health outcomes, including opioid overdose, sexual assault, and suicide attempts. The nature and consequences of ACEs in Tribal communities is unique because of historical trauma and stark socioeconomic disparities. In addition, there are gaps in the provision of adequate healthcare.

This collection addresses critical research gaps and extends efforts to prevent violence and other ACEs before they occur and to build evidence of effectiveness of community-level strategies and approaches at the outer levels of the social ecology to Tribal communities. Results from this data collection will be communicated to relevant public health officials and community stakeholders in the study locations. These local public health officials and community stakeholders will use the study results to guide strategies to further strengthen their local prevention efforts within their regions.

Data collection methods used in this study include well-established qualitative methods, including in-depth open-ended individual interviews and focus groups. Quantitative methods include brief structured surveys. There will be a total of six Tribal communities (three urban and three rural) in regions identified with higher opioid overdose mortality rates relatively to other areas in Indian Country. Due to COVID–19, at the time of the focus groups/interviews, social distancing and public health safety measures will be implemented, including considerations for phone/virtual meetings instead of in-person sessions.

The total estimated annualized burden hours are 918. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adults 18 years or older affected by the opioid epidemic living in Tribal urban and rural communities.	Information Letter	336	1	5/60	28
	Telephone screening	336	1	20/60	112
	Confirmation email/letter	252	1	3/60	13
	Reminder email	252	1	2/60	9
	Informed Consent	252	1	15/60	63
	Survey	252	1	45/60	189
	Focus group/interview	252	1	2	504
Total					918

Jeffrey M. Zirger,

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

[FR Doc. 2020–14331 Filed 7–1–20; 8:45 am]

BILLING CODE 4163–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20PM; Docket No. CDC–2020–0072]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Oral Health Basic Screening Survey for Children. The project provides state-specific data on dental caries (tooth decay) and dental sealants from a state-representative sample of elementary school children or children enrolled in Head Start programs and has been used by states to monitor oral health status of children and evaluate public health programs and policies.

DATES: CDC must receive written comments on or before August 31, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0072 by any of the following methods:

- *Federal eRulemaking Portal: http://www.Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *http://www.regulations.gov/.*

Please note: Submit all comments through the Federal eRulemaking portal (*http://www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Oral Health Basic Screening Survey for Children—Existing Collection in Use Without an OMB Control Number—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

Dental caries (tooth decay) is one of the most common chronic diseases among children in the United States and can lead to pain, infection, and diminished quality of life throughout the lifespan. Dental sealants are a cost-effective measure to prevent caries but remain underutilized.

To address states' critical need for state-level oral health surveillance data on dental caries and sealants, the Association of State and Territorial Dental Directors (ASTDD) developed and released an oral health screening survey protocol referred to as the Basic Screening Survey (BSS) in 1999 in collaboration with the Ohio Department of Health and with technical assistance from the CDC's Division of Oral Health.

BSS is a non-invasive visual observation of the mouth performed by trained screeners including dental and non-dental health professionals (*e.g.,* dentists, hygienists, school nurses). The BSS data collection is not duplicative of any other federal collection. Though the National Health and Nutrition Examination Survey (NHANES) collects national data on oral health status including dental caries and sealants based on clinical examination, it is not designed to provide state-level data. BSS is designed to be easy to perform, while being consistent and aligned with the oral health Healthy People objectives, which are based on NHANES measures. BSS is the only data source that provides state-representative data on oral health status based on clinical examination. BSS is also used to monitor state progress toward key national oral health objectives.

The BSS is a state-tailored survey administered and conducted by individual states. CDC has supported some of the 50 states to build and maintain their oral health surveillance system and ASTDD to provide technical assistance to states through state and partner cooperative agreements since 2001. Conducting BSS for third graders is a key component of that support.

The target populations include school children in grades K–3 and children enrolled in Head Start in 50 states and Washington, DC. ASTDD and CDC recommend that states conduct BSS at minimum for third graders at least once every five years. Individual states determine how often to conduct BSS and which grade or grades to target based on their program needs and available resources. Forty-seven states have conducted BSS for children, and all 47 conducted third grade BSS. Thirty-two states also have conducted BSS in one or more other grades (K–2) or in Head Start. CDC estimates that approximately 34 states, including 20 states currently funded by CDC, will conduct one BSS, at least for third grade, during the period for which this approval is being sought.

State health departments administer the survey by determining probability samples, arranging logistics with selected schools or Head Start sites, gaining consent, obtaining demographic data, training screeners, conducting the oral health screening at schools or Head Start sites. Screeners record four data points either electronically or on a paper form: (1) Presence of treated caries, (2) presence of untreated tooth decay, (3) urgency of need for treatment, and (4) presence of dental sealants on at least one permanent molar tooth.

State programs enter, clean and analyze the data; de-identify it; and respond to ASTDD's annual email request for state-aggregated prevalence of dental caries and sealants. ASTDD reviews the data to ensure that both survey design and data meet specific criteria before sending it to CDC for publication on the CDC's public-facing Oral Health Data website (*http://www.cdc.gov/oralhealthdata*).

BSS for children serves as a key state oral health surveillance data source and facilitates state capacity to (1) monitor children's oral health status, trends, and disparities, and compare with other states; (2) inform planning, implementation and evaluation of effective oral health programs and policies; (3) measure state progress toward Healthy People objectives; and (4) educate the public and policy makers regarding cross-cutting public health programs. CDC also uses the data to evaluate performance of CDC oral health funding recipients.

There are no costs to children respondents except their time. The estimated total annualized burden hours for the survey across the 34 states over the three years of this request are 40,207 with an average of 1,183 per state.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Child	Screening form	150,370	1	5/60	12,531
Parent/caretaker	Consent	150,370	1	1/60	2,506
Screener	Screening form	301	1	666/60	3,341
School/site	Participation form	2,890	1	68/60	3,275
State Official	Data Submission form	34	1	32,742/60	18,554
Total					40,207

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