

The draft guidance was initiated in response to industry's request for a formal dispute resolution process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available dispute resolution processes, the draft guidance describes a formal two-tiered dispute resolution process that provides a formal mechanism for requesting review and decision on issues that arise during inspections.

- Tier-one of the dispute resolution process provides a mechanism to raise scientific or technical issues to the ORA and center levels.

- Tier-two of the dispute resolution process provides a mechanism to raise scientific or technical issues to the agency's Dispute Resolution Panel for Scientific and Technical Issues Related to Pharmaceutical CGMP (DR Panel).

The draft guidance also covers the following topics:

- The suitability of certain issues for the formal dispute resolution process, including examples of some issues with a discussion of their appropriateness for the dispute resolution process.

- Instructions on how to submit requests for formal dispute resolution and a list of the supporting information that should accompany these requests.

- Public availability of decisions reached during the dispute resolution process to promote consistent application and interpretation of drug quality-related regulations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for

public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.

Description: The draft guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to CGMP. Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements, or during FDA's assessment of corrective actions undertaken as a result of such inspections. The draft guidance provides procedures that will encourage open and prompt discussion of disputes and lead to their resolution. The draft

guidance describes procedures for raising such disputes to the ORA and center levels and for requesting review by the DR Panel.

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time-consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms prior to the issuance of the Form FDA 483, the manufacturer can formally request dispute resolution and can use the formal two-tiered dispute resolution process described in the draft guidance.

Tier-one of the formal dispute resolution process involves scientific or technical issues raised by a manufacturer to the ORA and center levels. If a manufacturer disagrees with the tier-one decision, tier-two of the formal dispute resolution process would then be available for appealing that decision to the DR Panel.

If a manufacturer disagrees with the scientific or technical basis for an observation listed by an investigator on a Form FDA 483, the manufacturer can file a written request for formal dispute resolution with the appropriate ORA unit as described in the draft guidance. The request for formal dispute resolution should be made within 10 days of the completion of an inspection, and should include all supporting documentation and arguments for review, as described. If a manufacturer disagrees with the tier-one decision in the formal dispute resolution process, the manufacturer can file a written request for formal dispute resolution by the DR Panel. The manufacturer should provide the written request for formal dispute resolution and all supporting documentation and arguments, as described in the following paragraphs, to the DR Panel within 60 days of receipt of the tier-one decision.

All requests for formal dispute resolution should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the draft guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier-one dispute resolution or a request for tier-two dispute resolution;
- Name and address of manufacturer inspected (as listed on the Form FDA 483);
- Date of inspection (as listed on the Form FDA 483);