



03D-0386 MR-2 03/02

March 2, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 03D-0386, Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical cGMP.

Pfizer would like to acknowledge the effort put forth by the FDA in the publication of the Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical cGMP.

Pfizer supports the necessity for and actively encourages open debate and discussion with the investigator during the inspection. However, even with good communication, there may be instances where it is unclear which information is needed to answer an investigator's questions and concerns. The site may not understand the request until the FDA Form 483 is written and issued. Pfizer proposes to allow the submission of additional information at the Tier 1 and/or Tier 2 Levels as supporting information. This is particularly true if questions are raised during the activities of the Dispute Resolution Panel. Additional information, as distinguished from new information, should be considered for a fully knowledgeable review and resolution of issues.

Pfizer appreciates the opportunity to provide the attached comments to clarify and strengthen the proposed guideline.

Sincerely,

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Regulatory Monitoring
Global Manufacturing Compliance
Pfizer Inc.

03D-0386

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**Pfizer Comments on:
Draft FDA Guidance “Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical cGMP”
(Docket No. 2003D-0386)
August 2003**

Section	Guidance Line	Comment	Rationale
III	102-103	Add “and/or the firm” in the sentence: “As appropriate, the investigator can consult with FDA management or program officials, or appropriate product or technical experts <i>and/or the firm.</i> ”	Investigators should be encouraged to include the firm during discussions with FDA management or program officials. By including the firm, inaccurate observations can be avoided or agreements on corrective actions could be reached in advance of an observation being recorded.
III. A.	154-155	Modify the sentence to require a letter and an addendum to the FDA 483: “The resolution may take the form of a letter <i>and it will include an addendum to the existing Form FDA 483.</i> ”	Due to the public availability of 483’s, an addendum to the specific 483 at issue, noting that the observation was resolved in the manufacturer’s favor, would allow the public to have the complete information on the inspection at issue.
	157-158	Add “ with appropriate redaction, in accordance with applicable requirements” in the sentence: “All dispute resolved.....and public dissemination, <i>with appropriate.....</i> ”.	Since the information contained within a company’s response will be greater in detail and may contain proprietary information, the concept of a company approving the redaction and the manner by which the information is disseminated should be considered.
	164	It should read: “... <i>review of the decision</i> by...” instead of “...a review and decision...”	Typographical error.
III. B.	195-196	Change “...60 days of receipt of the tier-one decision.” To “...60 days of <i>issuance</i> of the Tier-One decision.”	Clarification as there is ambiguity in determining when something was received.
	198-203	Add a condition for the DR panel to have a face to face discussion with the manufacturer.	Some disputes can be misinterpreted to be a dispute of a direct compliance requirement when it may be a disagreement on the interpretation of the requirement.
	241-242	Add statement in Italics at the end of the sentence: “The Agency....dispute resolution is pending. <i>If the DR panel has deemed that an issue is appropriate for review and this issue is central to the enactment of further regulatory action, there could be a “hold” placed on this action pending a decision.</i> ”	
III. C.	234-238	Allow for new information to be submitted if by reviewing the observation, the firm understands the observation and realizes that this	The firm might not understand the investigator’s question during the inspection, and therefore not provide information

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		information would dispute the observation.	available at the time of the inspection.
	234-239	Information submitted to answer questions from the agency to clarify the observation, the response or the dispute, even if not found in the administrative record, should not be considered new information.	Firms, to answer questions from the agency, might need to provide information not discussed before. This information should be considered clarifying information rather than new information.
	237-238	Indicate documentation to be submitted to prove that the issue/information was discussed/presented during the inspection.	
IV. D.	470-474	Include examples of how a manufacturer could show it was unable to raise its disagreement during the inspection, i.e. lack of time, fear of retaliation.	