schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS4, L–AS5, L–AS6 and L–AS7 through February 28, 2011.

Dated: August 12, 2008.

Jeff Kupfer,

Acting Deputy Secretary.

Department of Energy

Deputy Secretary

Rate Order No. WAPA–141.

In the Matter of: Western Area Power Administration Rate Extension for Loveland Area Projects Transmission and Ancillary Services Formula Rates.

Order Confirming and Approving an Extension of the Loveland Area Projects Transmission and Ancillary Services Formula Rates

The Loveland Area Projects (LAP) transmission and ancillary services rate formulae were established following section 302(a) of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This act transferred to and vested in the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)), and other Acts that specifically apply to the project system involved.

By Delegation Order No. 00–037.00 effective December 6, 2001, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of the Western Area Power Administration (Western); (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). This rate extension is issued pursuant to the Delegation Order and the DOE rate extension procedures at 10 CFR part 903.23(b).

Background

The existing formula rates, approved under Rate Order No. WAPA–106, were approved for five (5) years and are effective through February 28, 2009. Subsequently, Rate Schedule L–AS3, Regulation and Frequency Response, was revised and approved for five (5) years under Rate Order No. WAPA–118 and is effective through May 31, 2011. Western is not seeking to extend Rate Schedule L–AS3 for Regulation and Frequency Response service as part of this extension.

Discussion

On February 28, 2009, Western's LAP transmission and ancillary services formula rates will expire, with the exception of Regulation and Frequency Response service, which will expire May 31, 2011. Western is proposing to extend the existing LAP transmission and ancillary services formula rates pursuant to 10 CFR part 903.23(b). The existing LAP rate formulae methodologies collect annual revenue sufficient to recover annual expenses (including interest) and capital requirements, thus ensuring repayment of the project within the cost recovery criteria set forth in DOE order RA 6120.2. Western is seeking this extension to provide more time for the evaluation of new rate requirements for transmission and ancillary services mandated under FERC Order 890 and the evaluation of adjustments to the formulae for ancillary services. For these reasons, Western is extending the existing rate formulae for transmission and ancillary services through February 28, 2011.

The process will take several months to complete because of the complex issues Western and its interested parties must address. It will also offer opportunities for public information and comment forums. For these reasons, Western seeks to extend existing Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS4, L–AS5, L–AS6 and L–AS7. Western did not have a consultation and comment period and did not hold public information and comment forums, in accordance with 10 CFR part 903.23(b).

Order

In view of the above and under the authority delegated to me, I hereby extend for a period effective from March 1, 2009, through February 28, 2011, the existing rate schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS4, L–AS5, L–AS6 and L–AS7 for LAP transmission and ancillary services, excluding L–AS3 for Regulation and Frequency Response service.

Dated: August 12, 2008.

Jeff Kupfer,

Acting Deputy Secretary.

[FR Doc. E8–19161 Filed 8–18–08; 8:45 am]

BILLING CODE 6450–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Meeting

DATE AND TIME: Friday, August 22, 2008, 1 p.m. Eastern Time.

PLACE: Clarence M. Mitchell, Jr. Conference Room on the Ninth Floor of the EEOC Office Building, 1801 ''L'' Street, NW., Washington, DC 20507.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Open Session

1. Announcement of Notation Votes,
2. Obligation of Funds for e-Government Application Hosting/ Managed Services and Extension of DOI/NBC Hosting, and
3. Obligation of Funds for Competitive Revolving Fund Online Registration and Payment Collection System Contract, and Sole Source Extension of Current Contract for Transition Period.

Note: In accordance with the Sunshine Act, the meeting will be open to public observation of the Commission's deliberations and voting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.)

Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTY) at any time for information on these meetings. The EEOC provides sign language interpretation at Commission meetings for the hearing impaired. Requests for other reasonable accommodations may be made by using the voice and TTY numbers listed above.

CONTACT PERSON FOR MORE INFORMATION: Stephen Llewellyn, Executive Officer on (202) 663–4070.

Dated: August 15, 2008.

Stephen Llewellyn,

Executive Officer, Executive Secretariat.

[FR Doc. E8–19279 Filed 8–15–08; 4:15 pm]

BILLING CODE 6570–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0428]

Electronic Study Data Submission for Phase 3 Janus Operational Pilot; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) is seeking sponsors interested in participating in a pilot project to test the submission and processing of clinical study data provided electronically in a standardized format. This pilot will test the data extract, validation, and load procedures developed to populate ''Janus,'' the study data repository component of a common, standards-based infrastructure that is being developed jointly by the Food and Drug Administration (FDA) and the National Cancer Institute (NCI) to support the exchange of clinical research data. The pilot also will test a new XML (extensible markup language)-based submission format for standardized clinical study data. We anticipate that a successful pilot will enable CDER to routinely receive, process, and store all standardized clinical study data in a

data warehouse environment that will enhance the center's capability to manage and review standardized study data.

DATES: Submit written or electronic requests to participate in the pilot project by November 17, 2008. General comments on the Janus operational pilot project are welcome at any time.

ADDRESSES: Submit written requests to participate and comments regarding this pilot project 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. Submit written comments 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: Bobbie Witczak, Food and Drug Administration, 5600 Fishers Lane (HFD–070), Rockville, MD 20857, 301–796–4126.

For specific questions regarding Voluntary Genomic Data Submissions, please contact: Federico Goodsaid, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, rm. 2148 Silver Spring, MD 20903, 301–796–1535

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing an opportunity to participate in a pilot project that involves the ongoing development and testing of a repository for standardized clinical study data (the Janus study data warehouse). This pilot will test the electronic receipt, processing, and storage of standardized clinical study data, including the successful validation and loading of data into the Janus study repository and subsequent access of that data by reviewers using a combination of analytical and visualization tools. The Janus study data repository is the data warehouse component of a common, standards-based infrastructure that is being developed jointly by FDA and the NCI to support the exchange of clinical research data. Janus is designed to enhance the agency's capability to manage and review standardized study data.

CDER has been accepting voluntary electronic submissions of standardized clinical study data since July 2004.[1] Applicants wishing to provide clinical study data in standardized format are advised to follow the Study Data Tabulation Model (SDTM) defined by the Clinical Data Interchange Standards Consortium (CDISC). CDISC is an open, multidisciplinary, nonprofit organization that has established worldwide industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trial data and metadata for medical and biopharmaceutical product development (*http://www.cdisc.org*).

Under current regulations, applicants are required to provide case report tabulations (i.e., study data) for certain studies included in a marketing application (see 21 CFR 314.50). In guidance for industry titled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Application and Related Submissions Using the eCTD Specifications,'' FDA makes recommendations about how to submit documents in electronic format for investigational new drug (IND) applications, biologic license applications (BLAs), and new drug applications (NDAs) using the electronic common technical document (eCTD) specifications. In Section III.E.4 of that guidance, FDA refers to the CDISC SDTM as the Study Data Specification for voluntary electronic submission of clinical study data.

In addition, FDA is planning to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for NDAs, BLAs, and abbreviated new drug applications (ANDAs).[2] This proposal would revise FDA's regulations to require that clinical data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments: (1) Be provided in electronic format and (2) use a standardized data structure, terminology, and code sets as referenced in FDA guidance to enable efficient and comprehensive data review.

The Janus study data repository is being developed by FDA and NCI through the Interagency Oncology Task Force (IOTF), which was established in 2003 to enable the two organizations to share knowledge and resources to facilitate the development of new cancer drugs and speed the development and their delivery to patients. As part of the IOTF agreement, FDA is working with NCI to build tools and an environment that facilitates and streamlines electronic interaction and collaboration among FDA and its stakeholders in the regulatory review process. The Janus initiative is part of a larger effort to implement a common, standards-based electronic infrastructure that supports the submission, validation, data warehousing, access, and analysis of structured scientific data to support regulatory review.

Phase 1 of the Janus implementation effort was a proof of concept pilot that successfully demonstrated the ability to load SDTM data into Janus, extract data from Janus using commercial-off-the-shelf (COTS) query tools, and produce data from Janus in SDTM format. Phase 2 of this initiative involved development of an operational pilot that includes a data import and validation facility, the integration of reviewer tools with the Janus repository, and provision of reviewer access to the data via selected analytical and visualization tools. Validation criteria for processing SDTM submissions were developed for use in that pilot based on the SDTM implementation guide and FDA business requirements. The SDTM validation specification for Janus established the business rules for error-checking functions that determine whether SDTM submission data can be loaded successfully into the Janus repository.[3]

CDER has received a limited number of SDTM submissions since it began accepting these standardized datasets. Our experience with these submissions during the phase 2 pilot has shown that additional collaboration with sponsors will be needed on the preparation, submission, and analysis of SDTM datasets to facilitate a common understanding of the data quality requirements that are necessary to realize long-term benefits of an integrated clinical trials data repository.

As a result, FDA is now announcing the start of phase 3 of the Janus operational pilot, which will enable a wider stakeholder community to participate in the Janus development initiative. The goals of the phase 3 pilot are as follows:

- Transition the phase 2 pilot to operational production;
- Test the electronic processing of standardized clinical study data, including the successful validation and loading of data into the Janus study repository and subsequent access to that data by reviewers using a combination of analytical and visualization tools;
- Test a new XML-based submission format for CDISC content (CDISC–HL7

[1] See *http://www.fda.gov/bbs/topics/news/2004/NEW01095.html*.

[2] See *http://www.reginfo.gov/public/do/eAgendaViewRule?ruleID=279292*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[3] See SDTM Validation Specification 1.0, Nov. 2007 at *http://www.fda.gov/oc/datacouncil/janus_operational_pilot.html*.

messages, see below) currently under development;

- Extend the Janus logical data model and service-oriented architecture to support submission of CDISC-HL7 messages;
- Integrate with NCI's Enterprise Vocabulary Service (EVS);
- Test the integration and analysis of clinical study data stored in Janus with pharmacogenomic data currently being received through the Voluntary Genomic Data Submissions (VGDS) program.[4]

A desired outcome of the phase 3 pilot is a production environment that supports the routine processing and management of all structured clinical study data provided in regulatory submissions.

The phase 3 operational pilot will also test a new submission format. Currently, SDTM datasets are provided in SAS transport format. FDA recognizes the limitations of the outdated SAS transport format and intends to transition towards a new, more robust XML-based submission format. FDA is currently sponsoring a project within HL7[5] to develop a standard XML exchange format (called ''messages'') for standardized clinical study data content as defined by CDISC. This ''CDISC Content to HL7 Message Project'' will enable the exchange of clinical study data in a standardized HL7–XML-based format. We believe this will facilitate loading study data into Janus and provide additional benefits. A successful phase 3 pilot will also enable FDA to routinely accept HL7–XML-based clinical study data submissions.

Concurrent with the phase 3 pilot, CDER also will be exploring ways to integrate related data standards initiatives with the Janus effort. These related initiatives include the enhancement of the current Janus logical model to incorporate preclinical and pharmacogenomics data and product safety data. Future efforts will continue to focus on business information requirements for managing product life-cycle data across all FDA regulated products.

II. Pilot Project Description

This pilot project is part of an ongoing effort to improve the efficiency of the review of study data within CDER. As we gain additional experience from this pilot, CDER expects to update its study data submission technical specifications as part of a continuing process to improve the quality of clinical study data provided electronically.

A. Approach

CDER is seeking applicants who have submitted or are planning to submit in the near future (i.e., within 6 months of publication of this notice) SDTM files in a regulatory submission in accordance with existing guidance and technical specifications. Our experience during phase 2 has shown that SDTM files routinely fail the Janus validation procedures and cannot be loaded into Janus automatically. Pilot participants should agree to work closely with Janus technical staff to review the validation errors, correct them, and resubmit the files. The ability to successfully load data into the Janus repository is an important pilot milestone. Experience gained as a result of working with participating sponsors during this pilot will help us improve the validation criteria, which subsequently will help improve the quality of future study data submissions. Pilot participants will also gain valuable experience in creating and submitting quality standardized data submissions. Of particular interest are pilot participants who are also able to provide pharmacogenomic data (i.e., VGDS) with the CDISC data. This will enable us to test the integration of clinical data stored in Janus with pharmacogenomic data. Although a VGDS is not required to participate in this pilot, it is a desirable component of the pilot and is encouraged whenever possible.

From this pool of pilot participants, we are also seeking five to eight companies willing to supply study data in the new HL7 XML format (in addition to SDTM datasets) for testing, processing, and loading into Janus. FDA will provide some technical support with the new HL7 XML format, such as help in understanding and interpreting the new specifications. Those who participate in this part of the pilot also will be provided secure access to their data in Janus so they can test the integrity of their data within the Janus environment. Although the SDTM files are part of a regulatory submission, all of the activities involved in this pilot will be conducted outside of a regulatory setting. That is, the SDTM datasets will be reviewed according to current review practices for any electronic dataset submission, and pilot activities will not impact the regulatory review clock, will not affect or delay reviewability assessments, filability decisions, or any regulatory actions.

B. How to Participate

Requests to participate in the pilot project should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document. The pilot enrollment period will last 6 months following publication of this notice. The pilot is expected to last approximately 1 year, but this duration will be subject to change as the pilot progresses. Updates to the pilot will be publicly posted on the FDA Janus Operational Pilot Web page.[6]

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments 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.

Dated: August 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19197 Filed 8–18–08; 8:45 am]

BILLING CODE 4160–01–S

[4] See *http://www.fda.gov/cder/genomics/VGDS.htm.*

[5] Health Level Seven in an American Standards Institute (ANSI)-accredited standards development organization operating in the health care arena. See *http://www.hl7.org.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[6] See *http://www.fda.gov/oc/datacouncil/janus_operational_pilot.html.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Behavioral Health Preventive Care Assessment Focus Group

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) 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 project was previously published in the