

public on service delivery, the Federal Trade Commission (“FTC” or “Commission”) is submitting a Generic Information Collection Request (Generic ICR): “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” to OMB for approval under the Paperwork Reduction Act.

DATES: Comments must be submitted by June 15, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Bridget Small, Federal Trade Commission, 600 Pennsylvania Avenue NW, CC-10402, Washington, DC 20580, (202) 326-3266.

SUPPLEMENTARY INFORMATION:

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

Abstract: 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 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 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 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.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 35.

Estimated Number of Annual Respondents: 5,764.¹

Frequency of Response: Once per request.

Annual Responses: 5,764.

Average Minutes Per Response: 18 (rounded to nearest whole minute).

Estimated Total Annual Burden Hours: 1,759.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The control number for the existing clearance (expiring May 31, 2020) is 3084-0159. The FTC seeks renewed three-year clearance under this control number for the prospective collection of information and the associated burden estimates.

Request for Comment:

On December 26, 2019, the Commission sought comment on the renewal of this generic clearance. 84 FR 70972. One relevant comment was received from an interested person. The commenter stated that he believed the collection and analysis of these qualitative statistics will be useful in improving the delivery of the many services of the FTC.

¹ Projected activities: (1) Eleven customer satisfaction surveys per year of 500 respondents each (surveys to get feedback about major campaigns, publications, websites, branding and other consumer and business education products to test their appeal and effectiveness), 0.25 hours (*i.e.* 15 minutes) per response; (2) Twelve focus groups per year, 10 respondents each (to test education products and websites), 2 hours per response; and (3) Twelve usability sessions per year, 12 respondents per website (to test the usability of FTC websites by inviting people to complete common tasks on those sites), 1 hour per response.

Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.*, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for those information collection requirements. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which is . . . privileged or confidential” as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10275, CMS-R-64, and CMS-10710]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect

information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 15, 2020*.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each

collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* CAHPS Home Health Care Survey; *Use:* The national implementation of the Home Health Care CAHPS Survey is designed to collect ongoing data from samples of home health care patients who receive skilled services from Medicare-certified home health agencies.

The survey is necessary because it fulfills the goal of transparency with the public about home health patient experiences. The survey is used by Medicare-certified home health agencies to improve their internal quality assurance in the care that they provide in home health. The HHCAHPS survey is also used in a Medicare payment program. Medicare-certified home health agencies (HHAs) must contract with CMS-approved survey vendors that conduct the HHCAHPS on behalf of the HHAs to meet their requirements in the Home Health Quality Reporting Program. *Form Number:* CMS-10257 (OMB control number: 0938-1066); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,195,930; *Total Annual Responses:* 1,294,820; *Total Annual Hours:* 453,239. (For policy questions regarding this collection contact Lori Teichman at 410-786-6684.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Indirect Medical Education and Direct Graduate Medical Education; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In

addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2018, the estimated Medicare program payments for indirect medical education (IME) costs was \$6.4 billion. Medicare program payment for direct graduate medical education (GME) is also based upon the number of FTE-IRs that work at a hospital. In FY 2018, the estimated Medicare program payments for GME costs was \$3.1 billion.

Since it is important to accurately count the number of IRs FTEs working at each hospital, original approval was obtained from the Office of Management and Budget (OMB) in 1985 to collect the IR information required in 42 CFR 412.105(f) and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS-R-64 (OMB control number: 0938-0456); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,245; *Total Annual Responses:* 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Owen Osaghae at 410-786-7550.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number) collection; *Title of Information Collection:* Generic Clearance for Improving Customer Experience (OMB Circular A-11, Section 280 Implementation); *Use:* Whether seeking a loan, Social Security benefits, veterans benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing

the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A-11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (i.e., in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. The Centers for Medicare and Medicaid Services (CMS) will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on *performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

CMS will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. CMS may also utilize observational techniques to collect this information.

Form Number: CMS-10710 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; Private Sector (business or other for-profits, not-for-profit institutions), State, Local or Tribal governments; Federal government; and Universities; *Number of Respondents:* 1,001,750; *Number of Responses:* Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 2 hours to participate in an interview.; *Total Annual Hours:* 51,175. (For questions regarding this collection contact Aaron Lartey at 410-786-7866).

Dated: May 8, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1117]

**Janssen Pharmaceuticals, Inc., et al.;
Withdrawal of Approval of 16 New
Drug Applications**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 15, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 011529	Parafon Forte DSC (chlorzoxazone), Caplets, 500 milligrams (mg).	Janssen Pharmaceuticals, Inc., 1000 Route 202 South, P.O. Box 300, Raritan, NJ 08869.
NDA 018029	Ritalin-SR (methylphenidate hydrochloride (HCl)) Extended-Release Tablets, 20 mg.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 018082	Depakene (valproic acid) Oral Solution, 250 mg/5 milliliter (mL).	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 019579	Terazol 7 (terconazole) Vaginal Cream, 0.4%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 020119	Vumon (teniposide) Injection, 10 mg/mL	HQ Specialty Pharma, 120 Route 17 North, Paramus, NJ 07652.
NDA 020388	Navelbine (vinorelbine tartrate) Injection, Equivalent to (EQ) 10 mg/mL base.	Pierre Fabre Medicament c/o Pierre Fabre Pharmaceuticals, Inc., 8 Campus Dr., Suite 202, Parsippany, NJ 07054.
NDA 020741	Prandin (repaglinide) Tablets, 0.5 mg, 1.0 mg, and 2.0 mg ..	Gemini Laboratories, LLC, 400 Crossing Blvd., 5th Floor, Bridgewater, NJ 08807.
NDA 020920	Natrecor (nesiritide) Injection, 1.5 mg/vial	Scios, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021001	Axert (almotriptan malate) Tablets, EQ 6.25 mg base and EQ 12.5 mg base.	Janssen Pharmaceuticals, Inc.
NDA 021203	Tricor (fenofibrate) Tablets, 54 mg and 160 mg	AbbVie Inc.
NDA 021543	Striant (testosterone buccal system) Extended-Release Tablets, 30 mg.	Auxilium Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.
NDA 021604	Children's ElixSure IB (ibuprofen) Oral Suspension, 100mg/5 mL.	Moberg Pharma North America LLC, 7 East Frederick Place, Suite 100, Cedar Knolls, NJ 07927.