the building and grounds, participants must bring government-issued photo identification and a copy of your written meeting registration confirmation. Persons without proper identification will be denied access.

Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes before the convening of the meeting each day.

Security measures will also include inspection of vehicles, inside and outside, at the entrance to the grounds and buildings. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required in order to bring pieces of equipment or medical devices at least two weeks prior to each public meeting. These arrangements need to be made with the appropriate public meeting coordinator. It is possible that certain requests, made in advance, of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of two weeks is required for approvals and security procedures. Any request not submitted at least two weeks in advance of the public meeting will be denied.

Parking permits and instructions are issued upon arrival by the guards at the main entrance.

All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh).

Dated: January 29, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3034 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1383–N2]

Medicare Program; Listening Session on the Draft Plan for Medicare Hospital Value-Based Purchasing—April 12, 2007

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the second Listening Session being conducted as part of the development of a plan for Medicare hospital value-based purchasing, as authorized by section 5001(b) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA). The purpose of the second Listening Session is to solicit comments on the Draft Plan that has been developed. Hospitals, hospital associations, and all interested parties are invited to attend and make comments in person. The perspectives expressed during this session and in writing will assist us in making revisions to the Draft Plan to create the final Medicare Hospital Value-Based Purchasing Plan to be completed by June 2007. The Draft Plan will be posted no later than March 22, 2007 on the CMS Web site, Hospital Center, under Spotlights at *http://www.cms.hhs.gov/center/hospital.asp.*

DATES:

Meeting Date: The listening session will be held on Thursday, April 12, 2007 from 10 a.m. until 5 p.m. e.d.t.

Registration and Request for Special Accommodations Deadline: Registration will open February 26, 2007. For security reasons, registration must be completed no later than 5 p.m. e.d.t. on Thursday, April 9, 2007. Requests for special accommodations must be received by 5 p.m. e.d.t. on Thursday, April 9, 2007. See Section III. below for detailed instructions.

Deadline for Submission of Written Comments or Statements: Written comments on the Draft Plan may be sent by mail, fax, or electronically and must be received by 5 p.m. e.d.t. on April 19, 2007.

ADDRESSES:

Meeting Location: The Listening Session will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Persons interested in attending the meeting or listening by teleconference must register by completing the on-line registration located at *http://registration.mshow.com/cms2/.* Individuals who need special accommodations should contact Robin Phillips at (410) 786–3010, by e-mail to *robin.phillips@cms.hhs.gov*, or by regular mail to Mail Stop C4–13–07 Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Written Comments or Statements: Written comments on the Draft Plan may be mailed to Mail Stop C4–13–07 Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244; e-mail to *cmshospitalVBP@cms.hhs.gov* or fax to 410–786–0330.

FOR FURTHER INFORMATION CONTACT: Robin Phillips, 410–786–3010 in the Medicare Feedback Group. You may also send inquires about this meeting via e-mail to *robin.phillips@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 5001(b) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) specifies that we develop a plan to implement a Value-Based Purchasing (VBP) Program for payments under the Medicare program for subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act) beginning with FY 2009. The Congress specified that the ''plan'' include consideration of the following issues:

- The ongoing development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings.
- The reporting, collection, and validation of quality data.
- The structure of value-based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the value-based payments.
- The disclosure of information on hospital performance.

In developing the plan, we must consult with relevant affected parties and consider experience with demonstrations that are relevant to the VBP program. We have created an internal Hospital Pay-for-Performance Workgroup that is charged with developing the VBP Plan for Medicare hospital services. This Workgroup is organized into four subgroups to address each of the required planning

issues: (1) Measures; (2) data collection and validation; (3) incentive structure; and (4) public reporting. It is also charged with preparing a set of design options, narrowing the set of design options to prepare a draft plan, and preparing a report on the plan for implementing VBP for Medicare hospital services, which will be provided to the Congress as required under section 5001(b)(3) of the DRA.

In the November 24, 2006 **Federal Register**, we announced that we would have a listening session to consider design questions posed in the Issues Paper that we posted on our Web site *http://www.cms.hhs.gov.* This listening session was held on January 17, 2007.

II. Listening Session Format and Agenda

The second listening session will be held on April 12, 2007 to consider the Draft Plan. This listening session will begin at 10 a.m. with an overview of the objectives for the session and a brief summary of the approach to developing the Draft Plan. Beginning at approximately 10:30 a.m., the remainder of the meeting will be devoted to addressing each section of the Plan. The agenda will provide opportunities for brief 2-minute comments from on-site session attendees. As time allows, telephone participants will also have the opportunity to provide brief 2-minute comments. A lunch break will occur from approximately 12:30 p.m. to 1:30 p.m. The meeting will conclude by 5 p.m. with brief comments on ''next steps.''

III. Registration Instructions

Persons interested in attending the meeting or listening by teleconference must register by completing the on-line registration located at *http://registration.mshow.com/cms2/.* The on-line registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt.

Individuals may also participate in the listening session by teleconference. Registration is required. The call-in number will be provided upon confirmation of registration.

An audio download of the listening session will be available through the CMS Hospital Center Web site within 72 hours after completion of the listening session.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on April 9, 2007. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 550 registrants.

The on-site check-in for visitors will begin at 9:15 a.m. Please allow sufficient time to go through the security checkpoints at both the entrance to the grounds and the entrance to the building. It is suggested that you arrive at central building by 9 a.m. so that you will have enough time to check-in before the session begins.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must check in by name with Security, provide a government-issued ID, and pass through a metal detector. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, including items such as laptops, cell phones, and palm pilots, are subject to physical inspection.

Authority: Section 5001(b) The Deficit Reduction Act (DRA) of 2005.

Dated: February 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3048 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0261]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXJADE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EXJADE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions 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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product EXJADE (deferasirox). EXJADE is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EXJADE (U.S. Patent No. 6,465,504) from Novartis AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of