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.

[FR Doc. 2020–10282 Filed 5–13–20; 8:45 am]

BILLING CODE 4120–01–P

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.

Application No.	Drug	Applicant
NDA 021611	Opana (oxymorphone HCl) Tablets, 5mg and 10mg	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.
NDA 022321	Embeda (morphine sulfate and naltrexone HCl) Extended-Release Capsules, 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg, and 100 mg/4 mg.	Alpharma Pharmaceuticals, LLC, 235 East 42nd St., New York, NY 10017.
NDA 022510	Abstral (fentanyl) Sublingual Tablets,100 micrograms (mcg), 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg.	Sentynl Therapeutics, Inc., 420 Stevens Ave., Suite 200, Solana Beach, CA 92075.
NDA 050641	Monodox (doxycycline monohydrate) Capsules, EQ 50mg base, EQ 75mg base, and EQ 100mg base.	Aqua Pharmaceuticals, LLC, 707 Eagleview Blvd., Suite 200, Exton, PA 19341.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 15, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 15, 2020 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10367 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0501]

Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's third-party disclosure and recordkeeping requirements for reportable food.

DATES: Submit either electronic or written comments on the collection of information by July 13, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 13, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 13, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–N–0501 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you