

United States Food and Drug Administration
Generic Clearance: FDA Rapid Response Surveys
OMB Control Number 0910-0500
Gen IC Request for Approval

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

Title of Gen IC: CDER COVID-19 Critical Care Drug Monitoring Survey Portal

1. Statement of Need:

A critical component of FDA's public health mission is to help ensure patients have access to safe and effective medicines. Drug shortages and supply chain disruptions hinder the ability of patients to have access to critical medicines and can occur for several reasons, including manufacturing and quality challenges, supply discontinuations, and increases in demand.

Supply chains for medical products are highly complex. Process and distribution logistics, including source (starting) materials, active (bulk), pharmaceutical ingredients, and finished (final) product are often not well understood given the number of manufacturers, variability in production capacity, geographic and environmental factors, and uncertain demand. Due to this level of complexity, supply chain strains, disruptions, and medical product shortages are multi-factorial and can occur at any point in the chain. These issues can be further exacerbated by factors such as pandemics, other biological threats, cyber-attacks, extreme weather events, and geopolitical instability that can reduce critical manufacturing capacity and the availability and integrity of critical goods, products, and services.

Based on CDER's regulatory and surveillance data, the supply chain of numerous drugs has been further disrupted since the beginning of the COVID-19 pandemic because of rapid increases in the number of hospitalized patients and, consequently, an increased demand for products used in the treatment of COVID-19. Hence, this pandemic has led to national and regional supply disruptions and shortages of drugs and biological products used in the treatment of COVID-19 in the United States.

On April 9, 2020, FDA obtained a PRA waiver to conduct a repeated cross-sectional, voluntary survey based on a purposive sample (i.e., a convenience sample that is not probability based and, therefore, not nationally representative) from external stakeholders of U.S. hospital and health system pharmacies. Data from these stakeholders regarding their organization's drug supply were first collected in April 2020 from severe COVID-19 hotspots (CA, FL, LA, MA, MI, NY, PA), and eventually in 45 states (starting May 2020).

FDA recognizes that the COVID-19 pandemic may continue to affect the supply chain of various drug and biological products after the expiration of the public health emergency. To mitigate potential disruptions in the supply chain, FDA seeks to continue collecting data from these voluntary surveys after the expiration of the public health emergency to monitor the drug supply and help identify early signals of drug supply chain vulnerability.

2. Intended Use of the Information:

FDA intends to use this information to mitigate potential disruptions in the supply chain by monitoring the drug supply and identifying early signals of drug supply chain vulnerability. FDA's current efforts for drug supply surveillance include the Center for Drug Evaluation and Research's Drug Supply Chain Surveillance System, which provides enhanced insight into the drug supply chain—from active ingredient suppliers to clinical settings such as hospitals and pharmacies. This system will utilize existing as well as new data sources to identify early signals that may indicate shortages so they can be prevented and mitigated. FDA is also in constant communication and closely working with manufacturers to prevent or reduce the impact of shortages.

3. Description of Respondents:

Respondents include hospitals and community pharmacies in 45 states; respondents will not change from the respondents contacted during the Public Health Emergency. The survey participants represented a total of over 550 in-patient hospitals including over 40 healthcare organizations (i.e., more than 1 hospital), consisting of 65,413 hospital beds and 8,293 intensive care unit beds, in 45 U.S. states and territories. The survey participants were predominately pharmacists (86.4%) followed by administrative personnel (4.5%) and other hospital personnel (9.1%), such as physician assistants and nurses. The states represented in the weekly surveys $\geq 75\%$ of the time (i.e., ≥ 68 weeks) included Maryland, Texas, Arizona, North Carolina, Indiana, Minnesota, Massachusetts, New York, and New Jersey.

4. How the Information is Collected:

FDA initially obtained information by telephone and has expanded engagement efforts through a [secure online portal](#). The list of drugs on the survey was generated through FDA outreach phone calls with external stakeholders from hospital and community pharmacies in eleven states with 5,000 or more cumulative COVID-19 cases. A total of 44 drugs were reported during the phone interviews as a critical need or on short supply by a healthcare professional at U.S. hospitals. Of the 44 drugs mentioned in the outreach interviews, 32 of those drugs were included in the survey based on hospital needs and an additional three drugs were included in the initial survey based on clinical and regulatory judgement.

5. Consistent with Currently Approved Supporting Statement

There are no deviations from the Rapid Response Survey 2020 version of the Supporting Statement.

6. **Burden:**

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Hospital or Health Care Organization Survey Respondent	300	15	75 per week x 52 weeks/year = 3,900 hours

177 unique users made 2,460 responses through February 10, 2023, based on information provided by the Office of Business Informatics. FDA estimates that there could be up to 300 respondents, based on the current total of 177 unique users, with respondents potentially corresponding to more than one hospital or pharmacy. In total, there are 49 survey questions, including both required (n=22) and optional (n=27) questions. Between 10 and 15 minutes is an estimate of time to complete a survey response in its entirety.

Below are the counts of respondents per year:

Year	Hospital Respondent	Pharmacy Respondent
2020	157	3
2021	61	2
2022	32	1
2023	9	--

7. **Date(s) to be Conducted:** Weekly, starting May 11, 2023, and ending September 30, 2023, due to the expiration date of the generic umbrella.

8. **Requested Approval Date:** March 2023

9. **FDA Contacts:**

Program Office Contact	FDA PRA Contact
Jamie Gamerman Jamie.Gamerman@fda.hhs.gov 240-402-5958	JonnaLynn Capezzuto Jonnalynn.capezzuto@fda.hhs.gov 301-796-3794