FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0188; FRS 30456]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before August 6, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0188.

Title: Call Sign Reservation and Authorization System, FCC Form 380.

Form Number: FCC Form 380.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, Not-for-profit institutions; and State, local, or tribal government.

Number of Respondents and Responses: 1,600 respondents; 1,600 responses.

Estimated Hours per Response: 0.166–0.25 hours.

Frequency of Response: On occasion reporting requirements.

Total Annual Burden: 333 hours.

Total Annual Cost: $162,000.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Nature and Extend of Confidentiality: There is need for confidentiality with this collection of information.

*Privacy Impact Assessmen*t: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 73.3550 provide that all requests for new or modified call signs be made via the on-line call sign reservation and authorization. The Commission uses an on-line system, FCC Form 380, for the electronic preparation and submission of requests for the reservation and authorization of new and modified call signs. Access to the call sign reservation and authorization system is made by broadcast licensees and permittees, or by persons acting on their behalf, via the internet's World Wide Web. This on-line, electronic call sign system enables users to determine the availability and licensing status of call signs; to request an initial, or change an existing, call sign; and to determine and submit more easily the appropriate fee, if any. Because all elements necessary to make a valid call sign reservation are encompassed within the on-line system, this system prevents users from filing defective or incomplete call sign requests. The electronic system also provides greater certitude, as a selected call sign is effectively reserved as soon as the user has submitted its call sign request. This electronic call sign reservation and authorization system has significantly improved service to all radio and television broadcast station licensees and permittees.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–11828 Filed 6–4–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–20PE]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Operational Readiness Review 2.0 to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 23, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Operational Readiness Review 2.0—Existing Information Collection in Use Without an OMB Control Number—Center for Preparedness and Response (CPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

To help evaluate the country's public health emergency preparedness and response capacity, the Centers for Disease Control and Prevention's Division of State and Local Readiness (DSLR) administers the Public Health Emergency Preparedness (PHEP) cooperative agreement. The PHEP program is a critical source of funding for 62 state, local, and territorial jurisdictions, including four major metropolitan areas (Chicago, Los Angeles County, New York City, and Washington, DC) to build and strengthen their ability to respond to and recover from public health emergencies.

The Operational Readiness Review (ORR) is a rigorous, evidence-based assessment used to evaluate PHEP recipients' planning and operational functions. The previous version of the ORR evaluated a jurisdiction's ability to execute a large emergency response requiring medical countermeasure (MCM) distribution and dispensing. The purpose of the new ORR 2.0 is to expand measurement and evaluation to all 15 Public Health Emergency Preparedness and Response Capabilities, which serve as national standards for public health preparedness planning. The capabilities are: 1—Community Preparedness, 2—Community Recovery, 3—Emergency Operations Coordination, 4—Emergency Public Information and Warning, 5—Fatality Management, 6—Information Sharing, 7—Mass Care, 8—Medical Countermeasure Dispensing and Administration, 9—Medical Materiel Management and Distribution, 10—Medical Surge, 11—Nonpharmaceutical Intervention, 12—Public Health Laboratory Testing, 13—Public Health Surveillance and Epidemiological Investigation, 14—Responder Safety and Health, and 15—Volunteer Management. These capabilities serve as national standards for public health preparedness planning.

The ORR 2.0 will have three modules: Descriptive, planning, and operational, which will allow DSLR to analyze the data for the development of descriptive statistics and to monitor the progress of each recipient towards performance goals. The four major metropolitan areas have additional reporting requirements that are incorporated into the operational module. The intended outcome of the ORR 2.0 is to assist CDC in identifying strengths and challenges facing preparedness programs across the nation, and to identify opportunities for improvement and further technical support.

Information will be collected from respondents using the new Operational Readiness Review (ORR) 2.0 platform, but a backup paper option is available for jurisdictions that require it. Information collected from respondents is a requirement of the PHEP Cooperative Agreement for participants to receive funding. CDC requests a three-year approval for this information collection. The total annualized burden estimate is 3,055 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
All PHEP Awardees: State, local, territorial, and metropolitan area jurisdictions.	Descriptive Module: Jurisdictional structure sheet.	62	1	3
	Critical contact sheet (CCS)	62	1	80/60
	Jurisdictional data sheet (JDS)	62	1	2.5
	Partner planning sheet	62	1	8
	Workforce development and training	62	1	1.5
All PHEP Awardees: State, local, territorial, and metropolitan area jurisdictions.	Planning Module: Capability 1	62	1	1
	Capability 2	62	1	1
	Capability 3	62	1	2
	Capability 4	62	1	1.5
	Capability 5	62	1	2.5
	Capability 6	62	1	1
	Capability 7	62	1	2
	Capability 8	62	1	3
	Capability 9	62	1	195/60
	Capability 10	62	1	2
	Capability 11	62	1	1.5
	Capability 12	62	1	1.5
	Capability 13	62	1	2.5
	Capability 14	62	1	1.5
	Capability 15	62	1	75/60
All PHEP Awardees: State, local, territorial, and metropolitan area jurisdictions.	Operations Module: Ops 1	62	3	20/60
	Ops 2	62	3	15/60
	Tabletop exercise (TTX)	62	1	1.5
	Partner role (Par1)	62	1	15/60
	Access and functional needs exercise accommodations or actions (Par2).	62	1	0.5
	Joint exercise with emergency management and health care coalitions (Par3).	62	1	6/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
	Vaccination of critical workforce (functional exercise, full-scale exercise, or incident).	62	1	12/60
	Vaccination of critical workforce (point of dispensing/dispensing/vaccination clinic setup).	62	1	12/60
	Vaccination of critical workforce (immunization information system).	62	1	12/60
	Five-year distribution FSE OR five-year pandemic influenza full-scale exercise.	62	1	0.5
PHEP Awardees: Major Metropolitan Area Jurisdictions.	Facility setup drill	4	1	45/60
	Site activation drill	4	1	1
	Staff notification and assembly drill	4	1	1
	Dispensing throughput drill	4	1	12/60
	Five-year dispensing full-scale exercise or incident.	4	1	6/60
	Five-year dispensing full-scale exercise for each point of dispensing site exercised.	4	1	6/60

Jeffrey M. Zirger,

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

[FR Doc. 2021–11872 Filed 6–4–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–2317]

Determination That QUELICIN PRESERVATIVE FREE (Succinylcholine Chloride) Injection, 20 Milligrams/Milliliter, 50 Milligrams/Milliliter, and 100 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 milligrams (mg)/milliliter (mL), 50 mg/mL, and 100 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3601, *Nicole.Mueller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency 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.

QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, is the subject of NDA 008845, held by Hospira, Inc., and initially approved on May 1, 1953. QUELICIN PRESERVATIVE FREE is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Baxter Healthcare Corp. submitted a citizen petition dated December 21, 2020 (Docket No. FDA–2020–P–2317), under 21 CFR 10.30, requesting that the Agency determine whether QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, was 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 QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, was not withdrawn for reasons of safety or