
Guidance for Industry

Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Counterterrorism and Emerging Threats (OCET)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)

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Safety

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides recommendations to industry regarding **postmarketing adverse event reporting** for drugs, biologics, medical devices, combination products,² and dietary supplements during a pandemic. FDA anticipates that during a pandemic, industry and FDA workforces may be reduced because of high employee absenteeism while reporting of *adverse events*³ related to widespread use of medical products indicated for the treatment or prevention of the pathogen causing the pandemic may increase. The extent of these possible changes is unknown. This guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for medical products and dietary supplements during a pandemic. FDA believes this approach will make it possible for firms with reporting responsibilities to focus their limited resources on the following types of reports:

- reports related to medical products indicated for the treatment or prevention of the pathogen causing the pandemic

¹ This guidance has been prepared by the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research (CDER) in cooperation with the Office of Counterterrorism and Emerging Threats (OCET) in the Office of the Commissioner and the Centers for Biologics Evaluation and Research (CBER), Devices and Radiological Health (CDRH), and Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration.

² For requirements related to combination products refer to 21 CFR part 4 (see 78 FR 4307). These are described in the guidance Postmarketing Safety Reporting for Combination Products, accessible at <https://www.fda.gov/media/111788/download>. In addition to application type-based reporting requirements (see 21 CFR 4.102(b)), Combination Product Applicants are also subject to certain safety reporting requirements associated with the constituent parts of the combination product (see 21 CFR 4.102(c)). FDA recommended reporting during a pandemic with high employee absenteeism for application-type based reporting requirements and those associated with the constituent parts of a combination product are as described in Table 1.

³ For purposes of this guidance, the term *adverse event* includes adverse experience and adverse reaction. The appendix lists in abbreviated form the current adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements. Refer to the relevant statutes, regulations, and guidance documents for complete information.

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- other reports indicated in this guidance
- reports on products presenting special concerns as specified by FDA

This guidance is not intended to discourage adverse event reporting during a pandemic by firms that are able to continue reporting operations. In addition, this guidance does not address monitoring and reporting of adverse events that might be imposed as a condition for medical products authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3).⁴ This guidance also does not address monitoring and reporting of adverse events as required by regulations establishing the conditions for investigational use of drugs, biologics, and devices. (See 21 CFR parts 312 and 812.)

FDA is revising the final guidance for industry entitled “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic” (2012 final guidance) to clarify that the guidance is applicable to any pandemic, not just an influenza pandemic. This action is necessary to address the Coronavirus Disease 2019 (COVID-19) pandemic and to ensure that the Agency’s recommendations in the 2012 final guidance apply to any pandemic, including COVID-19⁵. Accordingly, this guidance replaces the 2012 final guidance.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the COVID-19 pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

Pandemic preparedness is a global responsibility. It is expected that widespread human outbreaks of a pandemic, whether overseas or in the United States, will affect industry’s functions. Although overseas outbreaks may not seem to directly affect domestic operations, international medical product and dietary supplement production, availability, and adverse event reporting may be disrupted if a firm’s international sites are affected. Thus, industry should develop plans to ensure continuity of operations during a pandemic (discussed in section III.B). It is important that firms consider the adverse event reporting functions of their U.S. locations and their international locations in the face of a potential pandemic.

⁴ For information regarding Emergency Use Authorizations (EUAs), please refer to the guidance on *Emergency Use Authorization of Medical Products* (July 2007), available on the internet at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>.

⁵ The Secretary of Health and Human Services Alex M. Azar issued a “Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), which is available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>. The President also issued a Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

III. PREPAREDNESS FOR ADVERSE EVENT REPORTING DURING A PANDEMIC

A. Information on Pandemic Preparedness

The Department of Health and Human Services (HHS) provides a variety of information about pandemics, including general information on pandemic preparedness planning, e.g. [Pandemic Preparedness Resources](#).⁶ Manufacturers should refer to this web page frequently for updated information on pandemics.

B. Development of a Continuity of Operations Plan in the Case of a Pandemic

To access general information on pandemic preparedness planning, firms should refer to the [HealthCare Emergency Preparedness Information Gateway](#) website.⁷ This site includes resources for developing a continuity of operations plan (COOP) to ensure that a firm's operations continue during all stages of a pandemic.⁸

This guidance is limited to FDA recommendations for reporting adverse events during a period of pandemic. Each firm's pandemic COOP plan should include instructions for reporting adverse events and provide a plan for the submission of any stored reports not submitted in the regulatory timeframes.

C. FDA Expectations for Adverse Event Reporting During a Pandemic

1. Reporting Requirements During a Pandemic

During a pandemic, adverse event reporting processes as required by statute and regulation should be maintained to the maximum extent possible. All adverse event data should be handled using each firm's usual standard operating procedures, and regulatory and statutory requirements for adverse event reporting should be met to the maximum extent possible.

Firms should develop and prepare to implement their COOP in the event that they are not able to fulfill all adverse event reporting requirements because of pandemic-related high employee absenteeism. FDA recommends that in planning, firms consider the following types of factors (not all-inclusive):

- What activities are directly relevant to the processing and submission of mandatory adverse event reports to FDA?
- How would sites based in the United States and abroad be differentially affected by a pandemic?

⁶ Available at <https://www.cdc.gov/coronavirus/2019-ncov/php/pandemic-preparedness-resources.html>.

⁷ Available at <https://asprtracie.hhs.gov/>.

⁸ See Continuity of Operations (COOP) /Business Continuity Planning available at <https://asprtracie.hhs.gov/technical-resources/17/continuity-of-operations-coop-business-continuity-planning/110>.

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- What are the relative amounts of resources dedicated to mandatory adverse event reporting at each site?

Firms that are unable to fulfill adverse event reporting requirements during a pandemic should maintain documentation of both of the following conditions:

1. Declaration of a pandemic (e.g., by the World Health Organization), including date of declaration of the pandemic and ending date of the pandemic, and
2. High absenteeism and/or other factors (e.g., an increase in adverse event reporting) that is/are preventing the firm from meeting adverse event reporting requirements

The appropriate FDA organizational units responsible for adverse event reporting compliance should be notified when these conditions exist as soon as practicable, recognizing that notifications may be delayed due to the need to address more urgent safety issues.

2. *Enforcement Approach During a Pandemic with High Employee Absenteeism*

FDA anticipates that during a pandemic, industry and FDA workforces may be reduced because of high employee absenteeism at the same time that reporting of adverse events related to pandemic-related medical products may increase.

FDA encourages all firms to plan for these circumstances to maintain the highest feasible level of adverse event monitoring and reporting throughout the pandemic period when a firm is experiencing pandemic-related high employee absenteeism. Recognizing that a pandemic may reduce a firm's capacity to comply with adverse event reporting requirements, however, FDA offers this general guidance to help manufacturers strategize use of their resources.

As explained below, FDA does not intend to object if, because of pandemic-related high employee absenteeism, certain required adverse event reports are not submitted to the FDA within the timeframes required by statute and regulation, provided that any delayed reports are submitted within 6 months of the restoration of adverse event reporting processes to their pre-pandemic state (see section III.D for discussion of prioritizing timeframes for submission of stored reports).

Table 1 indicates which reports firms may generally *store if necessary* because of pandemic-related high employee absenteeism, without FDA objection. Where Table 1 indicates a type of report may be stored if necessary, this means that FDA does not intend to object if firms maintain newly received information regarding the underlying adverse events and do not submit reports in the timeframes mandated by statute or regulation. However, any delayed reports must be submitted after adverse event reporting processes have been restored to the pre-pandemic state. Firms should maintain records to identify what has been stored and when the processes were restored.

This guidance does not apply to adverse event reporting during a pandemic by firms that are able to continue reporting operations. Firms that are able to report more than the minimum described in Table 1 but less than that required by the statute and applicable regulations should prioritize the order of report submissions. For example, reports with regulatory timeframes of 30 days or less (e.g., 15-day reports, 30-day reports) should be submitted before periodic safety reports. During a pandemic, all firms are strongly encouraged to submit as many required reports as possible. This will minimize reporting burdens once adverse event reporting processes have been restored to the pre-pandemic state.

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FDA intends to communicate with firms if there are products and issues that present special concerns and for which the agency therefore expects compliance with reporting as required by statute and regulation during the pandemic. Special concerns could include:

- product-related safety issues such as (but not limited to) newly emerging safety issues (e.g., an antihypertensive drug associated with liver failure or a non-pandemic-related vaccine associated with anaphylaxis)
- product problems with associated adverse events (e.g., nonfatal serious infections associated with a pre-filled syringe that was recalled due to bacterial contamination)

As indicated in Table 1, if FDA has specified a product as presenting special concerns, firms must submit required adverse event reports regardless of the more general recommendations in Table 1. Aside from this circumstance, in Table 1, reporting recommendations for drugs and biologics are prioritized by type of product so that reporting can focus on products that are likely to have greater use and may necessitate greater monitoring during a pandemic. Further, 15-day reports have priority over periodic reports. For medical devices, the reporting priority is specified by outcome (i.e., fatal outcome vs. nonfatal outcome). Table 1 also includes reporting recommendations for other products and additional details.

D. Reporting After the Pandemic

After the pandemic is resolved and a pre-pandemic state has been restored, it is expected that firms will resume fulfilling all reporting requirements on time as well as submit reports that were stored because of pandemic-related high employee absenteeism. Firms should follow their plan for the submission of the stored reports not submitted in the regulatory timeframes. Firms are generally expected to submit stored reports to FDA within 6 months of restoration of the adverse event reporting process to the pre-pandemic state, or after notification by the Agency, any time frame established by FDA. Firms should prioritize the order of submission for stored reports. For example, reports with regulatory timeframes of 30 days or less (e.g., 15-day reports, 30-day reports) should be submitted before periodic safety reports.

Firms that cannot meet adverse event reporting requirements at the minimum levels identified in this guidance should consult the appropriate FDA organizational unit responsible for adverse event reporting compliance.

IV. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 50 hours per response to prepare an adverse event reporting plan for a COOP and 8 hours per response to notify FDA when reporting as required by statute and regulation is not feasible, to maintain documentation of the pandemic conditions and resultant high absenteeism, and to maintain records to identify what reports have been stored and when the reporting process was restored, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

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Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4480, Silver Spring, MD 20993-0002.

This guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) and are approved under OMB control numbers 0910-0116, 0910-0291, 0910-0230, 0910-0308, 0910-0437, and 0910-0543. In addition, the guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the Act (21 U.S.C. 379aa and 379aa-1), which include collections of information approved under OMB control numbers 0910-0636 and 0910-0635.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0701 (expires 05/31/2021).

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Table 1. FDA Approach to Postmarketing Safety Reporting During a Pandemic if Processes of Mandatory Adverse Event Reporting Are Not Feasible Because of High Employee Absenteeism

Type of Product or Application	Type of Report(s)/Statutory or Regulatory Timeframe(s) ¹	FDA Recommended Reporting During a Pandemic With High Employee Absenteeism
Products with special concerns as specified by FDA (any product or application type below) ²	As per regulation(s) and/or statute(s) relating to the FDA-specified product	Submit ³
Prescription drug products marketed without an approved New Drug Application (NDA): drugs compounded or repackaged by outsourcing facilities ⁴	15-day Alert report, 15-day Alert report -follow up / 15 calendar days	Submit
Prescription drug products marketed without an approved New Drug Application (NDA): other drugs	15-day Alert report, 15-day Alert report -follow up / 15 calendar days	Store if necessary ⁵
Approved NDA, Approved Abbreviated New Drug Application (ANDA) <ol style="list-style-type: none"> 1. use for the pathogen causing the pandemic or the disease caused by the pathogen⁶ 2. approved within prior three years 3. all other products 	15-day Alert report, 15-day Alert report -follow up / 15 calendar days <u>AND</u> Reports to applicant (or licensed manufacturer) instead of FDA / 5 calendar days	Approved NDA, Approved ANDA <ol style="list-style-type: none"> 1. Submit 2. Submit 3. Submit death outcome reports. Store if necessary other serious outcome (non-death) reports.
Approved Biologics License Application (BLA) <ol style="list-style-type: none"> 1. use for the pathogen causing the pandemic or the disease caused by the pathogen⁶ 2. approved within prior three years 3. all other biologics 		Approved BLA <ol style="list-style-type: none"> 1. Submit 2. Submit 3. Submit death outcome reports. Store if necessary other serious outcome (non-death) reports.

¹ Refer to the appendix for Current Requirements for Postmarketing Safety Reports.

² FDA will specifically communicate with firms regarding which products present special concerns. Refer to section III.C.2 of this guidance for further discussion of special concern products.

³ As used in this document, “submit” means that the Agency continues to expect compliance with the specific regulatory requirements for submission, including applicable timeframes.

⁴ Reporting is to be continued because of the potential for increased production of compounded drugs during a pandemic, including the COVID-19 pandemic, by this relatively new industry.

⁵ Refer to section III.C.2 of this guidance.

⁶ Whether or not the use is included in the labeling for the drug.

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Type of Product or Application	Type of Report(s)/ Statutory or Regulatory Timeframe(s)	FDA Recommended Reporting During a Pandemic With High Employee Absenteeism
Approved NDA: all products	Periodic adverse drug experience report ⁷ / Quarterly for 3 years from the date of U.S. approval of the application (or license) and then annually thereafter	Store if necessary
Approved ANDA: all products		
Approved BLA: all products		
Nonprescription Drugs Marketed without an Approved Application ⁸	Serious adverse event report / 15 business days	Store if necessary
Dietary Supplement Products	Serious adverse event report / 15 business days	Store if necessary
Blood and Blood Components	Blood collection/transfusion fatality report / As soon as possible (oral or written) and 7 days (written)	Submit
Source Plasma	Donor fatality report / As soon as possible (oral)	Submit
Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/P)	Adverse reaction report / 15 calendar days	Submit
Medical Device	Manufacturer Medical Device Report (MDR) to FDA / 5 work days	Submit
	Manufacturer MDR to FDA / 30 calendar days	1. Submit if patient death 2. Store, if necessary, if nonfatal serious injury or device malfunction ⁹
	MDR from importer to manufacturer and FDA / 30 calendar days	1. Submit if patient death 2. Store, if necessary, if nonfatal serious injury
	MDR from user facility to manufacturer (and/or FDA) / 10 work days	1. Submit if patient death 2. Store, if necessary, if nonfatal serious injury

⁷ Includes periodic safety update reports (PSURs) and periodic benefit-risk evaluation reports (PBRERs) if applicant has a waiver allowing submission of PSURs or PBRERs in lieu of periodic adverse (drug) experience reports.

⁸ For purposes of section 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), *nonprescription drug* means a drug that is (1) not subject to section 503(b) of the FD&C Act and (2) not subject to approval in an application submitted under section 505 of the FD&C Act. See section 760(a)(2) of the FD&C Act (21 U.S.C. 379aa(a)(2)).

⁹ The recommendations are also applicable to events reported under the Voluntary Malfunction Summary Reporting (VMSR) Program. See 83 FR 40973 for more details regarding VMSR Program conditions of participation.

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APPENDIX: CURRENT REQUIREMENTS FOR POSTMARKETING SAFETY REPORTS

Type of Product or Type of Application	Section of 21 CFR or FD&C Act	Type of Report(s)/ Timeframe	Type of Information	Persons with Reporting Responsibility
DRUGS AND BIOLOGICS				
Prescription Drug Products Marketed without an Approved NDA	310.305	15-day Alert report; 15-day Alert report-followup / 15 calendar days Reports to manufacturer (or licensed manufacturer) instead of FDA / 5 calendar days	Serious and unexpected adverse drug experience; New information from follow up of 15-day Alert report Serious adverse drug experiences	Manufacturers, packers, distributors Packers and distributors
Approved NDA (prescription and nonprescription drugs), Approved ANDA (prescription and nonprescription drugs), and Approved BLA (biologics)	314.80, 314.98, and 600.80, respectively	15-day Alert report; 15-day Alert report-followup / 15 calendar days Reports to applicant (or licensed manufacturer) instead of FDA / 5 calendar days Periodic adverse drug experience report / Quarterly for 3 years from the date of U.S. approval of the application/issuance of license and annually thereafter unless otherwise required by FDA	Serious and unexpected adverse drug experience; New information from follow up of 15-day Alert report Serious adverse drug experiences <ul style="list-style-type: none"> • Individual case safety reports for each adverse drug experience not submitted to FDA as a 15-day Alert report, excluding reports from postmarketing studies, reports in the scientific literature, and foreign marketing experience • Summary portion: includes narrative summary and analysis of adverse drug experiences that occurred during the reporting interval including 15-day Alert reports previously submitted to FDA, an index of individual case safety reports included in the report, and history of actions taken since the last Periodic report. 	Applicants (§§ 314.80, 314.98), licensed manufacturers (§ 600.80), manufacturers, packers, and distributors (§§ 314.80, 314.98, and 600.80) and joint manufacturers, shared manufacturers, or any other participant involved in divided manufacturing (§ 600.80) Manufacturers, packers, and distributors (§§ 314.80, 314.98, and 600.80) and joint manufacturers, shared manufacturers, or any participant involved in divided manufacturing (§ 600.80) Applicants (§§ 314.80, 314.98) or licensed manufacturers (§ 600.80)

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Type of Product or Type of Application	Section of 21 CFR or FD&C Act	Type of Report(s)/ Timeframe	Type of Information	Persons with Reporting Responsibility
DRUGS AND BIOLOGICS (cont'd)				
Nonprescription Drugs Marketed without an Approved Application	FD&C Act Subchapter H Sec.760	Serious adverse event report, new medical information (followup) report / 15 business days	Serious adverse events	Manufacturers, packers, or distributors
DIETARY SUPPLEMENTS				
Dietary Supplements	FD&C Act Subchapter H Sec.761	Serious adverse event report, new medical information (followup) report / 15 business days	Serious adverse events	Manufacturers, packers, or distributors
BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA				
Blood and Blood Components	606.170	Blood collection/transfusion fatality report / notification as soon as possible (by telephone, fax, e-mail or express mail) and written report of investigation within 7 days	Fatalities associated with complications of blood collection or transfusion	Blood collecting facility or transfusing facility
Source Plasma	640.73	Donor fatality report / as soon as possible (by telephone)	Fatalities associated with Source Plasma collection	Source Plasma establishments

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HUMAN CELLS, TISSUE, AND CELLULAR AND TISSUE-BASED PRODUCTS				
Type of Product or Type of Application	Section of 21 CFR or FD&C Act	Type of Report(s)/ Timeframe	Type of Information	Persons with Reporting Responsibility
Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/P)	1271.350(a)	Adverse reaction report / 15 calendar days	Communicable disease associated with HCT/P if fatal, life-threatening, results in permanent impairment of body function or permanent damage to body structure or necessitates medical or surgical intervention	Establishments that make the HCT/P available for distribution
MEDICAL DEVICES				
Medical Devices	803.50	Medical device reporting (MDR) to FDA / 30 calendar days	Device may have caused/contributed to death or serious injury, or device malfunctioned and would be likely to cause/contribute to death or serious injury if malfunction recurs	Manufacturers
	803.53	MDR to FDA / 5 work days	MDR reportable event necessitates remedial action to prevent unreasonable risk of substantial harm to public health, or report requested by FDA	Manufacturers
	803.56	Supplemental (followup) reports / within 30 calendar days	Followup information received on a previously submitted 5-day or 30-day MDR	Manufacturers
	803.40	MDR to manufacturer and FDA / 30 calendar days	Device may have caused/contributed to death or serious injury	Importers
	803.40	MDR to manufacturer/ 30 calendar days	Device has malfunctioned and would be likely to cause/contribute to death or serious injury if malfunction recurs	Importers
	803.30	MDR to manufacturer and FDA / 10 work days	Device may have caused/contributed to death	User Facilities
	803.30	MDR to manufacturer (or FDA if manufacturer not known) / 10 work days	Device may have caused/contributed to serious injury	User Facilities
	803.33	Annual Report / yearly by January 1	Summary of previously submitted reports (not required if no reports)	User Facilities