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# Guidance for Industry

## Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza 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)**

**Xxxx 2011  
Safety**

OMB Control Number 0910-xxxx  
Expiration Date: xx/xx/xxxx  
See additional PRA statement in Section IV of this guidance

# Guidance for Industry

## Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

*Additional copies are available from:*

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*and/or*

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<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

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**Xxxx 2011**

**Safety**

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**TABLE OF CONTENTS**

84

85

86

87I. **INTRODUCTION**.....1

88II. **BACKGROUND**.....2

89III. **PREPAREDNESS FOR ADVERSE EVENT REPORTING DURING AN  
90 INFLUENZA PANDEMIC**.....2

91 A. **Information on Pandemic Influenza Preparedness**.....2

92 B. **Development of a Continuity of Operations Plan in the Case of an Influenza Pandemic**.....2

93 C. **FDA Expectations for Adverse Event Reporting During an Influenza Pandemic**.....3

94 1. *Reporting Requirements During an Influenza Pandemic*.....3

95 2. *Enforcement Approach During an Influenza Pandemic with High Employee Absenteeism*.....4

96 D. **Reporting After the Influenza Pandemic**.....5

97IV. **PAPERWORK REDUCTION ACT OF 1995**.....5

98**Table 1. FDA Approach to Postmarketing Safety Reporting During an Influenza Pandemic if  
99Normal Processes of Mandatory Adverse Event Reporting Are Not Feasible Because of High  
100Employee Absenteeism**.....7

101

102**APPENDIX 1: CURRENT REQUIREMENTS FOR POSTMARKETING SAFETY  
103REPORTS**.....9

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## Guidance for Industry<sup>1</sup>

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# Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

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112 This guidance represents the Food and Drug Administration’s (FDA’s) current thinking on this topic. It  
 113 does not create or confer any rights for or on any person and does not operate to bind FDA or the public.  
 114 You can use an alternative approach if the approach satisfies the requirements of the applicable statutes  
 115 and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for  
 116 implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate  
 117 number listed on the title page of this guidance.  
 118

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### 122I. INTRODUCTION

123

124 This guidance provides recommendations to industry regarding postmarketing adverse event  
 125 reporting for drugs, biologics, medical devices, and dietary supplements during an influenza  
 126 pandemic. FDA anticipates that during an influenza pandemic, industry and FDA workforces  
 127 may be reduced because of high employee absenteeism, while reporting of *adverse events*<sup>2</sup>  
 128 related to widespread use of medical products indicated for the treatment or prevention of  
 129 influenza may increase. The extent of these possible changes is unknown. This guidance  
 130 discusses FDA’s intended approach to enforcement of adverse event reporting requirements for  
 131 medical products and dietary supplements during an influenza pandemic. FDA believes this  
 132 approach will make it possible for firms with reporting responsibilities to focus their limited  
 133 resources on the following types of reports:

- 134 • reports related to medical products indicated for the treatment or prevention of
- 135 influenza
- 136 • other reports indicated in this guidance
- 137 • reports on products presenting special concerns as specified by FDA

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

14  
 15<sup>2</sup> For purposes of this guidance, the term *adverse event* includes adverse experience and adverse reaction.  
 16 Appendix 1 lists in abbreviated form the current adverse event reporting requirements for drugs, biologics, medical  
 17 devices, and dietary supplements. Refer to the relevant statutes, regulations, and guidance documents for complete  
 18 information.

19

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

147

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

153

154

## 155 II. BACKGROUND

156

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

166

167

## 168 III. PREPAREDNESS FOR ADVERSE EVENT REPORTING DURING AN 169 INFLUENZA PANDEMIC

170

### 171 A. Information on Pandemic Influenza Preparedness

172

173 The Department of Health and Human Services (HHS) manages the U.S. Government flu  
174 information Web site ([www.pandemicflu.gov](http://www.pandemicflu.gov)), which provides a variety of information about  
175 influenza, including general information on pandemic influenza preparedness planning.  
176 Manufacturers should refer to the Web site frequently for updated information on influenza.

177

### 178 B. Development of a Continuity of Operations Plan in the Case of an Influenza 179 Pandemic

180

181 To access general information on pandemic influenza preparedness planning, firms should refer  
182 to the [pandemicflu.gov](http://www.pandemicflu.gov) Web site.<sup>4</sup> This site recommends that each firm should develop a

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22<sup>3</sup> For information regarding Emergency Use Authorizations (EUAs), please refer to the guidance on *Emergency Use  
23 Authorization of Medical Products* (July 2007), available on the Internet at

24 <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>.

25

26<sup>4</sup> Available at <http://www.pandemicflu.gov> under "For Professionals, Business Planning."

183continuity of operations plan (COOP) to ensure that its operations continue during all stages of  
184pandemic influenza. Guidance on developing COOP plans is available from various sources.  
185For example, the U.S. Department of Homeland Security (DHS) has issued a *Pandemic Influenza*  
186*Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*,  
187which addresses the development and implementation of a “Continuity of Operations – Essential  
188(COP-E)” plan.<sup>5</sup>

189

190This guidance is limited to FDA recommendations for reporting adverse events during a period  
191of pandemic influenza. Each firm’s pandemic influenza COOP plan should include instructions  
192for reporting adverse events and provide a plan for the submission of any stored reports not  
193submitted in the regulatory timeframes.

194

195 **C. FDA Expectations for Adverse Event Reporting During an Influenza**  
196 **Pandemic**

197

198 **1. Reporting Requirements During an Influenza Pandemic**

199

200During an influenza pandemic, normal adverse event reporting processes should be maintained  
201to the maximum extent possible. All adverse event data should be handled using each firm’s  
202usual standard operating procedures, and regulatory and statutory requirements for adverse event  
203reporting should be met to the maximum extent possible.

204

205Firms should develop and prepare to implement their COOP in the event that they are not able to  
206fulfill all adverse event reporting requirements because of pandemic-related high employee  
207absenteeism. FDA recommends that in planning, firms consider the following types of factors  
208(not all-inclusive):

- 209 • What activities are directly relevant to the processing and submission of mandatory  
210 adverse event reports to FDA?
- 211 • How would sites based in the United States and abroad be differentially affected by a  
212 pandemic?
- 213 • What are the relative amounts of resources dedicated to mandatory adverse event  
214 reporting at each site?

215

216Firms that are unable to fulfill normal adverse event reporting requirements during an influenza  
217pandemic should maintain documentation of both of the following conditions:

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29<sup>5</sup> Available at <http://www.pandemicflu.gov> under “For Professionals, Federal Government, Other Federal Agency  
30Activities.”

218

- 219 1. Declaration of an influenza pandemic (e.g., by federal government), including date of  
 220 declaration of the pandemic and ending date of the pandemic, and  
 221 2. High absenteeism and/or other factors (e.g., an increase in adverse event reporting) that  
 222 is/are preventing the firm from meeting normal adverse event reporting requirements

224

225The appropriate FDA organizational units responsible for adverse event reporting compliance  
 226should be notified when these conditions exist.

227

- 228 2. *Enforcement Approach During an Influenza Pandemic with High Employee*  
 229 *Absenteeism*

230

231FDA anticipates that during an influenza pandemic, industry and FDA workforces may be  
 232reduced because of high employee absenteeism at the same time that reporting of adverse events  
 233related to influenza-related medical products may increase.

234

235FDA encourages all firms to plan for these circumstances to maintain the highest feasible level  
 236of adverse event monitoring and reporting throughout the pandemic period when a firm is  
 237experiencing pandemic-related high employee absenteeism. Recognizing that a pandemic may  
 238reduce a firm's capacity to comply with adverse event reporting requirements, however, FDA  
 239offers this general guidance to help manufacturers strategize use of their resources.

240

241As explained below, FDA does not intend to object if, because of pandemic-related high  
 242employee absenteeism, certain required adverse event reports are not submitted to the FDA  
 243within the timeframes required by statute and regulation, provided that any delayed reports are  
 244submitted within 6 months of the restoration of adverse event reporting processes to their pre-  
 245pandemic state (see section III.D for discussion of prioritizing timeframes for submission of  
 246stored reports).

247

248Table 1 indicates which reports firms may generally *store if necessary* because of pandemic-  
 249related high employee absenteeism, without FDA objection. Where Table 1 indicates a type of  
 250report may be stored if necessary, this means that FDA does not intend to object if firms  
 251maintain newly received information regarding the underlying adverse events and do not submit  
 252reports in the timeframes mandated by statute or regulation. However, any delayed reports must  
 253be submitted after adverse event reporting processes have been restored to the pre-pandemic  
 254state. Firms should maintain records to identify what has been stored and when the processes  
 255were restored.

256

257This guidance does not apply to adverse event reporting during an influenza pandemic by firms  
 258that are able to continue reporting operations. Firms that are able to report more than the  
 259minimum described in Table 1 but less than that required by the statute and applicable  
 260regulations should prioritize the order of report submissions. For example, reports with  
 261regulatory timeframes of 30 days or less (e.g., 15-day reports, 30-day reports) should be  
 262submitted before periodic safety reports. During an influenza pandemic, all firms are strongly  
 263encouraged to submit as many required reports as possible. This will minimize reporting  
 264burdens once adverse event reporting processes have been restored to the pre-pandemic state.

265

266FDA intends to communicate with firms if there are products and issues that present special  
 267concerns and for which the agency therefore expects compliance with normal reporting as  
 268required by statute and regulation during the influenza pandemic. Special concerns could  
 269include:

- 270 • product-related safety issues such as (but not limited to) newly emerging safety issues  
 271 (e.g., an antihypertensive drug associated with liver failure or a non-influenza vaccine  
 272 associated with anaphylaxis)
- 273 • product problems with associated adverse events (e.g., nonfatal serious infections  
 274 associated with a pre-filled syringe that was recalled due to bacterial contamination)  
 275

276As indicated in Table 1, if FDA has specified a product as presenting special concerns, firms  
 277must submit required adverse event reports regardless of the more general recommendations in  
 278Table 1. Aside from this circumstance, in Table 1, reporting recommendations for drugs and  
 279biologics are prioritized by type of product so that reporting can focus on products that are likely  
 280to have greater use and may necessitate greater monitoring during an influenza pandemic.  
 281Further, 15-day reports have priority over periodic reports. For medical devices, the reporting  
 282priority is specified by outcome (i.e., fatal outcome vs. nonfatal outcome). Table 1 also includes  
 283reporting recommendations for other products and additional details.

284

#### 285 **D. Reporting After the Influenza Pandemic**

286

287After the influenza pandemic, it is expected that firms will resume fulfilling all reporting  
 288requirements on time as well as submit reports that were stored because of pandemic-related high  
 289employee absenteeism. Firms should follow their plan for the submission of the stored reports  
 290not submitted in the regulatory timeframes. Firms are generally expected to submit stored reports  
 291to FDA within 6 months of restoration of the adverse event reporting process to the pre-  
 292pandemic state. Firms should prioritize the order of submission for stored reports. For example,  
 293reports with regulatory timeframes of 30 days or less (e.g., 15-day reports, 30-day reports)  
 294should be submitted before periodic safety reports.

295

296Firms that cannot meet adverse event reporting requirements at the minimum levels identified in  
 297this guidance should consult the appropriate FDA organizational unit responsible for adverse  
 298event reporting compliance.

299

#### 300**IV. PAPERWORK REDUCTION ACT OF 1995**

301

302This guidance contains information collection provisions that are subject to review by the Office  
 303of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.  
 3043501-3520).

305

306The time required to complete this information collection is estimated to average 50 hours per  
 307response to prepare an adverse reporting plan for a COOP and 8 hours per response to notify  
 308FDA when normal reporting is not feasible, to maintain documentation of influenza pandemic  
 309conditions and resultant high absenteeism, and to maintain records to identify what reports have  
 310been stored and when the reporting process was restored, including the time to review  
 311instructions, search existing data sources, gather the data needed, and complete and review the  
 312information collection. Send comments regarding this burden estimate or suggestions for  
 313reducing this burden to:

***Contains Nonbinding Recommendations***

314Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and  
315Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. **Xxxx**, Silver Spring, MD  
31620993-0002.

317

318This guidance also refers to previously approved collections of information found in FDA's  
319adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170,  
320640.73, 1271.350, and part 803. These regulations contain collections of information that are  
321subject to review by the Office of Management and Budget (OMB) under the Paperwork  
322Reduction Act of 1995 (44 U.S.C. 3501-3520) and are approved under OMB control numbers  
3230910-0116, 0910-0291, 0910-0230, 0910-0308, 0910-0437, and 0910-0543. In addition, the  
324guidance also refers to adverse event reports for nonprescription human drug products marketed  
325without an approved application and dietary supplements required under sections 760 and 761 of  
326the Act (21 U.S.C. 379aa and 379aa-1), which include collections of information approved under  
327OMB control numbers 0910-0636 and 0910-0635.

328

329An agency may not conduct or sponsor, and a person is not required to respond to, a collection of  
330information unless it displays a currently valid OMB control number. The OMB control number  
331for this information collection is 0910-**xxxx** (expires **xx/xx/xxxx**).

332 **Table 1. FDA Approach to Postmarketing Safety Reporting During an Influenza Pandemic if Normal Processes of**  
 333 **Mandatory Adverse Event Reporting Are Not Feasible Because of High Employee Absenteeism**  
 334

Type of Product or Application	Type of Report(s)/Statutory or Regulatory Timeframe(s) <sup>6</sup>	FDA Recommended Reporting During an Influenza Pandemic With High Employee Absenteeism
Products with special concerns as specified by FDA (any product or application type below) <sup>7</sup>	As per regulation(s) and/or statute(s) relating to the FDA-specified product	Submit <sup>8</sup>
Prescription drug products marketed without an approved NDA	15-day Alert report, 15-day Alert report -follow up / 15 calendar days	Store if necessary <sup>9</sup>
Approved NDA, Approved ANDA 1. labeled indication for influenza 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 1. Submit 2. Submit 3. Store if necessary
Approved BLA 1. Pandemic influenza vaccines 2. Biologics (vaccines or nonvaccines) approved within prior three years 3. Other biologics (vaccines or nonvaccines)		Approved BLA 1. Submit 2. Submit 3. Submit death outcome reports. Store if necessary other serious outcome (non-death) reports.
Approved NDA: all products	Periodic adverse drug experience report <sup>10</sup> / 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		

39<sup>6</sup>40<sup>71</sup> Refer to Appendix 1 for Current Requirements for Postmarketing Safety Reports.41<sup>7</sup> 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.42<sup>8</sup> As used in this document, “submit” means that the Agency continues to expect compliance with the specific regulatory requirements for submission, including applicable timeframes.43<sup>9</sup> Refer to section III.C.2 of this guidance.44<sup>10</sup> Includes periodic safety update reports (PSURs) if applicant has a waiver allowing submission of PSURs in lieu of periodic adverse (drug) experience reports.

47

48

**Contains Nonbinding Recommendations**

335

<b>Type of Product or Application</b>	<b>Type of Report(s)/ Statutory or Regulatory Timeframe(s)</b>	<b>FDA Recommended Reporting During an Influenza Pandemic With High Employee Absenteeism</b>
Nonprescription Drugs Marketed without an Approved Application <sup>11</sup>	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
	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

<sup>11</sup> 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 52503(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&CA Act 53(21 U.S.C. 379aa(a)(2)).

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337

**APPENDIX 1: 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
<b>DRUGS AND BIOLOGICS</b>				
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  • 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)

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
<b>DRUGS AND BIOLOGICS (cont'd)</b>				
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
<b>DIETARY SUPPLEMENTS</b>				
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
<b>BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA</b>				
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
<b>HUMAN CELLS, TISSUE, AND CELLULAR AND TISSUE-BASED PRODUCTS</b>				
Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/P)	1271.350	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	Establishments that manufacture HCT/P

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
			medical or surgical intervention	
<b>MEDICAL DEVICES</b>				
Medical Devices	803.50	Medical device report (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 one month	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