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# Field Alert Report Submission Questions and Answers Guidance for Industry

## ***DRAFT GUIDANCE***

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Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Office of Regulatory Affairs (ORA)**

**July 2018  
Pharmaceutical Quality/Manufacturing Standards (CGMP)**

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# Field Alert Report Submission Questions and Answers Guidance for Industry

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**TABLE OF CONTENTS**

- I. INTRODUCTION..... 1**
- II. BACKGROUND ..... 1**
- III. QUESTIONS AND ANSWERS..... 2**
  - 1. What is a FAR and what triggers its submission? ..... 2**
  - 2. Who is responsible for submitting the FAR? ..... 6**
  - 3. When should I submit a FAR? ..... 6**
  - 4. How do I submit a FAR?..... 6**
  - 5. Where do I submit a FAR? ..... 8**
  - 6. Should I submit a follow-up or final FAR? ..... 9**

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**Field Alert Report Submission  
Questions and Answers  
Guidance for Industry<sup>1</sup>**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

**I. INTRODUCTION**

This guidance provides the agency’s current thinking regarding the requirements for submission of field alert reports (FARs) by applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) and outlines FDA’s recommendations for FAR submissions to help increase their consistency and relevancy. The guidance also addresses certain frequently asked questions.

In general, FDA’s guidance documents 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**

The FAR regulations found in 21 CFR 314.81(b)(1) and 314.98(b) establish an early warning system to help protect patient health. Under these regulations, NDA and ANDA applicants must submit certain information to FDA about distributed drug products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). Specifically, an NDA or ANDA applicant<sup>2</sup> must submit a FAR to FDA within 3 working days of receiving the following kinds of information for distributed drug product(s):

<sup>1</sup> This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration.

<sup>2</sup> For purposes of this guidance, *applicant* has the meaning set forth in 21 CFR 314.3. Under § 314.98(b), each ANDA applicant must make the reports required under § 314.81.

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39 (i) Information concerning any incident that causes the drug product or its  
40 labeling to be mistaken for, or applied to, another article.

41  
42 (ii) Information concerning any bacteriological<sup>3</sup> contamination, or any significant  
43 chemical, physical, or other change or deterioration in the distributed drug  
44 product, or any failure of one or more distributed batches of the drug product to  
45 meet the specification established for it in the application.

46  
47 On May 2, 2013, FDA issued a *Federal Register* notice to notify the pharmaceutical industry  
48 about a voluntary pilot project using extensible markup language (XML) functionality to  
49 automate Form FDA 3331, NDA-Field Alert Report. The pilot, a collaborative effort between  
50 CDER and the Office of Regulatory Affairs (ORA), was the first step in moving FDA away from  
51 manual data entry to a more automated system of receiving FARs. It also allowed both CDER  
52 and ORA to receive FAR information simultaneously. All firms were encouraged to participate.

53  
54 In June 2017, the pilot project was completed and a new version of the automated form—Form  
55 FDA 3331a, NDA/ANDA Field Alert—which incorporates feedback from pilot project  
56 participants, was approved by the Office of Management and Budget (OMB). Form FDA 3331a  
57 is available on FDA’s Field Alert Reports website.<sup>4</sup> Although CBER did not participate in the  
58 pilot program, applicants holding NDAs or ANDAs regulated by CBER may also use the new  
59 form.

### **III. QUESTIONS AND ANSWERS**

60  
61  
62  
63  
64 This section outlines your responsibilities as an NDA or ANDA applicant regarding FAR  
65 submissions and makes recommendations about providing information to FDA about any root  
66 cause investigations, corrective actions, and other actions you take in response to a FAR.

#### **1. What is a FAR and what triggers its submission?**

67  
68  
69  
70 *a. What is a FAR?*

71  
72 FARs are part of an early warning system to protect patient health. Per § 314.81(b)(1), you must  
73 submit a FAR for distributed drug products and articles to FDA if you receive information of the  
74 following kinds:

75  

---

<sup>3</sup> FDA has interpreted the term *bacteriological* used in § 314.81(b)(1)(ii) to mean *microbiological*, which includes any kind of microbial contamination, such as bacteria, yeast, fungus, or virus. The contamination of distributed drug product by yeast, fungus, or virus would also be reportable as a *change or deterioration in the distributed drug product*, or as a *failure of one or more distributed batches of the drug product to meet the specification established for it in the application*.

<sup>4</sup> See <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm529729.htm>.

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- 76 • Information concerning any incident that causes a drug product or its labeling to be  
77 mistaken for, or applied to, another article.  
78
- 79 • Information concerning any bacteriological contamination, or any significant chemical,  
80 physical, or other change or deterioration in the distributed drug product, or any failure of  
81 one or more distributed batches of the drug product to meet the specification established  
82 for it in the application.  
83

84 You should submit a FAR using Form FDA 3331a (see question 4a). In that form, and in this  
85 guidance, the term *problem* refers to the incident<sup>5</sup> or possible/actual quality issue<sup>6</sup> that is the  
86 subject of the FAR.  
87

88 *b. What are initial, follow-up, and final FARs?*  
89

90 This guidance uses the terms *initial*, *follow-up*, and *final* FARs, consistent with the language in  
91 Form FDA 3331a.  
92

- 93 • *Initial FAR* refers to the FAR that you submit to comply with the requirements of  
94 § 314.81(b)(1), and it is the first time you have submitted a FAR about a specific problem  
95 as described in question 1a.  
96
- 97 • *Follow-up FAR* refers to any subsequent FARs you submit to provide additional  
98 information about the problem identified in the initial FAR. Examples of additional  
99 information include significant findings of the ongoing investigation; additional facilities  
100 or lots identified within scope; and sample analyses, laboratory test results, or potential  
101 root causes identified.  
102
- 103 • *Final FAR* refers to the FAR you submit to close out the initial FAR identifying the root  
104 cause and describing any corrective actions taken or to be taken.  
105

106 Although follow-up and final FARs are not required, they are recommended. For more  
107 information on follow-up and final FARs, see III.6 in this guidance.  
108

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<sup>5</sup> See § 314.81(b)(1)(i).

<sup>6</sup> See § 314.81(b)(1)(ii).

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109 c. *What is considered a significant chemical, physical, or other change or deterioration in*  
110 *the distributed product?*

111  
112 To determine whether a chemical, physical, or other change or deterioration in the distributed  
113 drug product is significant, you should evaluate the potential impact of the change or  
114 deterioration on the drug product's identity, strength, purity, stability, and efficacy and how that  
115 change or deterioration could impact an individual using the product. Any such assessment  
116 should be based on factors specific to your distributed product. These factors could include  
117 intended use, route of administration, dosage, length of treatment, and patient population.

118  
119 You should also clearly document an investigation conducted according to 21 CFR 211.192  
120 (production record review) or 211.198 (complaint files), including the determination of whether  
121 a problem resulted in a significant chemical, physical, or other change or deterioration, along  
122 with the rationale (including factors considered) for the determination. (See, e.g., question 1d for  
123 information about consumer complaints.)

124  
125 d. *Does every consumer complaint warrant submission of a FAR?*

126  
127 No. Every consumer complaint should be evaluated within 3 working days to determine if the  
128 information provided in the complaint meets the criteria outlined in § 314.81(b)(1). You must  
129 submit a FAR within that time frame if you determine that the information identified in the  
130 complaint meets the criteria for a FAR.

131  
132 e. *Do I have to submit a FAR for packaging or components used in the manufacture of the*  
133 *distributed product?*

134  
135 If you receive information about packaging or components that meets the criteria set forth in  
136 § 314.81(b)(1), you must submit a FAR within 3 working days of your receipt of that  
137 information. For example, if you receive information that a stopper used for a vial could result in  
138 contamination of a distributed batch, the information must be submitted in a FAR.

139  
140 f. *If the product approved under an NDA/ANDA is only distributed outside the United*  
141 *States, am I still subject to the FAR requirements?*

142  
143 Yes. Any drug product marketed under an approved NDA or ANDA, whether distributed  
144 domestically or abroad, is subject to FAR requirements.<sup>7</sup>

145  
146 g. *If a product has not been distributed and an out-of-specification (OOS) result is*  
147 *discovered, is a FAR still required?*

148  
149 No. A FAR is only required for distributed drug products. However, if you discover an OOS  
150 result and your investigation<sup>8</sup> for example, indicates a failure of one or more distributed batches

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<sup>7</sup> See § 314.81(b)(1).

<sup>8</sup> See § 211.192.

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151 of the drug product to meet the specification established in the application, or other kinds of  
152 information as specified in § 314.81(b)(1), then you must submit a FAR.<sup>9</sup>

153  
154 *h. If an OOS result for a distributed drug product is discovered during stability testing, but*  
155 *the result is invalidated within 3 working days, do I need to submit a FAR?*  
156

157 No. OOS results for a distributed drug product that are scientifically invalidated (e.g., an  
158 analytical laboratory error is confirmed) within 3 working days do not require a FAR. If an OOS  
159 result is not scientifically invalidated, you must submit a FAR within 3 working days of your  
160 initial receipt of the OOS information.

161  
162 *i. Do aseptic process simulation (media fill) failures for a distributed drug product require*  
163 *a FAR?*  
164

165 A media fill validation failure indicates a potential problem related to sterility assurance that  
166 requires an investigation, including assessment of the impact on distributed drug products  
167 produced since the last successful media fill.<sup>10</sup> As such, you must submit a FAR for any  
168 distributed drug product within the scope of the media fill failure investigation within 3 working  
169 days of receiving information about such a failure if the information meets the criteria set forth in  
170 § 314.81(b)(1).

171  
172 *j. If the root cause of a problem related to a distributed drug product is identified and*  
173 *corrected within 3 working days, should I still submit a FAR?*  
174

175 Yes, if you receive information as outlined in § 314.81(b)(1), you must submit a FAR within 3  
176 working days regardless of whether an investigation identifies a root cause or leads to a  
177 corrective action. The report should include detailed information regarding the identified root  
178 cause and any completed or ongoing corrective action.

179  
180 *k. Is a FAR required if a recall is initiated?*  
181

182 If the recall is for an NDA/ANDA product and the information leading to the recall meets the  
183 criteria under § 314.81(b)(1), you must submit a FAR. You should also submit a recall  
184 notification to FDA through your local recall coordinator  
185 (<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>). If the recall is initiated  
186 after an initial FAR is submitted, we encourage you to submit a follow-up or final FAR at the  
187 time of the recall notification.<sup>11</sup>

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<sup>9</sup> See also guidance for industry *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production*. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

<sup>10</sup> See § 211.192.

<sup>11</sup> See 21 CFR part 7; FDA, 2016, Chapter 7: Recall Activities, Investigations Operations Manual; and guidance for industry *Product Recalls, Including Removals and Corrections*.

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### **2. Who is responsible for submitting the FAR?**

As the NDA/ANDA applicant, you must submit the FAR.<sup>12</sup> If you have a contractual agreement with another person or entity to perform manufacturing, holding, packaging, labeling, or distribution activities or services for your products, you still hold ultimate responsibility for reporting FARs. You should establish, maintain, and follow a procedure for receiving and responding to any reportable information from contracted entities concerning your products.<sup>13</sup>

### **3. When should I submit a FAR?**

#### *a. What is the required time frame for the submission of a FAR?*

You must submit a FAR within 3 working days of receipt of the information described in § 314.81(b)(1). We consider *working days* to be any day from Monday through Friday, excluding U.S. Federal holidays. For example, if any information meeting the criteria requiring a FAR is identified on Friday (day 0), then day 1 begins on the first working day after the information is identified (Monday), and you must submit the FAR by close of business on Wednesday (day 3). This time frame applies regardless of where the information meeting the criteria requiring a FAR is identified. For example, the day a contract lab learns of a sterility failure is day 0, and you must submit the FAR by close of business on day 3.

#### *b. What will happen if I do not submit a FAR within the 3-day time frame?*

If you fail to submit a required FAR within this time frame, you would—at a minimum—be in violation of § 314.81(b)(1). You would also be in violation of section 505(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>14</sup> Violating section 505(k) is a prohibited act under section 301(e) of the FD&C Act.<sup>15</sup> We may include this as an observation on Form FDA 483, Inspectional Observations. Any FDA finding that you have failed to submit a FAR, as required, may result in a regulatory action, whether or not the finding was cited on a Form FDA 483.

### **4. How do I submit a FAR?**

#### *a. Is a form available to submit FARs?*

Yes. We recommend that you use Form FDA 3331a to submit your FARs electronically. Submitting electronically will expedite FDA's review process and fulfill your obligation to submit the FAR to the relevant district office. We will, however, accept other types of submissions as described in § 314.81(b)(1).

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<sup>12</sup> See §§ 314.81(b) and 314.98(b).

<sup>13</sup> See guidance for industry *Contract Manufacturing Arrangements for Drugs: Quality Agreements*.

<sup>14</sup> 21 U.S.C. 355(k).

<sup>15</sup> 21 U.S.C. 331(e).

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228 Form FDA 3331a and its instructions are available on the FAR website at  
229 [https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm529729.h](https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm529729.htm)  
230 [tm](https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm529729.htm).

231  
232 *b. Is it necessary to submit a paper copy of a FAR if the FAR has been submitted*  
233 *electronically?*

234  
235 No. Electronic submission of Form FDA 3331a as outlined in the Form FDA 3331a instructions  
236 meets FAR requirements under § 314.81(b)(1).

237  
238 *c. Does submission of FDA Form 3331a satisfy the written follow-up requirement for FARs*  
239 *submitted initially by telephone?*

240  
241 Yes, using Form FDA 3331a as instructed will satisfy the written follow-up requirement for  
242 FARs initially submitted by telephone or other rapid means as set forth in § 314.81(b)(1). Once  
243 you use Form FDA 3331a to submit your FAR electronically, the information you entered will  
244 be available to CDER or CBER and the FDA district office responsible for the facility involved.

245  
246 *d. Can FARs associated with multiple NDAs/ANDAs be submitted on one form?*

247  
248 No. If multiple NDAs or ANDAs are involved, submit one Form FDA 3331a for each NDA or  
249 ANDA. See question 4e for additional information on submitting FARs for a facility-wide  
250 problem that affects drug products covered by multiple applications or application types.

251  
252 *e. How should I report a facility-wide problem that affects drug products covered by*  
253 *multiple applications or application types?*

254  
255 You must submit a separate initial FAR for each application (NDA or ANDA) that is affected by  
256 the problem.<sup>16</sup> If you conduct a single comprehensive investigation into the problem at a facility  
257 and you submit a follow-up or final FAR, you can submit one follow-up and/or final FAR that  
258 references all of the affected products, including the NDA/ANDA number(s) and the date(s) the  
259 problem was identified.

260  
261 *f. What if I don't know the information asked for on Form FDA 3331a at the time of*  
262 *submission?*

263  
264 In an initial FAR, provide whatever information you have that is related to the problem within 3  
265 working days of receipt of the information described in § 314.81(b)(1). Please be sure to report  
266 the NDA/ANDA number, the drug product generic name and trade/brand name (if any), the  
267 product quality issue, and your contact information. When you learn more about the problem  
268 reported in the initial FAR, we recommend that you submit any new information in a follow-up  
269 or final FAR (see III.6).

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<sup>16</sup> See § 314.81(a).

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270  
271 g. *Form FDA 3331a asks for the “date when notified about problem(s) or when problem(s)*  
272 *first became known to application holder.” Is this the date when the information was*  
273 *confirmed as an actual problem?*  
274

275 No, it is the date you received information of the kinds outlined in § 314.81(b)(1). Any follow-up  
276 and final FARs should contain the same initial date.

277

### 278 **5. Where do I submit a FAR?**

279

280 When you use the automated features of Form FDA 3331a, your FAR will be submitted  
281 simultaneously to CDER and to the FDA district office you select on page ii of the form. CDER  
282 will forward FARs to CBER, as appropriate. Form FDA 3331a provides contact information  
283 (e.g., email and postal addresses) for all district offices. For specific information about which  
284 district office to select on page ii of the form, see the questions and answers below.

285

286 a. *If the problem occurs at a domestic facility in the United States, where do I indicate that*  
287 *facility’s information on the FAR and where should I submit the FAR?*  
288

289

290 You should list the facility information in Form FDA 3331a’s box 1—“Firm Name and Address  
291 Where Problem Occurred”—and select the FDA district office responsible for that facility on  
292 page ii of the form. We recommend that you also cc: the district office where your headquarters  
293 is located if different from the FDA district office you selected on the form.

294

295 b. *If the problem occurs at a foreign facility, where do I indicate that facility’s information*  
296 *on the FAR and where should I submit the FAR?*

297

298 You should list the foreign facility information in Form FDA 3331a’s box 1—“Firm Name and  
299 Address Where Problem Occurred”—and, on page ii, select the FDA district office where your  
300 firm’s attorney, U.S. agent, or other authorized official resides or maintains a place of business in  
301 the United States.<sup>17</sup>

302

303 c. *If multiple firms or locations are implicated in an investigation, which firm or location*  
304 *should I list on the FAR as the site where the problem occurred?*

305

306 You should enter the name and address of the finished drug product manufacturer for the NDA  
307 or ANDA in Form FDA 3331a’s box 1—“Firm Name and Address Where Problem Occurred.”  
308 However, if the problem involves the active pharmaceutical ingredient (API) or any raw  
309 material, you should list the supplier’s facility information in box 1 instead. If the problem  
310 involves a firm other than the finished drug product manufacturer, such as a labeling and  
311 packaging firm, you should list that firm’s information in box 1. If any firm other than the  
finished drug product manufacturer is listed in box 1, you should include the name and address

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<sup>17</sup> See 21 CFR 207.40 and 314.50(a)(5).

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312 of the finished drug product manufacturer in box 14, “Remarks,” as well as any additional sites  
313 implicated but not already included in box 1.

314  
315 *d. If it is unclear where the problem occurred, which location should I list on the FAR and*  
316 *where should I submit the FAR?*

317  
318 If it is unclear where the problem occurred, you should list the site where, to the best of your  
319 knowledge, the problem most likely occurred (see question 5c) in Form FDA 3331a’s box 1—  
320 “Firm Name and Address Where Problem Occurred”—and, on page ii, select the FDA district  
321 office responsible for that location. For example, if your NDA/ANDA product is found to have  
322 one or more bottles containing the wrong tablet at the time the FAR is submitted, it could be  
323 unclear if the problem occurred at the tableting facility or during distribution in bulk containers  
324 to the contract packager, packaging at a contract facility, subsequent shipping and handling, or  
325 dispensing at the pharmacy. We recommend that you cc: the FDA district office where your  
326 headquarters are located if different from the district office responsible for the location where the  
327 problem occurred. List additional sites implicated in box 14, “Remarks.”

328  
329 If during the course of an investigation you wish to change the information initially provided or  
330 you have determined where the problem occurred, you should update the establishment name,  
331 address, and/or facility establishment identifier (FEI) number or the data universal numbering  
332 system (DUNS) number of the firm where the problem occurred in a follow-up FAR. If a new  
333 district office is the receiving district for your follow-up FAR, please also cc: the original district  
334 office that received the initial FAR.

335  
336 **6. Should I submit a follow-up or final FAR?**

337  
338 Although follow-up and final FARs are not required under § 314.81(b)(1), we recommend that  
339 you submit these additional voluntary reports, when warranted, as soon as possible.<sup>18</sup> We use the  
340 information in these reports to assess the risk to public health and the adequacy of the firm’s  
341 response.

342  
343 *a. When should I submit a follow-up FAR?*

344  
345 Though not required, we encourage you to submit follow-up FARs when (1) there are significant  
346 findings during any investigation for the same problem as that identified in the initial FAR (e.g.,  
347 additional lots impacted, different locations identified) or (2) you learn that information  
348 submitted in a previous FAR is incorrect.

349  
350 *b. During the open investigation, if I discover that additional lots of the same drug product*  
351 *have the same issues as those identified in the initial FAR, should I submit a new FAR?*

352  
353 If you choose to submit a follow-up FAR, you should submit a follow-up FAR that identifies the  
354 additional lots. In the follow-up FAR, you should reference the discovery date from the initial

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<sup>18</sup> For a description of follow-up and final FARs, see question 1b.

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355 FAR, update FDA on the progress of the investigation, identify corrective actions that you have  
356 taken as well as those you intend to take, and provide the anticipated date for closing out the  
357 investigation in Form FDA 3331a's box 14 "Remarks."  
358

359 *c. If I receive an additional consumer complaint while there is a FAR for the same problem*  
360 *still being investigated, should I submit a follow-up FAR?*  
361

362 No. A follow-up FAR should not be submitted if all of the following are true:  
363

- 364 • The problem is the same as that identified in the initial FAR.
  - 365 • The drug product is covered under the same NDA/ANDA as originally reported.
  - 366 • The investigation into the root cause of the initial FAR is still ongoing.
  - 367 • The drug product is part of the same lot as originally reported.
- 368

369 When there is an ongoing root cause investigation for a FAR (i.e., one for which no final FAR  
370 has been submitted), we recommend that you provide a cumulative list of related complaints in  
371 your final FAR rather than submitting a FAR for every consumer complaint received.  
372

373 *d. When should I submit the final FAR?*  
374

375 We recommend submitting final FARs promptly to inform FDA when you identify the root  
376 cause, take corrective action, or close the investigation. Investigations should be closed as soon  
377 as possible.