Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, are the subject of NDA 020305, held by Hoffmann-La Roche, Inc., and initially approved on March 16, 1995. KYTRIL is indicated for the prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin, and for the prevention and treatment of postoperative nausea and vomiting in adults.

On April 30, 2012, Hoffman-La Roche notified FDA that KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, were being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Kurt R. Karst, on behalf of Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated May 27, 2015 (Docket No. FDA–2015–P–1898), under 21 CFR 10.30, requesting that the Agency determine whether KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, were withdrawn for reasons of safety or effectiveness We have carefully reviewed our files for records concerning the withdrawal of KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to KYTRIL (granisteron hydrochloride) tablets, EQ 1 mg and 2 mg base, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32496 Filed 12–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Externally-Led Patient-Focused Drug Development Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the opportunity for externally-led patient-focused drug development meetings. The Patient-Focused Drug Development (PFDD) initiative is part of FDA's commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The PFDD initiative aims to more systematically obtain the patient perspective on specific diseases and their treatments. FDA recognizes that there are many more disease areas than can be addressed in the planned FDA meetings under PDUFA V. To help expand the benefits of FDA's PFDD initiative, FDA welcomes patient organizations to identify and organize patient-focused collaborations to generate public input on other disease areas, using the process established through Patient-Focused Drug Development as a model.

ADDRESSES: FDA recommends that patient organizations who are interested in conducting an externally-led PFDD meeting initially engage with FDA by submitting a letter of intent (LOI) to *patientfocused@fda.hhs.gov.* Submission details are outlined on FDA's Web site: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.*

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1144, Silver Spring, MD 20993–0002, 301–796–0684.

SUPPLEMENTARY INFORMATION: As part of its commitments under the Prescription Drug User Fee Act reauthorization of 2012, FDA has taken several steps to inform the benefit-risk assessments that inform CDER's regulatory decisions concerning new drugs. Among these efforts is the PFDD initiative that aims to more systematically obtain the patient perspective on specific diseases and their treatments. FDA has committed to obtaining the patient perspective on at least 20 disease areas during the course of PDUFA V. PFDD meetings give FDA an important opportunity to hear directly from patients, patient advocates, and caretakers about the symptoms that matter most to them; the impact the disease has on patients' daily lives; and patients' experiences with currently available treatments. The patient perspective is critical in helping FDA understand the context in which regulatory decisions are made for new drugs. This patient input can inform FDA's decisions and oversight both during drug development and during our review of a marketing application.

The Agency recognizes that there has been growing external interest in expanding efforts to gather patient input in support of drug development and evaluation. To help expand the benefits of FDA's PFDD initiative, FDA welcomes patient organizations to identify and organize patient-focused collaborations to generate public input on other disease areas, using the process established through Patient-Focused Drug Development as a model. An externally-led PFDD meeting and any resulting products (*e.g.,* surveys or reports) will not be considered FDA-sponsored or FDA-endorsed, and FDA does not guarantee specific involvement in such meetings. However, FDA will be

open to participating in a well-designed and well-conducted meeting on a case-by-case basis. Given the expanse of diseases affecting the U.S. patient population and the effort required to conduct a successful PFDD meeting, externally-led PFDD meetings should target disease areas where there is an identified need for patient input on topics related to drug development. FDA will determine its level of participation in these meetings on an individual basis, taking into account a number of factors, including any identified need for a better understanding of patient perspective, recent interactions with patient stakeholders, proposed meeting details, and FDA staff capacity. More information regarding considerations to take into account when deciding to plan an externally-led PFDD meeting can be found on this Web site: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.*

FDA recommends that patient organizations who are interested in conducting an externally-led PFDD meeting submit an LOI that communicates (1) the value of the proposed meeting in the context of drug development for a particular disease area, and (2) important details regarding the meeting plan. Guidelines for developing a letter of intent are provided here: *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM453857.pdf.* Please submit the letter of intent to *patientfocused@fda.hhs.gov.* FDA's CDER Office of Strategic Programs will receive and review the letter.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32476 Filed 12–24–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than February 26, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–24, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Sickle Cell Disease Treatment Demonstration Program—Quality Improvement Data Collection.

OMB No. 0915–xxxx–New

Abstract: In response to the growing need for resources devoted to sickle cell disease and other hemoglobinopathies, the United States Congress, under Section 712 of the American Jobs Creation Act of 2004 (Pub. L. 108–357) (42 U.S.C. 300b–1 note), authorized a demonstration program for the prevention and treatment of sickle cell disease (SCD) to be administered by the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services. The program is known as the *Sickle Cell Disease Treatment Demonstration Program* (SCDTDP). The SCDTDP is designed to improve access to services for individuals with sickle cell disease, improve and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait. The specific aims for the program are threefold: (1) Increase the number of providers treating persons with sickle cell disease, (2) increase the number of providers prescribing hydroxyurea, and (3) increase the number of providers knowledgeable about treating sickle cell disease as well as increase the number of sickle cell patients that are seen by providers knowledgeable about sickle cell disease.

To achieve the goals and objectives of the program, the SCDTDP uses quality improvement (QI) methods in a collective impact model which supports cross-sector collaboration for achieving measurable effects on major social issues. The collective impact model requires shared measurement which facilitates tracking progress in a standardized method in order to promote learning and enhance continuous improvement.

Need and Proposed Use of the Information: The purpose of the proposed data collection strategy is to implement a system to monitor the progress of MCHB-funded activities in improving care and health outcomes for individuals living with sickle cell disease/trait and meeting the goals of the SCDTDP. Each regional grantee site will be asked to report on a core set of evidence-based measures related to healthcare utilization among individuals with sickle cell disease and the quality of care of the SCD population.

The data collected for the Sickle Cell Disease Treatment Demonstration Program will consist of administrative medical claims data collected from State Medicaid Programs and Medicaid Managed Care Organizations that administer Medicaid on behalf of states. The data is collected either for or by State Medicaid offices for delivery of services subject to Medicaid reimbursement.

The data collection strategy will provide an effective and efficient mechanism to do the following: (1) Assess the improvements in access to care for sickle cell patients provided by activities in the SCDTDP; (2) collect, coordinate, and distribute data, best practices, and findings from regional grantee sites to drive improvement on quality measures; (3) refine a common model protocol regarding the prevention and treatment of sickle cell disease; (4) examine/address barriers that individuals and families living with sickle cell disease face when accessing quality health care and health education; (5) evaluate the grantees' performance in meeting the objectives of the SCDTDP; and (6) provide HRSA and Congress with information on the overall progress of the program.

Likely Respondents: Four regional grantee sites funded by HRSA under the SCDTDP will be the respondents for this data collection activity and submit responses gathered from State Medicaid