | 12 | 1 | 1 | 12 |
| Total | | | | 12 |

Dated: November 19, 2004.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–26319 Filed 11–26–04; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1997N–0484S]

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 25, 2004 (69 FR 29786), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0543. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 19, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–26235 Filed 11–26–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N–0204]

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 19, 2004 (69 FR 51468), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0233. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 19, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–26270 Filed 11–26–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004P–0141]

### Determination That 7.5% and 8.4% Sodium Bicarbonate Injection in Polyethylene Terephthalate Abboject Vials Were 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 7.5% and 8.4% sodium bicarbonate injection in polyethylene terephthalate (PET) Abboject vials were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for 7.5% and 8.4% sodium bicarbonate injection.

**FOR FURTHER INFORMATION CONTACT:** Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**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 abbreviated new drug application (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

CDC Responses to comments.
**April 27, 2005**

**Re: Response to the National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection (LTBI), Federal Register, Volume 69, No. 228; November 29, 2004**

**Comments from:**
**Tuberculosis Control Branch, California Department of Health Services, and California Tuberculosis Controllers Association**

**Methodologic limitations**: This passive surveillance system will likely result in an underestimate of the number of adverse events associated with treatment for LTBI. Lack of a denominator will mean that the risk of these events cannot be calculated.

Can these data be better collected in conjunction with prospective studies? Alternatively, can an investigation be stimulated in response to patterns of events noted through the FDA Medwatch system?

**CDC response**: CDC is initiating the second phase of Task Order #13- Factors associated with acceptance of, adherence to, and toxicity from treatment for latent TB infection which is a prospective study that will obtain data on toxicity from treatment for latent TB infection. Also, with the established CDC and FDA collaboration, there is a greater possibility that an investigation will be initiated in response to patterns of events noted through the FDA MedWatch system.

**Burden of reporting**: The Federal Register notice estimates 1 hour average time burden per case of adverse event. This is a vast underestimate of the time and burden it would take for this reporting process. The initial report made by the reporting agency will take much more time in locating and reviewing records and recording the events. Even if CDC project officers can assist, coordinating access to relevant information will be time consuming. Additional time by the state will be spent to support the surveillance system, to respond to queries by local health departments (LHDs) regarding the protocol, and to coordinate communications and response. Without additional funding, some local jurisdictions will not have the ability to implement and participate in the surveillance system. Competing activities at the state and local level may be prioritized.

**CDC response**: The one-hour average time burden per case of adverse event is the amount of time the reporter of the event spends in filling up the basic information about the patient. CDC does not want to place too much burden on the reporting agency and that is one of the main reasons why the CDC medical team is sent to the reporting site to investigate the adverse event. The rest of the data on the form is filled out by the CDC medical team during telephone calls or onsite investigation. The collective time burden on the reporting agency can probably be one or more hours depending on the condition of the patient. So, based on your comment, we are changing this average time burden per case to eight hours.

**Reporting flow and coordination**: In California, reports are most likely to originate from LHDs. Traditionally, TB surveillance has proceeded from LHD to the State to CDC. Surveillance instructions suggest that local health departments and private providers can report directly to CDC. While CDC will coordinate with the state, reporting flow should follow current mechanisms.

**CDC response**: Historically, the reports that CDC have received and investigated so far have come from local health departments coordinated through the state and we anticipate that this practice will continue. We will encourage anyone who reports an adverse event to CDC to report the event to the local health department and we will follow up with the local and state health departments.

**Potential negative consequences of the surveillance system**: Collection and dissemination of information on these adverse events may discourage implementation of targeted testing and treatment for LTBI. This is a potential detrimental outcome since case reports can not provide sufficient evidence basis for this decision. Local health departments have reported that case reports of INH-related hepatitis have created significant barriers to implementing appropriate LTBI treatment.

**CDC response**: While reports of adverse events associated with treatment of LTBI may create barriers to LTBI treatment, we think that this possible negative consequence does not outweigh the benefits of monitoring these severe adverse events. The intent of the surveillance system is to provide data that will assist public health officials, policy makers, and healthcare providers in preventing severe adverse events associated with treatment of LTBI. The data will be the basis in supporting periodic evaluation of guidelines for treatment of LTBI and revision of these guidelines as needed.

**Relationship of Medwatch and CDC surveillance systems**: It is not clear how the FDA Medwatch and the CDC surveillance systems will intersect. If Medwatch is notified of an adverse event associated with treatment of LTBI, will DTBE be notified? And vice versa?

**CDC response**: CDC and FDA are developing a memorandum of understanding where both agencies will notify each other of any report of hospitalization or death associated with treatment of LTBI.

**Exclusion of serious adverse events that do not result in hospitalization or death**: It is likely that there are other adverse events of importance that may not result in hospitalization or death. Serious events as defined by the FDA include life-threatening conditions in addition to those leading to hospitalization or death.

**CDC response**: The national surveillance system receives reports of serious adverse events but collects data, through onsite investigation by a medical team, on hospitalization or death associated with treatment of latent TB infection. The CDC

Medical Board decided to conduct onsite investigation only on hospitalizations or deaths to maximize use of staff resources.

**Dissemination of findings**: FDA should be included in the partners for dissemination of findings

**CDC response**: FDA will be included in the partners for dissemination of findings.

**Process for comment review and response**: The process by which these comments will be reviewed and addressed is unclear.

**CDC response**: The process by which these comments are reviewed and addressed is the following: The OMB Clearance Group sends for review all the comments they receive to the CDC project officer who develops the CDC response to these comments. The CDC response will be sent to those who commented and also will be attached to the OMB protocol.