

United States Food and Drug Administration

FDA Rapid Response Surveys  
(Umbrella Generic)

OMB Control No. 0910-0500  
Request for Extension

SUPPORTING STATEMENT

Terms of Clearance: This generic clearance for FDA is approved for 3 years under the following conditions: (1) For individual “surveys,” FDA shall submit a generic IC in ROCIS along with: (a) an abbreviated supporting statement in the template agreed to by OMB and FDA (including the problem being investigated, the method of selecting the sample, any deviations from the methods, procedures, or uses described in the overall supporting statement, and the estimated burden); (b) participant screeners; and (c) instruments/moderator guides. (2) OMB will respond with clearance or questions within 10 working days (or quicker if desk officer is alerted to an urgent public health need).

**Part A. Justification**

1. Circumstances Making the Collection of Information Necessary

FDA is responsible for regulating biologics, drugs, foods, cosmetics, medical products, radiological products, animal food and drugs, and tobacco. Important questions about FDA-regulated products, such as those concerning user experience, durability, and rare effects may not be answered until after the product has been marketed. To protect the public health, FDA must be able to rapidly collect information pertaining to adverse events associated with FDA-regulated products after they have been marketed.

Over the years, medical science and technology have become increasingly complex. Due to economic pressures and organizational changes within health care organizations, this science and technology is not only used by highly trained health care professionals but has also moved into facilities where the users may not be as sophisticated. Additionally, many of these increasingly complex drugs and medical products, for instance, are now found in the home. These changes have increased the need to obtain timely information from postmarket surveillance systems and to quickly disseminate information to the health care and consumer communities on public health safety issues.

Analysis of a potential health or medical problem often cannot be made based on the information contained in adverse event reports submitted through the MedWatch program. For instance, for devices, it can take up to 90 days before the surveillance plan is begun (the manufacturer has 30 days after receiving notification that FDA is requesting surveillance of a particular product to submit a surveillance plan, and FDA then has 60 days to accept the plan), and much longer until the plan has been completed. This link to the manufacturing community does not fulfill the need for rapid information when FDA

must decide quickly if particular adverse event reports signal a widespread public health problem. FDA requires a timely link to the clinical community in order to obtain information for more emergent situations.

Also, the reports of adverse events that FDA receives from the clinical community typically are not complete and hence there is considerable underreporting. When necessary, FDA contacts the individual reporter of a particular adverse event to obtain more information than what was provided in the MedWatch report. However, there is often insufficient information from the reporter to determine whether an adverse event signals a potential public health hazard. Lack of sufficient information often hampers FDA's ability to understand quickly and thoroughly evaluate the problem; determine the factors that contributed to the adverse event; determine the scope of a possible public health problem; and determine what steps must be recommended to the health-care community to prevent further injury.

FDA will submit to OMB each survey (Gen IC) along with an abbreviated supporting statement using a template which is included in this ICR submission.

OMB will, in general, provide feedback or approve the individual collections within ten working days. In our experience, we have learned that some rapid response surveys are of a more significant nature than others and require very rapid turn-around by OMB to ensure FDA can be responsive to emerging public health emergencies. For those surveys it may be necessary to request a 5-day review and approval from OMB. FDA will flag submissions for which we request a quicker than normal review. FDA recognizes, however, that timing on any action may fluctuate based on several factors including the content of the particular GenIC, competing priorities, etc.

## 2. Purpose and Use of the Information Collection

The purpose of the information collection is to provide a tool to obtain quickly important and vital information from appropriate sources so FDA may take suitable public health or regulatory action when needed.

There are a variety of ways FDA is alerted to potential problems with products, including consumer complaints, inspection data, test results, adverse event reports and reports of illness. We might also learn of a problem from industry, one of our state or federal partners or from governments of other countries. FDA monitors the reports of adverse events associated with the use of medical products that enter the MedWatch mandatory and voluntary reporting programs. Reports are triaged based on perceived risk to the patient. Some reports signal an immediate hazard, but more commonly it is the experienced FDA clinical analysts that detect product problems, particularly those related to product use, through careful investigation of reported incidents and searching for additional sources of information.

The data collected from these rapid response surveys will provide FDA with information to allow a more complete analysis of the problem; determine the existence and extent of a

public health problem; and then, if necessary, to disseminate the information to the health care community. When FDA receives such information, the agency may have an immediate need for additional data to better understand potential vulnerabilities or to perform a risk/hazard analysis. All of these processes must be accomplished in a timeframe that limits, to the extent possible, further incidents causing injury or harm to the public. The degree of perceived risk to the public is the most important consideration for any FDA public health action (product recall, Safety Alert, Public Health Notification, Ad Hoc Committee, workshop, publication, etc.) It is imperative that these risk determinations are completed as quickly as possible to avoid further incidents causing death, injury or harm to the public.

When these data sources fail to provide enough information to perform a risk/hazard analysis, FDA proposes to use rapid response surveys to answer important questions. For example, an adverse event report describing an anaphylactic-type reaction during the use of a certain catheter may require a follow up rapid response survey. Possible questions include:

- Was this reaction related to the patient's illness or the stress of the procedure and is, therefore, not medical product related?
- Is there a biomaterial in this medical product that could cause this reaction?

Because the health care community often does not recognize that a product may have contributed to an adverse event and because there is significant underreporting, it is critically important to know whether other health care professionals may have seen this problem. These other professionals may have not reported a similar event because they did not recognize that the reaction might have been related to the product. Through rapid response surveys, FDA can quickly contact the appropriate user population, can immediately determine if the report was an isolated incident or had occurred more often and was a signal of a potentially serious problem with the product.

Another example includes the likelihood that a certain food caused an illness. Information FDA may need might include:

- the severity of the illness,
- any steps taken during production to reduce the likelihood of contamination.

FDA proposes to use 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.

FDA works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on FDA-regulated products including food, dietary supplements, cosmetics, animal food and feed, medical devices, drugs, biologics, and any other products under FDA's jurisdiction.

The problems encountered with a variety of FDA-regulated products dictates that each survey effort will be unique in that each will involve a different type of product used by different health care professionals.

Respondents to this collection of information will change depending on the particular product in question. For example, respondents could include facilities or professionals which have the most experience in the use of certain FDA-regulations products, foods, cosmetics, dietary supplements, animal food and feed, drugs, tobacco products, etc. Once FDA identifies the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified either through FDA's list or through the appropriate professional organizations.

The data will be collected and analyzed by the offices conducting the rapid response survey. Public health analysts and epidemiologists, and when necessary, statisticians and other Agency scientists, will analyze the data to determine whether a public health risk exists, and how it must be addressed.

### 3. Use of Improved Information Technology and Burden Reduction

The methodology for contacting the reporting sample will vary depending on the product and the health professionals and others targeted as respondents. Most will be electronic, and some of these will be accomplished with the help of professional associations. Some phone interviews may also take place. While we expect that all surveys will be conducted using electronic means there may be an occasion where other means may be appropriate or necessary.

### 4. Efforts to Identify Duplication and Use of Similar Information

FDA scientists routinely utilize literature searches and other secondary data sources to aid in answering some questions about the use of medical products. However, many of the product issues relate to emerging technologies and sciences where little has been written about these problems. FDA's surveillance system is a large national system that is designed to pick up not only common problems, which may appear in the literature, but more importantly, to pick up signals for seemingly rare events that may have far reaching public health implications. These rare events usually have not been identified previously, or when they do appear in a journal, they are reported as "case studies" which do not provide FDA with the broader scope needed to define the public health impact.

Manufacturers are contacted routinely to learn of their experience in investigating and evaluating particular issues. Additionally, FDA scientists contact other public and private health organizations and associations, such as the Center for Disease Control, Product Quality Research Institute, American Association of Pharmaceutical Scientists, Generic Pharmaceutical Industry Association, National Association of Pharmaceutical Manufacturers, Nonprescription Drug Manufacturers Association, National Pharmaceutical Alliance, Parenteral Drug Association, Pharmaceutical Research and Manufacturers of America, American College of Radiology, Senior Citizen Groups, or

ECRI Institute), to determine if the databases maintained at those organizations contain any useable information. In addition, FDA will contact other experts in science, medicine and public health as well as consumers, product sponsors and manufacturers, importers, and retailers.

While these outreach efforts can be useful, they may not be complete enough to aid FDA in determining rapidly the exact nature and public health impact of a problem.

5. Impact on Small Businesses or Other Small Entities

Some hospitals are considered ‘small businesses’ and they may be contacted as respondents. However, most product adverse events that will be under investigation are rare events, and larger institutions are more likely to have experience with these products.

6. Consequences of Collecting the Information Less Frequently

The FDA postmarket surveillance program will be less effective in providing timely, necessary information to the health care community on avoiding serious injuries and deaths with FDA-regulated products whose problem mechanisms are not well understood and for which FDA has no tool to obtain needed information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

One special consequence is requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of the questionnaire.

Given the need for FDA to obtain information about possible risks to the public health in a rapid timeframe, 30 days will be the outside limit of the requested length of time to respond. If there is the possibility of a public health emergency, respondents may be asked to respond within 15 days. For any necessary shorter turnaround timeframes, electronic contact will be made to encourage faster responses.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register on April 20, 2023 (88 FR 24423). We received one comment, which was generally supportive of FDA’s use of RRS. (Comment) The comment suggested that FDA “authorize, develop, and implement a mechanism that provides States and the most local level of public health departments immediate notification and access to RRS results when the FDA issues a RRS wholly or partially in their areas of jurisdiction.” (Response) FDA already has in place mechanisms to share pertinent health information with State, local, and tribal authorities. We currently share aggregated data (without personally identifiable information) of hospital reporting RRS. However, FDA’s use of RRS has not recently developed data about potential safety problems or risk management solutions that would require development of a new mechanism for

immediate notification and access to RRS results. For example, FDA used a RRS to identify and maintain a list of drugs essential for the care and management of hospitalized patients with COVID-19, particularly for ventilated patients in the intensive care units. FDA used the information to help to identify drugs that may be at risk of a regional or national shortage, and to help ensure these drugs remain available to meet the needs of our nation. FDA also used a RRS to engage stakeholders when developing the food safety surveillance sampling assignments. FDA shared information with key external stakeholders on the hot pepper and cucumber sampling assignments and garnered industry feedback through survey questions to ensure that sample collection is done as effectively and efficiently as possible. Neither of these surveys developed information that would require development of a new mechanism for immediate notification and access to RRS results. The latest update survey data from FDA can be found here: FDA COVID-19 Critical Care Drug Monitoring Survey Portal - Ongoing Surveillance of Critical Drugs Related to COVID-19 Supply Disruptions | FDA. Please also note that if you or your hospital stakeholders are experiencing a drug shortage and need assistance on how to obtain supply, please refer to the information at [Drugshortages@fda.hhs.gov](mailto:Drugshortages@fda.hhs.gov). FDA Drug Shortage Staff responds to all reports received on a daily basis.

Currently, FDA determines whether a rapid response survey is needed based on information contained in adverse event reports; obtained from contacting the individuals who made the reports; gathered from expertise of scientists within, and sometimes outside, the agency; and from any other data sources available.

9. Explanation of Any Payment or Gift to Respondents

Respondents will receive no gift or payment for their participation in the questionnaires.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. 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.

The identity of the respondent providing information to the FDA Rapid Response Surveys will not be documented when data is collected by phone.

Written or electronic questionnaire forms sent from FDA, or from a partnering professional organization working with FDA to collect the data, will not ask for identifying information and questionnaires will not be coded in any way that will identify the respondent. Therefore, FDA will not know the identity of the respondent to any returned form. Data provided in response to E-mail surveys will be taken from the E-mail and entered into another form without identifiers and the E-mail will be deleted.

Whenever possible, we will work through a third party (i.e., health care association) so that the third party may contact a particular respondent for follow-up when necessary,

while still keeping the identification of the respondent unknown to FDA. The sample of survey respondent’s contact pool is from third party membership databases that already exist.

Lists of all responder samples used for each inquiry will only be held long enough to determine the response rate and to re-contact each respondent if we have not achieved a response rate that permits FDA scientists to judge whether a public health hazard exists. Lists will be destroyed following the data collection and any necessary follow-up so no possible link may be made between the obtained information and the respondent.

In preparing this Supporting Statement, FDA consulted with the FDA Privacy Office to assure appropriate handling of information collected FDA determined that PII is not collected and the Privacy Act of 1974 does not apply.

11. Justification for Sensitive Questions

None of the questions will be sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA Rapid Response Survey	10,000	1	10,000	0.5 (30 minutes)	5,000

12b. Annualized Cost Burden Estimate

We project that risk managers working in hospitals will complete the majority of the surveys. The average hourly wage for this professional group is \$62.22. Therefore, the estimated annualized cost for respondents is \$311,100 (\$62.22 x 5,000 hours).

The hourly mean wage of “General Medical and Surgical Hospitals” was selected from the U.S. Bureau of Labor Statistics (<http://www.bls.gov/oes/current/oes119111.htm#nat>), Occupational and Employment and Wages data. We used the hourly mean wage of “General Medical and Surgical Hospitals” because there is no specific category for “Risk Managers of Hospitals.”

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA may incur costs to hire a contractor to select respondents, draft the questionnaire, cognitively test the questionnaire, and conduct and analyze the survey for which we estimate \$8,000 per survey resulting in a total of \$160,000 for 20 surveys.

Assuming a cost of \$325,348 per one full-time equivalent (salary plus overhead, full-time 40-hour week) divided by the total number of hours worked (2,080 hours) per year, the fully loaded wage rate is \$156 per hour. An FTE may devote 30% (624 hours) of their time preparing, reviewing and monitoring a project resulting in \$97, 344 (624 hours x \$156/hour) spent annually. An FTE supervisory may spend 25% (520 hours) of their time reviewing and monitoring a project resulting in \$81,120 (520 hours x \$156/hour) spent annually. Therefore, we estimate \$178,464 is spent on government salaries.

Therefore, FDA's total annualized estimated cost to the Federal government is \$338,464.

15. Explanation for Program Changes or Adjustments

We have adjusted the total burden hours that results in a decrease of 50,000 responses and 25,000 total hours. This reduction in burden is a result of fewer rapid response surveys being conducted.

16. Plans for Tabulation and Publication and Project Time Schedule

Rapid Response Surveys can provide information on potential risk to patients, but they do not yield quantitative data about safety that can be generalized. Policy makers can use Rapid Response Survey findings to test and refine their ideas but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

With this in mind, FDA will disseminate Rapid Response Survey findings only when appropriate, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," and will include specific discussion of the limitations of survey results with regard to being non-quantitative and not generalizable. Information for quality encompasses (1) utility, the usefulness of the information to its intended users, including the public; (2) objectivity, whether information is being presented in an accurate, clear, complete, and unbiased manner; and (3) integrity, the information is protected from unauthorized access or revision. FDA uses a number of mechanisms to ensure the quality of the information we disseminate. FDA reviews the quality of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance, and dissemination.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and expiration date will be listed on the survey form used for each survey.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.