
Guidance for Industry

Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)
Pharmaceutical CGMPs
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Additional copies of this Guidance are available from

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Internet: <http://www.fda.gov/cder/guidance/index.htm>.

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Guidance for Industry¹

Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP

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 document is intended to provide guidance to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP) requirements. This document is not intended to cover medical devices regulated by the Center for Devices and Radiological Health (CDRH) or foods or dietary supplements regulated by the Center for Food Safety and Applied Nutrition (CFSAN).

Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during the Agency's assessment of corrective actions undertaken as a result of such inspections. As these disputes may involve complex judgments and issues that are scientifically or technologically important, it is critical to have procedures in place that will encourage open, prompt discussion of disputes and lead to their resolution. This guidance describes procedures for raising such disputes to the Office of Regulatory Affairs (ORA) and center levels and for requesting review by the Dispute Resolution Panel for Scientific and Technical Issues Related to Pharmaceutical CGMP (DR Panel).

Manufacturers are encouraged to seek clarification of scientific or technical issues with the inspection team at any time during an inspection. Although there are existing processes to encourage dialogue between FDA and manufacturers, the processes described in this document

¹This guidance has been prepared by the Dispute Resolution Working Group formed as part of the August 2002 FDA Initiative, Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach. The Working Group included representatives from the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA).

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38 apply to CGMP questions raised during inspections and are intended to supplement the dispute
39 resolution processes currently in place, including:

40

41 • 21 CFR 10.75, Internal Agency Review of Decisions. Allows manufacturers to ask for a
42 review of Agency decisions at each successive supervisory level through the chain of
43 command, ending with the FDA Commissioner's office.

44

45 • CDER/CBER guidance for industry entitled *Formal Dispute Resolution: Appeals Above*
46 *the Division Level*. Describes procedures a sponsor may use to formally appeal disputes
47 to the office or center level on scientific and procedural issues that arise during drug
48 development, new drug review, and post-marketing oversight processes. The guidance
49 may be found on CDER's and CBER's Web sites.²

50

51 • CVM guidance for industry #79 entitled *Dispute Resolution Procedures for Science-*
52 *Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)*,
53 July 2005. Describes procedures for handling requests for internal review of scientific
54 controversies relating to decisions affecting animal drugs or other products that are
55 regulated by CVM. The guidance may be found on CVM's Web site.³

56

57 • Investigations Operations Manual (IOM), Chapter 5, Subchapter 510, Sections 512
58 (Report of Observations) and 516 (Discussions with Management). Describes processes
59 for discussing inspectional observations with a manufacturer. The IOM is available on
60 ORA's Web site.⁴

61

62 For the purposes of this document, the term *manufacturer*⁵ includes any domestic or foreign
63 applicant or manufacturer of a human or veterinary drug, or human biological drug product
64 regulated by the Agency under the Federal Food, Drug, and Cosmetic Act (the Act) or section
65 351 of the Public Health Service Act (the PHS Act).

66

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

72

73 **II. SCOPE OF THE GUIDANCE**

74

² The CDER/CBER guidance can be found on the Internet at <http://www.fda.gov/cder/guidance/index.htm> and <http://www.fda.gov/cber/gdlns/dispute.htm>.

³ The CVM guidance can be found on the Internet at: <http://www.fda.gov/cvm/Guidance/published.htm#79>.

⁴ The IOM can be found on the Internet at: http://www.fda.gov/ora/inspect_ref/iom/iomtc.html.

⁵ The activities of a manufacturer encompass the processes and functions described in 21 CFR 207.3(8), 21 CFR 210.3(12), and 21 CFR 600.3(t).

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75 The policies and procedures described in this guidance document cover all disputes on scientific
76 or technical issues related to CGMP that arise as the result of CGMP and preapproval
77 inspections (PAI) for manufacturers of veterinary and human drug products, including related
78 Active Pharmaceutical Ingredients (APIs). For disputes that arise during prelicense and
79 preapproval inspections for human biological drug products regulated by CBER or for
80 application review issues that arise during PAI inspections for human or veterinary drug
81 products, the existing CDER/CBER and CVM guidances listed in Section I of this document
82 should continue to be used.

83
84 This guidance does not cover disputes over procedures or administrative matters that may arise
85 during the inspection process. At any time, a manufacturer may informally raise a procedural or
86 administrative matter with ORA or with the CDER, CBER, or CVM Ombudsman, in accordance
87 with 21 CFR 10.75. The procedures described in this guidance do not apply to such informal
88 dispute resolution through the CDER, CBER, or CVM Ombudsman.

89
90 If a dispute involves a combination product including a device component, the dispute may be
91 addressed through CDRH's dispute resolution process, depending on the nature of the dispute.⁶
92

93 **III. DISPUTE RESOLUTION PROCESS**

94
95 During inspections of manufacturers, investigators are expected to make every reasonable effort
96 to discuss observations relating to manufacturing quality as they are observed, or on a daily basis
97 to minimize surprise, errors, and misunderstandings when a Form FDA 483 is issued. At the
98 conclusion of an inspection, investigators will normally meet with the manufacturer's
99 management to again discuss observations and solicit views and additional relevant information.
100 These processes are described in detail in the Investigations Operations Manual (IOM), Sections
101 512 and 516, as listed in Section I of this document.

102
103 When a scientific or technical issue arises during an inspection, we recommend that a
104 manufacturer initially attempt to reach agreement on the issue informally with the investigator.
105 A manufacturer should discuss with the investigator any observation that the manufacturer
106 believes is not justified from a scientific or technical standpoint. As appropriate, the investigator
107 can consult with FDA management or program officials, or appropriate product or technical
108 experts. The investigator may invite the company to participate in certain consultative
109 discussions. If agreement on the issue is not reached with the investigator prior to issuance of
110 the Form FDA 483, a manufacturer can formally request dispute resolution after the investigator
111 issues the Form FDA 483.

112
113 Certain scientific or technical issues may be too complex or time-consuming to resolve during
114 the inspection. If resolution of a scientific or technical issue is not accomplished through
115 informal mechanisms prior to the issuance of a Form FDA 483, manufacturers can use the formal
116 two-tiered dispute resolution process described in this guidance.

⁶ CDRH guidance document, *Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel*; Final Guidance for Industry and FDA, July 2, 2001.

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- 117
- 118 • Tier one of the formal dispute resolution process refers to scientific or technical issues
- 119 raised to the ORA and center levels.
- 120 • Tier two of the formal dispute resolution process refers to scientific or technical issues
- 121 raised to the DR Panel.

122 These processes are described in detail in the following subsections.

123

124 **A. Tier-One Dispute Resolution at the Office of Regulatory Affairs and Center**

125 **Levels**

126

127 Pharmaceutical manufacturers can formally dispute the scientific or technical basis for CGMP

128 inspectional observations after issuance of a Form FDA 483. In such cases, the formal dispute

129 resolution process starts in the appropriate *ORA unit*⁷ as listed below and may advance to the

130 applicable center.

- 131
- 132 • For domestic manufacturers of veterinary and human drugs, the formal dispute resolution
- 133 process begins in the appropriate district office, ORA.
- 134
- 135 • For foreign manufacturers of veterinary and human drugs, the formal dispute resolution
- 136 process begins in the Division of Field Investigations, ORA.
- 137
- 138 • For domestic or foreign manufacturers of human biological drug products inspected by
- 139 Team Biologics, the formal dispute resolution process begins in the Office of
- 140 Enforcement, ORA.
- 141

142 A manufacturer should seek clarification of a disputed scientific or technical issue within 30

143 days of issuance of the Form FDA 483. (FDA defines *days* to mean calendar days throughout

144 this guidance.) FDA may refuse to address a dispute resolution request not raised during this

145 time frame. The Agency, at its discretion, may contact the manufacturer to obtain additional

146 information and/or seek clarification.

147

148 If a manufacturer disagrees with the scientific or technical basis for an observation listed by an

149 investigator on a Form FDA 483, the following steps may be taken:

150

- 151 1. The manufacturer may file a written request for formal dispute resolution with the
- 152 appropriate ORA unit as listed above. The manufacturer should provide all supporting
- 153 documentation and arguments for review.
- 154
- 155 2. The appropriate ORA unit may evaluate the written request for formal dispute resolution,
- 156 and may include Agency staff not previously involved in the dispute, as appropriate.
- 157

⁷ For the purposes of Sections III A and B in this document, the phrase *ORA unit* will refer to the district office, the Division of Field Investigations, or the Office of Enforcement, as appropriate.

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158 If the ORA unit agrees with the manufacturer,

- 159
- 160 • The ORA unit will issue a written response to the manufacturer within 30 days of receipt
161 of the request, noting its agreement with the manufacturer and resolution of the dispute.
162 The resolution may take the form of a letter. It may also take the form of an addendum to
163 the existing Form FDA 483.
 - 164
 - 165 • All disputes resolved at the ORA level will be copied to the relevant program center for
166 information and public dissemination following appropriate redaction.

167

168 If the ORA unit disagrees with the manufacturer,

- 169
- 170 • The ORA unit will issue a written response to the manufacturer generally within 30 days
171 of receipt of the request. Responses that disagree with a manufacturer's position will
172 incorporate a review and decision by the relevant program center, which may require
173 additional time as described below.
 - 174
 - 175 • The written response will be copied to the relevant program center for information and
176 public dissemination after appropriate redaction, in accordance with applicable
177 requirements.

178

179 If the ORA unit is unable to complete its review of the request and respond within 30 days, the
180 ORA unit will notify the manufacturer, explain the reason for the delay (which may include the
181 need for an additional 30 days for center review), and discuss the time frame for completing the
182 review.

183

184 3. If a manufacturer disagrees with the tier-one decision, the manufacturer can appeal that
185 decision to the DR Panel.

186

B. Tier-Two Dispute Resolution with the DR Panel on Scientific and Technical 187 Issues

188

189

190 The DR Panel provides a formal way for manufacturers to defend the science in their
191 manufacturing and quality control processes before a neutral panel of experts and to appeal an
192 ORA and center-level decision concerning the science underlying the inspectional observation.

193

194 The DR Panel resides at the Office of the Commissioner. The DR Panel considers requests for
195 tier-two dispute resolution by manufacturers and provides an opportunity for a manufacturer to
196 present its case in support of its position on a scientific or technical issue. The DR Panel's
197 membership includes representatives from each of the program centers and ORA, as well as the
198 Chair of the FDA Council on Pharmaceutical Quality, but will not include decision makers who
199 have addressed the disputed issue at the ORA and center level.

200

201 If a manufacturer disagrees with the tier-one decision in the formal dispute resolution process,
202 the manufacturer can file a written request for formal dispute resolution by the DR Panel. The

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203 manufacturer should provide the written request for formal dispute resolution and all supporting
204 documentation and arguments to the DR Panel for review within 60 days from issuance of the
205 tier-one decision.
206

207 The DR Panel will evaluate the written request for formal dispute resolution. The DR Panel will
208 determine whether or not to consider the specific issue in the appeal. If necessary, additional
209 internal and external experts, as well as attorneys from the Office of Chief Counsel (OCC), may
210 be added to the DR Panel to facilitate evaluation of the specific issue.
211

212 If the DR Panel determines that the request is appropriate for review, it will schedule a meeting
213 to discuss the issue within 90 days. The DR Panel may communicate with the manufacturer at
214 its discretion and may request the manufacturer to be present during the meeting.
215

216 If the DR Panel agrees with the manufacturer on the issue,
217

- 218 • The executive secretary of the DR Panel will issue a written response to the manufacturer
219 within 30 days of the meeting, noting its agreement with the manufacturer and resolution
220 of the dispute.
221
- 222 • All disputes resolved at the DR Panel level will be copied to the relevant FDA units for
223 their information and public dissemination after appropriate redaction, in accordance
224 with applicable requirements.
225

226 If the DR Panel disagrees with the manufacturer on the issue,
227

- 228 • The executive secretary of the DR Panel will issue a written response to the manufacturer
229 within 30 days of the meeting, noting its decision on the issue, except as provided below.
230
- 231 • The executive secretary of the DR Panel will notify the relevant FDA units of the DR
232 Panel's decision for their information and public dissemination after appropriate
233 redaction, in accordance with applicable requirements.
234

235 If the DR Panel determines that the request does not qualify for review (see Section IV), the
236 executive secretary of the DR Panel will notify the manufacturer in writing within 30 days of
237 receipt of the appeal and communicate the DR Panel's decision to the program offices.
238

239 If FDA is unable to complete its review of the request and respond within 30 days, the executive
240 secretary of the DR Panel will notify the manufacturer, explain the reasons for the delay, and
241 discuss the time frame for completing the review.
242

C. How to Request Formal Dispute Resolution

245 All Agency decisions in the formal dispute resolution process will be based on the
246 manufacturer's documentation that was available at the time of the inspection, unless a
247 manufacturer can provide a reasonable explanation why it did not present relevant information

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248 during the inspection or the manufacturer was specifically requested to provide new information
249 as part of the Agency's dispute resolution review. Submission of new information may result in
250 the dispute being returned to an earlier point in the process, as the Agency deems appropriate.
251

252 The following list of addresses can be used to request formal dispute resolution.
253

- 254 1. For a tier-one dispute resolution request from domestic manufacturers of veterinary and
255 human drugs, the request should be submitted to:

256
257 Director of the district office responsible for the inspection
258 The following Internet site lists district office addresses:
259 http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html.
260

- 261 2. For a tier-one dispute resolution request from foreign manufacturers of veterinary and
262 human drugs, the request should be submitted to:

263
264 Director, Division of Field Investigations
265 Office of Regional Operations
266 Office of Regulatory Affairs
267 Food and Drug Administration
268 Mail Code: HFC-100
269 5600 Fishers Lane, Room 13-64
270 Rockville, Maryland 20857
271

- 272 3. For a tier-one dispute resolution request from domestic or foreign manufacturers of
273 human biological drug products inspected by Team Biologics, the request should be
274 submitted to:

275
276 Director, Division of Compliance Management and Operations
277 Office of Enforcement
278 Office of Regulatory Affairs
279 Food and Drug Administration
280 Mail Code: HFC-210
281 5600 Fishers Lane
282 Rockville, MD 20857
283

- 284 4. For a tier-two dispute resolution request, the request should be submitted to the
285 appropriate center contact as listed below:

- 286
287 • For CDER:

288
289 Formal Dispute Resolution Project Manager (DPRM)
290 Office of Compliance
291 Center for Drug Evaluation and Research
292 Food and Drug Administration

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293 Mail Code: HFD-320
294 5600 Fishers Lane
295 Rockville, MD 20857
296

- For CVM:

298
299 Ombudsman
300 Office of the Center Director
301 Center for Veterinary Medicine
302 Food and Drug Administration
303 Mail Code: HFV-7
304 7519 Standish Place
305 Rockville, MD 20855
306

- For CBER:

308
309 Assistant to the Director for Policy
310 Office of Compliance and Biologics Quality
311 Center for Biologics Evaluation and Research
312 Food and Drug Administration
313 Mail Code: HFM-600
314 1401 Rockville Pike, Suite 200N
315 Rockville, MD 20852
316

D. Supporting Information to be Provided by Manufacturers

317
318
319 All requests for formal dispute resolution should be in writing and include adequate information
320 to explain the nature of the dispute and to allow the Agency to act quickly and efficiently. Each
321 request should include the following:

1. Cover sheet that clearly identifies the submission in bold, uppercase letters:

322
323
324
325 **REQUEST FOR TIER-ONE DISPUTE RESOLUTION**

326
327 or

328
329 **REQUEST FOR TIER-TWO DISPUTE RESOLUTION (REVIEW BY THE**
330 **DISPUTE RESOLUTION PANEL FOR SCIENTIFIC AND TECHNICAL ISSUES**
331 **RELATED TO PHARMACEUTICAL CGMP)**
332

2. Name and address of manufacturer inspected (as listed on the Form FDA 483)
3. Date of inspection (as listed on the Form FDA 483)
4. Date the Form FDA 483 issued (from the Form FDA 483)

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339 5. FEI Number, if available (from the Form FDA 483)
340
341 6. Names and titles of FDA employees who conducted inspection (from the Form FDA 483)
342
343 7. Office responsible for the inspection, e.g., district office, as listed on the Form FDA 483
344
345 8. Application number if the inspection was a preapproval inspection
346
347 9. Comprehensive statement of each issue to be resolved
348
349 • Identify the observation in dispute.
350 • Clearly present the manufacturer’s scientific position or rationale concerning the
351 issue under dispute with any supporting data.
352 • State the steps that have been taken to resolve the dispute, including any informal
353 dispute resolution that may have occurred before the issuance of the Form FDA 483.
354 • Identify possible solutions.
355 • State desired outcome.
356
357 10. Name, title, telephone and fax number, and e-mail address (as available) of manufacturer
358 contact.
359

E. FDA Response to Requests for Dispute Resolution

360
361
362 FDA will respond in writing to all requests for dispute resolution filed under the procedures
363 described in this guidance. The written response should specifically agree or disagree with the
364 outcome desired by the manufacturer, agree or disagree with parts of the proposed outcome, or
365 indicate a resolution that is different from that proposed by the manufacturer. If the Agency does
366 not agree with the manufacturer’s position, the response should include reasons for the
367 disagreement.
368

369 The Agency official responsible for replying to a request for dispute resolution should make all
370 reasonable efforts to resolve the dispute and provide a written response to the manufacturer
371 according to timelines suggested above in Section III. A and B.
372

373 The Agency may, under appropriate circumstances, take regulatory action while a request for
374 formal dispute resolution is pending.
375

IV. SUITABILITY OF ISSUES FOR FORMAL DISPUTE RESOLUTION

376
377
378 Any dispute involving a scientific or technical issue related to CGMP regulations that arises
379 during an FDA inspection, as discussed above, may be suitable for the dispute resolution process
380 described in this guidance.
381

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382 The following text provides examples concerning the appropriateness of several issues for the
383 dispute resolution process detailed in this guidance.

384

A. Failure to Comply With a Precise Element of CGMP Regulations

386

387 According to 21 CFR 211.100(a), a manufacturer producing a finished pharmaceutical product
388 must have written procedures for production and process controls, and these written procedures
389 must be designed to ensure that the drug has the identity, strength, quality, and purity it purports
390 or is represented to have.

391

392 • Failure to have written procedures for production and process controls would be a
393 failure to comply with a precise element of the CGMP regulations and would not be
394 appropriate for the formal dispute resolution process described in this document.

395

396 • However, observations pertaining to the adequacy of the process and production
397 control design activities could be subject to scientific debate and may be appropriate
398 for dispute resolution as described in this guidance.

399

400 Another example relates to the regulatory provisions governing the testing and approval or
401 rejection of components, drug product containers, and closures (21 CFR 211.84), which require
402 appropriate sampling, testing, or examination of each lot of components, drug product
403 containers, or closures.

404

405 • Failure to conduct testing or examination of each lot would be failure to comply with
406 a precise element of the regulations and would not be appropriate for the formal
407 dispute resolution process described in this guidance.

408

409 • However, the appropriateness of a particular test or sampling scheme could involve
410 the exercise of scientific judgment. A disagreement between a manufacturer and an
411 investigator concerning the adequacy of a particular test or sampling scheme could be
412 subject to scientific debate and may be appropriate for dispute resolution as described
413 in this guidance.

414

415 A third example relates to the CGMP regulation requirements that a manufacturer thoroughly
416 investigates any unexplained discrepancy associated with its review of product production and
417 control records (21 CFR 211.192).

418

419 • Failure to investigate an unexplained discrepancy would be a failure to comply with a
420 precise element of the CGMP regulations and would not be appropriate for the formal
421 dispute resolution process described in this guidance.

422

423 • However, the extent or adequacy of the investigation could be subject to scientific
424 debate. Observations pertaining to the adequacy of an investigation into an
425 unexplained discrepancy may also be appropriate for dispute resolution as described
426 in this guidance.

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B. Failure to Comply With a Precise Requirement Established in an Approved Application

If, as part of the conditions established in an approved application, a manufacturer is required to conduct a particular test on a finished product and the manufacturer fails to conduct that test, this failure represents a failure to comply with a precise requirement established in an approved application. Any disagreement about the need for such a test should be raised in the application review process. Such disagreement is not appropriate for the dispute resolution process described in this guidance, but may be raised using the processes described in the CDER/CBER and CVM guidances listed in Section I of this document.

C. The Regulatory Significance of Failing to Comply With a Precise Requirement

The CGMP regulations require that all changes to production and process control procedures be approved by the quality control unit (21 CFR 211.100(a)). If a manufacturer makes a change in production and process control procedures, but does not obtain approval of those procedures by the manufacturer's quality control unit, this would be a failure to comply with a precise requirement of the CGMP regulations. The manufacturer may contend that the failure in this particular case was not significant because it did not have an adverse effect on product quality and may convey this contention to the Agency through existing informal communication channels, including Form FDA 483-response correspondence.

In such a case, the significance of this observation would not be appropriate for dispute resolution as described in this guidance, as the observation concerns a failure to comply with a precise requirement of the regulations. The regulatory significance of an observation is determined by the Agency after considering all relevant information, including the manufacturer's response to the inspectional observations. The Agency encourages manufacturers to provide all information relevant to the regulatory significance of an observation as part of this response, but such disputes are not within the scope of this guidance on scientific and technical disputes concerning the interpretation and application of CGMP requirements.

Manufacturers must have internal written production and process control procedures (21 CFR 211.100(a)) and, as part of these procedures, manufacturers often establish procedural *action limits* that are tighter than release specifications. When the *action limits* are exceeded, the internal written procedures may call for some type of investigation to determine if the process is drifting toward a loss of control, or the procedures may call for other assessments to determine if the product will meet appropriate specifications throughout its expected shelf life. If a manufacturer's internal written procedures require certain actions when *action limits* are exceeded, failure to follow these written production and process control procedures is a failure to comply with 21 CFR 211.100(b). The manufacturer may contend that this failure is not significant in that the product met all regulatory specifications when released. As discussed above, this contention about significance is not appropriate for the formal dispute resolution process described in this guidance.

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D. Issues Not Raised During the Inspection

If, during an inspection, an investigator notes what appears to be an objectionable condition and a manufacturer disagrees with that observation, the manufacturer should voice its disagreement with the investigator. By doing so, the investigator has the opportunity to evaluate the manufacturer's position and consult, as needed, with Agency experts. The Agency may not accept a request for dispute resolution concerning a disagreement that was not initially raised by the manufacturer during the inspection unless a manufacturer can provide a reasonable explanation why it did not present relevant information during the inspection.

V. COMMUNICATION OF DISPUTE RESOLUTION DECISIONS

FDA believes that decisions made in the dispute resolution process, along with all supporting documentation, should be publicly available consistent with FDA's disclosure regulations (21 CFR Part 20) and applicable statutes, unless the decisions involve information that would otherwise be withheld under these regulations and statutes. The Agency will redact, as appropriate, any documents requested through the Freedom of Information process.

When appropriate, a summary of the relevant issues and Agency views will be provided in a question and answer format and posted on the FDA Web site with all identifying information excluded. Information gained from these decisions should promote consistent application and interpretation of pharmaceutical CGMP requirements.

VI. 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 30 hours to prepare and submit each request for tier-one dispute resolution and 8 hours to prepare and submit each request for tier-two dispute resolution. This includes the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to Edward M. Sherwood, Center for Drug Evaluation and Research (HFD-3), Food and Drug Administration, Rockwall II, Rm. 7231, 5515 Security Lane, Rockville, MD 20857, 301-594-2847.

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511 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of
512 information unless it displays a currently valid OMB control number. The OMB control number
513 for this information collection is 0910-0563 (expires 05/31/2008).

514