Dated: October 29, 2009.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 11/06/2009

Suitable/Available Properties

Building

Montana

Bldg. 743
Glacier National Park
West Glacier MT 59921
Landholding Agency: GSA
Property Number: 54200940005
Status: Surplus
GSA Number: 7–I–MT–0544–AB
Comments: 678 sq. ft., most recent use—dormitory, off-site use only.

Bldg. 744
Glacier National Park
West Glacier MT 59936
Landholding Agency: GSA
Property Number: 54200940006
Status: Surplus
GSA Number: 7–I–MT–0544AA
Comments: 1812 sq. ft., most recent use—dormitory, off-site use only.

Suitable/Available Properties

Land

Missouri

Tract LLWAS K3 Mexico City Ave.
Kansas City MO 64153
Landholding Agency: GSA
Property Number: 54200940004
Status: Surplus
GSA Number: 7–U–MO–0687AA
Comments: 0.034 w/easements.

Unsuitable Properties

Building

Guam

9 Bldgs.
Naval Base
Piti GU
Landholding Agency: Navy
Property Number: 77200940006
Status: Unutilized
Directions: 92, 204, 211NH, 292, 453, 454, 4407PP, 5120, 5125
Reasons: Extensive deterioration, Secured Area.

Unsuitable Properties

Building

Hawaii

Kauhola Point Lighthouse
Kauhola Point HI
Landholding Agency: Coast Guard
Property Number: 88200940001
Status: Unutilized
Reasons: Extensive deterioration.

New Mexico

13 Bldgs.
Los Alamos National Lab
Los Alamos NM 87545
Landholding Agency: Energy
Property Number: 41200940004
Status: Unutilized
Directions: 54–0306, 54–0315, 54–0324, 54–0325, 54–1058, 54–0296, 54–0304, 54–0367, 54–0483, 54–1027, 54–1028, 54–1030, 54–1041
Reasons: Extensive deterioration, Secured Area.

[FR Doc. E9–26420 Filed 11–5–09; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Update to the Report on Residual Radioactive and Beryllium Contamination at Atomic Weapons Employer Facilities and Beryllium Vendor Facilities

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of the release of an update to *The Report on Residual Radioactive and Beryllium Contamination at Atomic Weapons Employer Facilities and Beryllium Vendor Facilities* under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7484–7385.

This update is the third revision to the original report. The original report was issued in November, 2002; the first update was issued in October, 2003; and the second update was issued in December, 2006. The purpose of the original report and subsequent updates is to evaluate whether significant residual contamination remained at atomic weapons employer or beryllium vendor facilities after such facilities had concluded work for the Department of Energy (DOE) or its predecessor agencies.

NIOSH was required to submit the original report by section 3151(b) of the National Defense Authorization Act for Fiscal Year 2002, Public Law 107–107 (December 18, 2001), which amended EEOICPA. EEOICPA was amended again in section 3169 of the National Defense Authorization Act of Fiscal Year 2005, Public Law 108–375 (October 28, 2004) which directed NIOSH to update the residual contamination report by December, 2006.

This third revision to the original report has been prepared because the determination of residual contamination for several sites has changed since the issuance of the December 2006 version of the report. Specifically, this updated report is being submitted due to several recent changes in facility designations by DOE and the Department of Labor, and due to new information for certain facilities that was acquired and evaluated since the issuance of the December 2006 version of the report.

DOE uses the designations in this report to modify its publicly available list of EEOICPA-covered facilities, which includes the time periods determined by DOL to be covered under EEOICPA.

The entire report can be viewed on the Office of Compensation and Analysis Support Web site at *http://www.cdc.gov/niosh/ocas/*.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Interim Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number).

Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E9–26843 Filed 11–5–09; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0507]

Agency Information Collection Activities: Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in the requirements for submission of labeling for human prescription drugs and biologics in electronic format.

DATES: Submit written or electronic comments on the collection of information by January 5, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, *Elizabeth.Berbakos@fda.hhs.gov*, 301–796–3792

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format; (OMB Control Number 0910 0530)—Extension

FDA is requesting that OMB extend approval under the Paperwork Reduction Act (44 USC 3501–3520) for the information collection resulting from the requirement that the content of labeling for prescription drug products be submitted to FDA electronically in a form that FDA can process, review, and archive. This requirement was set forth in the final rule entitled ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format'' (December 11, 2003; 68 FR 69009), which amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs) (21 CFR 314.50(l)(1)(i)), including supplemental NDAs, abbreviated new drug applications (ANDAs) (21 CFR 314.94(d)(1)(ii)), including supplemental ANDAs, and annual reports (21 CFR 314.81(b)(2)(iii)(b)) (the final rule also applied to certain Biologics License Applications, but the information collection for these requirements is not part of this OMB approval request).

This OMB approval request is only for the burden associated with the electronic submission of the content of labeling. The burden for submitting labeling as part of NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports, has been approved by OMB under Control Number 0910–0001.

When we last requested that OMB extend approval for this information collection (see the **Federal Register** of March 29, 2006 (71 FR 15752)), we received several comments. Generally, the comments said that, unlike FDA's December 11, 2003, final rule, the agency has now identified Extensible Markup Language (XML) as the required file format for Structured Product Label documents (SPL), and that the burden hours and costs that were calculated in the final rule were based on the submission of the content of labeling in PDF. The comments said that the burden estimate in March 29, 2006, **Federal Register** notice does not take into account the amount of time required to obtain, install, and update the program required to create the electronic files in the new format, and that SPL is a relatively new format requiring an initial investment in software, training, and process change that cannot simply be converted from the Word or PDF version of labeling. The comments said that the process for creating the SPL labeling includes significant effort in mapping, coding, recreation of the file, and quality control.

In the December 13, 2006, **Federal Register** (71 FR 74924), we said that we will respond to the comments as soon as we have gathered sufficient information to address the costs specified in the comments, and that the public will have an opportunity to comment on the response at that time. The burden hours and costs associated with making these submissions using the SPL standard are discussed here.

We estimate that it should take applicants approximately 1.25 hours to convert the content of labeling from Word or PDF to SPL format. The main task involved in this conversion is copying the content from one document (Word or PDF) to another (SPL). Over the past few years, several enhancements have been made to SPL authoring software which significantly reduces the burden and time needed to generate well-formed SPL documents. SPL authors may now copy a paragraph from a Word or PDF document and paste the text into the appropriate section of an SPL document. In those cases where an SPL author needs to create a table, the table text may be copied from the Word or PDF document and pasted into each table cell in the SPL document, eliminating the need to retype any information. Enhancements have also been made to the software for conversion vendors. Conversion software vendors have designed tools which will import the Word version of the content of labeling and, within minutes, automatically generate the SPL document (a few formatting edits may have to be made).

Based on the number of content of labeling submissions received during 2006, 2007, and 2008, we estimate that approximately 5,000 content of labeling submissions are made annually with original NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports by approximately 450 applicants. Therefore, the total annual hours to convert the content of labeling from Word or PDF to SPL format would be approximately 6,250 hours.

Concerning costs, we continue to conclude that there are no capital costs or operating and maintenance costs associated with this collection of information. In May 2009, FDA issued a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing.'' The guidance describes how to electronically create and submit SPL files using defined code

sets and codes for establishment registration and drug listing information, including labeling. The information collection resulting from this guidance, discussed in the **Federal Register** of January 8, 2009 (74 FR 816), has been approved by OMB under Control Number 0910–0045. As discussed in the January 8, 2009, **Federal Register** notice, to create an SPL file and submit it to FDA, a registrant would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's electronic submission gateway (ESG). Registrants (and most individuals) have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and the Internet are usually available at public facilities, e.g., a community library. In addition, there should be no additional costs associated with obtaining the appropriate software. In 2008, FDA collaborated with GlobalSubmit to make available free SPL authoring software that SPL authors may utilize to create new SPL documents or edit previous versions. (Information on obtaining this software is explained in section IV.A of the guidance ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing.'') In addition to the software, FDA also provides technical assistance and other resources, code sets and codes, and data standards regarding SPL files.

After the SPL file is created, the registrant would upload the file through the ESG, as explained in the January 8, 2009, **Federal Register** notice. A digital certificate is needed to use the ESG. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents. A fee of up to $20.00 is charged for the digital certificate and the registrant may need to renew the certificate not less than annually. We are not calculating this fee as a cost for this extension because all applicants who submit content of labeling are also subject to the drug establishment registration and listing requirements and would have already acquired the digital certificate as a result of the May 2009 guidance on drug establishment registration and listing.

FDA estimates the burden of this collection of information as follows:

TABLE 1.

	Number of respondents	Annual frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Content of labeling submissions in NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports	450	11.11	5,000	1.25	6,250

There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26760 Filed 11–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture Comparative Database.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on September 2nd, 2009 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by December 7, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrg.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Hospital Survey on Patient Safety Culture (Hospital SOPS) Comparative Database. The Hospital SOPS Comparative Database consists of data from the AHRQ Hospital Survey on Patient Safety Culture. Hospitals in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The database was developed by AHRQ in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals in their efforts to improve patient safety.

In 1999, the Institute of Medicine called for health care organizations to develop a ''culture of safety'' in which their workforces and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health