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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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that the Agency determine whether CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, were withdrawn from sale for reasons of safety or effectiveness.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under § 314.161 that CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, were not withdrawn for reasons of safety or effectiveness.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other information suggesting that CARDENE SR (nicardipine HCl) extended-release capsules, 30 mg, 45 mg, and 60 mg, were withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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,

methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

In the **Federal Register** of June 15, 2017 (82 FR 27508), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups	800	1	800	1.75	1,400
Customer comment cards/forms	1,325	1	1,325	0.25 (15 minutes)	331.25
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	12,000	1	12,000	0.33 (20 minutes)	3,960
Usability studies	800	1	800	1.75	1,400
Total					8,491.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 24, 2017.

Anna K. Abram,

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

[FR Doc. 2017–23443 Filed 10–26–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Teleconference

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following Subcommittee meetings of the National Committee on Vital and Health Statistics to be held virtually.

Name: National Committee on Vital and Health Statistics (NCVHS), Virtual Meetings of the Subcommittee.

Dates and Times:

NCVHS Population Health Subcommittee; Tuesday, November 28, 2017: 9:00 a.m.—1:00 p.m. ET

NCVHS Privacy, Confidentiality, and Security Subcommittee; Tuesday, November 28, 2017: 1:30 p.m.—5:30 p.m. ET

NCVHS Standards Subcommittee; Wednesday, November 29, 2017: 1:00 p.m.—5:00 p.m. ET

Place: WebEx/teleconference—To participate in the virtual meeting, please use the following URL *http://www.ncvhs.hhs.gov/* that points to the NCVHS homepage. Further information and meeting agendas will be available on the NCVHS Web site including instructions for accessing the live meeting broadcast.

Status: Open by WebEx/teleconference. There will be an open comment period during the final 10 minutes of each of the three virtual meetings where the public can provide comments via the WebEx on-line meeting interface. Written comments may also be provided to the Executive Secretary at the contact information provided below.

Purpose: The NCVHS virtual meeting of the Population Health Subcommittee will convene to discuss: (1) Follow up work on the NCVHS September 11–12, 2017 Next Generation Vital Statistics Hearing, including the draft hearing report and follow up analyses being conducted on the Committee's behalf, and; (2) topics and projects to be considered for the 2018 workplan.

The NCVHS virtual meeting of the Privacy, Confidentiality and Security Subcommittee will convene to discuss a draft environmental scan report of the health information privacy and security landscape in the U.S. that extends beyond HIPAA. This will include formal presentations from invited experts to further inform the draft environmental scan research being conducted on the Committee's behalf. The agenda also will include discussion of privacy-related topics under consideration for the 2018 workplan.

The NCVHS virtual meeting of the Standards Subcommittee will convene to consider the Subcommittee's workplan and high level milestones for three possible projects in 2018: (1) A Chief Information Officer (CIO) Forum; (2) the challenge of patient identification and matching for healthcare providers and patients; and (3) potential guidance pertaining to the prior authorization transaction. In addition, CMS will provide a briefing to the Subcommittee on the New Medicare Card Project.

For more Information Contact: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the NCVHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Dated: October 23, 2017.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2017–23358 Filed 10–26–17; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–1059]

Towing Safety Advisory Committee; December 2017 Meeting

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Towing Safety Advisory Committee and its Subcommittees will meet in New Orleans, Louisiana to review and discuss recommendations from its Subcommittees and to receive briefs on items listed in the agenda under **SUPPLEMENTARY INFORMATION**. All meetings will be open to the public.

DATES:

Meetings. The Subcommittees of the Towing Safety Advisory Committee will