collect patient experience data to inform regulatory decision making may use.

In addition, FDA committed to meet certain performance goals under PDUFA VI. These goal commitments were developed in consultation with patient and consumer advocates, health care professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making,'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

Prior to the issuance of each guidance, as part of the development, FDA will conduct a public workshop to gather input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders.

II. Purpose and Scope of Meeting

FDA is announcing a public workshop to convene a discussion on topics related to approaches to collecting comprehensive and representative patient and caregiver input on burden of disease and current therapy. The purpose of this public workshop is to obtain feedback from stakeholders on considerations for: (1) Standardized nomenclature and terminologies for patient-focused drug development, (2) methods to collect meaningful patient input throughout the drug development process, and (3) methodological considerations for data collection, reporting, management, and analysis of patient input. FDA is seeking information and comments from a broad range of stakeholders, including patients, patient advocates, academic and medical researchers, expert practitioners, drug developers, and other interested persons. FDA will publish a discussion document outlining the topic areas that will be addressed in the draft guidance. This document will be published approximately 1 month before the workshop date on the Web site at: *https://www.fda.gov/Drugs/NewsEvents/ucm574725.htm.* FDA is interested in seeking information and comments on the approaches and considerations proposed in the discussion document, as well as the examples provided. FDA is also interested in seeking information and comments on additional examples where the approaches proposed in the discussion document have been successfully applied that could be included in guidance. After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public docket, and publish a draft guidance by the end of the third quarter of fiscal year 2018.

Registration: Interested parties are encouraged to register early. To register electronically, please visit: *https://pfdd.eventbrite.com.* Persons without access to the internet can call 240–402–6525 to register. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Request for Oral Presentations: There will be time allotted during the workshop for open public comment. Sign-up for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate, and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Transcripts: As soon as a transcript is available, FDA will post it at *https://www.fda.gov/Drugs/NewsEvents/ucm574725.htm.*

Dated: October 23, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23437 Filed 10–26–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–2660]

Determination That CARDENE SR (Nicardipine HCl) Extended-Release Capsules, 30 Milligrams, 45 Milligrams, and 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CARDENE SR (nicardipine HCl) extended-release capsules, 30 milligrams (mg), 45 mg, and 60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nicardipine HCl extended-release capsules, 30 mg, 45 mg, and 60 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 301–796–6650.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with 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.

CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, are the subject of NDA 020005, initially approved on February 21, 1992. CARDENE SR is indicated for the treatment of hypertension.

In a letter dated September 15, 2014, EKR Therapeutics, Inc., requested withdrawal of NDA 020005 for CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg. In the **Federal Register** of October 4, 2016 (81 FR 68427), FDA announced that it was withdrawing approval of NDA 020005, effective November 3, 2016.

Jubilant Generics submitted a citizen petition dated April 27, 2017 (Docket No. FDA–2017–P–2660), under 21 CFR 10.30, requesting that the Agency determine whether CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, 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 CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, 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 CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, or 60 mg, 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: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23438 Filed 10–26–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0487]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 27, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0697. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

OMB Control Number 0910–0697—Extension

The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This voluntary feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address the following: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate,