Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–14332 Filed 7–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1360]

Teva Branded Pharmaceutical Products R&D, Inc.; Withdrawal of Approval of a New Drug Application for ZECUITY (Sumatriptan Iontophoretic Transdermal System)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of the new drug application (NDA) for ZECUITY (sumatriptan iontophoretic transdermal system) held by Teva Branded Pharmaceutical Products R&D, Inc. (Teva), 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355. Teva requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of July 2, 2020.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: On January 17, 2013, FDA approved NDA 202278 for ZECUITY (sumatriptan iontophoretic transdermal system) for the acute treatment of migraine with or without aura in adults. On June 2, 2016, FDA issued a Drug Safety Communication announcing the FDA is investigating the risk of serious burns and potential permanent scarring with the use of ZECUITY for migraine headaches. (*https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-evaluating-risk-burns-and-scars-ZECUITY-sumatriptan-migraine-patch*). On June 10, 2016, Teva suspended sales, marketing and distribution to investigate the cause of burns and scars associated with ZECUITY.

On July 19, 2019, Teva requested withdrawal of NDA 202278 for ZECUITY under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. In its letter requesting withdrawal of approval, Teva stated that it voluntarily discontinued manufacture and sale of products under NDA 202278 in 2016 for commercial reasons and has agreed to withdrawal of the application for those reasons only.

For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 202278 for ZECUITY (sumatriptan iontophoretic transdermal system), and all amendments and supplements thereto, is withdrawn under § 314.150(d).

Distribution of ZECUITY into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14284 Filed 7–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

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: Submit written comments (including recommendations) on the collection of information by August 3, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Radioactive Drug Research Committees—21 CFR 361.1

OMB Control Number 0910–0053—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. This information collection request supports those regulations. Specifically, § 361.1 (21 CFR 361.1) sets forth specific regulations about establishing and composing radioactive drug research committees (RDRCs) and their role in approving and monitoring basic research studies using radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulations and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each RDRC will select a chairman, who will sign all applications, minutes, and reports of the committee. Each committee will meet at least once each quarter in which research activity has been authorized or conducted. Minutes will be kept and will include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC will submit an annual report to FDA. The annual report will include the names and qualifications of the members of and of any consultants used by the RDRC, using Form FDA 2914 entitled ''Radioactive Drug Research Committee Report on Research Use of Radioactive Drugs Membership Summary.'' The annual report will also include a summary of each study conducted during the preceding year, using Form

FDA 2915 entitled ''Radioactive Drug Research Committee Report on Research Use of Radioactive Drugs Study Summary.''

Under § 361.1(d)(5), each investigator will obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant or, based on a pregnancy test, be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator will immediately report to the RDRC all adverse effects associated with use of the drug, and the committee will then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under the regulations are also specified and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on our experience with these reporting and recordkeeping requirements and the number of submissions we received under the regulations over the past 3 years.

In the **Federal Register** of January 21, 2020 (85 FR 3390), we 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] [2]

21 CFR section and applicable form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 361.1(c)(3) reports and (c)(4) approval (Form FDA 2914: Membership Summary) [3].	62	1	62	1	62
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary) [4].	40	10	434	3.5	1,519
§ 361.1(d)(8) adverse events	10	1	10	.5 (30 minutes)	5
Total			506		1,586

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.
[3] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094979.pdf.*
[4] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf.*

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section	Number of recordkeepers	Number of records per recordkeepers	Total annual responses	Average burden per recordkeeping	Total hours
§ 361.1(c)(2) RDRC	62	4	248	10	2,480
§ 361.1(d)(5) human research subjects	40	10	434	.75 (45 minutes)	326
Total			682		2,806

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.

We have adjusted our estimate for the information collection to reflect an annual decrease of 525 hours and 147 responses since last OMB review. This adjustment corresponds to fewer submissions we have received under the information collection over the last few years.

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14262 Filed 7–1–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exceptions or Alternatives To Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, Health and Human Services (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