necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection;

Title: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; *Use:* The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN (paper or electronic) to CMS, along with a claim for reimbursement. This clearance request is for CMNs with the form numbers, CMS 846–849, 10125 and 10126. *Form Numbers:* CMS–846, 847, 848, 849, 10125, 10126 (OCN: 0938–0679); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 462,000; *Total Annual Responses:* 462,000; *Total Annual Hours:* 92,400. (For policy questions regarding this collection contact Doris Jackson at 410–786–4459. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *November 23, 2012:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 18, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–23367 Filed 9–21–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0966]

Prescription Drug User Fee Act V Patient-Focused Drug Development; Consultation Meetings; Request for Notification of Patient Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request that patient stakeholders notify FDA of their intention to participate in periodic consultation meetings on process issues related to FDA's patient-focused drug development initiative. This initiative is being conducted to fulfill FDA performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). These periodic consultation meetings will address important considerations and challenges in establishing a process for conducting a series of patient-focused drug development meetings that will be useful to both the patient community and FDA. The purpose of this request for notification is to ensure continuity and progress in these discussions by establishing consistent patient stakeholder representation.

DATES: Submit notification of intention to participate in this series of meetings by October 3, 2012. The first stakeholder meeting on process issues will be held on October 10, 2012, from 2 p.m. to 3:30 p.m. These discussions will continue on an approximately bimonthly basis as needed during PDUFA V.

ADDRESSES: Submit notification of intention to participate in this series of meetings by email to *PatientFocused@fda.hhs.gov.* The first meeting with patient stakeholders will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 51, Rm. 1300, Silver Spring, MD 20993–0002. Entrance for the consultation meetings' participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Andrea Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 1168, Silver Spring, MD 20993–0002, 301–796–7641, FAX: 301–847–8443, *Andrea.Tan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). Title I of FDASIA reauthorizes the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary user fee resources to maintain a predictable and efficient review process for human drug and biologic products. The reauthorization of PDUFA includes performance goals and procedures that represent FDA's commitments during fiscal years 2013–2017. These commitments are referred to in section 101 of FDASIA and are available on the FDA Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

Section X of these commitments relates to enhancing benefit-risk assessments in regulatory

decisionmaking. A key part of regulatory decisionmaking is establishing the context in which the particular decision is made. In drug regulation, this context includes a thorough understanding of the severity of the treated condition and the adequacy of the existing treatment options. Patients who live with a disease have a direct stake in the outcome of the review process and are in a unique position to contribute to weighing benefit-risk considerations that can occur throughout the medical product development process. Though several programs exist to facilitate patient representation, there are currently few venues in which the patient perspective is discussed outside of a specific product's marketing application review. The human drug and biologic review process could benefit from a more systematic and expansive approach to obtaining input from patients who are experiencing a particular disease or condition.

FDA is committed to obtaining input from patients and, as set out in the commitment letter, will conduct public meetings to consider 20 different disease areas over the 5-year authorization of the program. For each disease area, FDA will conduct a public meeting to discuss such topics as the impact of the disease on patients, the spectrum of severity for those who have the disease, the measures of benefit that matter most to patients, and the adequacy of the existing treatment options for patients. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is seeking comment on a proposed list of disease areas for consideration at these meetings.

FDA recognizes that there is significant interest in patient-focused drug development within the patient community. To ensure that patient stakeholders have an additional opportunity to engage in a discussion of key process considerations as this initiative moves forward in PDUFA V, FDA is convening a series of periodic consultation meetings with patient stakeholders to address key process questions for patient-focused drug development. These periodic consultation meetings will be separate from the disease-specific public meetings that are part of FDA's commitments in PDUFA V; however, the process consultation discussions may help inform the best strategies for conducting future disease-specific meetings. FDA anticipates that the periodic consultation meetings will be focused on process questions for consideration by FDA and patient stakeholders. Examples of potential process topics include the following:

1. Given the limits of FDA staff resources and time available, how to prioritize and balance different disease areas identified by different patient stakeholders.

2. How to approach issues when patient stakeholders for the same disease area have different and potentially conflicting views.

3. How to balance access to FDA for patient stakeholders who are local to FDA headquarters versus those in other locations who have less physical access.

4. How to support engagement of patients in disease areas for which no formal advocacy organizations exist. What role, if any, might already organized groups play?

Patient stakeholders provided critical input in the development of the patient-focused drug development proposal during the PDUFA V discussions. FDA expects that there will be continued interest among patient stakeholders as this PDUFA V enhancement is implemented. FDA is publishing this **Federal Register** notice to request that patient stakeholders notify the Agency of their intention to participate in this series of process consultation meetings on patient-focused drug development. FDA believes that consistent patient stakeholder representation at these meetings will be important for ensuring progress in these discussions.

II. Notification of Intention To Participate in Periodic Consultation Meetings

If you are an individual patient stakeholder who intends to participate in periodic consultation meetings regarding FDA's implementation of the patient-focused drug development initiative, please provide notification by email to *PatientFocused@fda.hhs.gov* by October 3, 2012. If you represent an organization that intends to participate in these meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed and provide notification by email to *PatientFocused@fda.hhs.gov* by October 3, 2012. All notification emails should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Seating will be limited, so early notification is encouraged. FDA may limit the number of participants from each organization based on space limitations. Patient stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification and will be included in future communications from FDA about implementing patient-focused drug development. If stakeholders decide to participate at a later time, they may notify FDA of their intent to participate in future meetings as described previously in this document (see **ADDRESSES**). FDA intends to post summary meeting minutes on its Web site after each meeting has concluded.

Dated: September 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23453 Filed 9–21–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0967]

Prescription Drug User Fee Act Patient-Focused Drug Development; Public Meeting and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment related to FDA's patient-focused drug development initiative. This initiative is being conducted to fulfill FDA performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). This effort provides for a more systematic approach under PDUFA V for obtaining patient perspective on the disease severity and the currently available treatments for a set of disease areas. FDA is publishing a preliminary list of nominated disease areas for the patient-focused drug development initiative and the criteria used for nomination. The public is invited to comment on this preliminary list through a public docket and at a public meeting where FDA will provide an overview of the patient-focused drug development initiative with discussion of the nominated disease areas.

DATES: Submit either electronic or written comments by November 1, 2012. The public meeting will be held on October 25, 2012, from 9 a.m. to 12:30 p.m. Registration to attend the meeting must be received by October 18, 2012. See the **SUPPLEMENTARY INFORMATION**