Moore, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430; or Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information'' dated September 2003. The draft document applies to comparability protocols that would be submitted in BLAs, or supplements to these applications, for therapeutic recombinant DNA derived protein products, naturally derived protein products, plasma derivatives, vaccines and allergenics, therapeutic DNA plasmids and NDAs, ANDAs and investigational new drugs (INDs) for protein drug products, and not sufficiently characterizable peptide products (e.g., complex mixture of small peptides).

The draft guidance does not pertain to comparability protocols for human blood and blood components intended for transfusion and for further manufacture, somatic cell therapy, and gene therapy vectors (except therapeutic DNA plasmids). It also does not pertain to vaccines for veterinary use because these are regulated by the U.S. Department of Agriculture.

The draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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 collection of information in the guidance was approved under OMB control numbers 0910–0001, 0910–0032, and 0910–0338.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic.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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of 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. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cvm/guidance/published.htm*.

Dated: August 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–22577 Filed 9–3–03; 10:00 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' In the draft guidance, the agency describes a formal, two-tiered dispute resolution process intended to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP) that arise during FDA inspections of pharmaceutical manufacturers.

DATES: Submit written or electronic comments on the draft guidance by March 3, 2004. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collection of information by November 4, 2003.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448; or Communications Staff (HFV–12), Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance and on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the collection of information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary Jane Mathews, Center for Drug Evaluation and Research (HFD–3), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–2847.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' The guidance was drafted as part of the FDA initiative ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products.

The agency formed the Dispute Resolution Working Group comprising representatives from the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The working group met weekly on issues related to the dispute resolution process and met with stakeholders in December 2002 to seek their input.

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);

• Date the Form FDA 483 issued (from the Form FDA 483);
• Firm establishment inventory (FEI) number, if available (from the Form FDA 483);
• Names and titles of FDA employees who conducted inspection (from the Form FDA 483);
• Office responsible for the inspection, e.g., district office, as listed on the Form FDA 483;
• Application number if the inspection was a preapproval inspection;
• Comprehensive statement of each issue to be resolved:
• Identify the observation in dispute.
• Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data.
• State the steps that have been taken to resolve the dispute, including any informal dispute resolution that may have occurred before the issuance of the Form FDA 483.
• Identify possible solutions.
• State expected outcome.
• Name, title, telephone and fax number, and e-mail address (as available) of manufacturer contact.

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: FDA has reviewed the total number of informal disputes that currently arise between manufacturers and investigators (and FDA district offices) when a manufacturer disagrees with the scientific or technical basis for an observation listed on a Form FDA 483. FDA estimates that approximately 12 such disputes occur annually. FDA believes that the number of requests for formal dispute resolution under the draft guidance would be higher because manufacturers have expressed reluctance to dispute with the agency scientific or technical issues raised in an investigation in the absence of a formal mechanism to resolve the dispute. In addition, manufacturers have requested the formal mechanisms in the draft guidance to facilitate the review of such disagreements. Therefore, FDA estimates that approximately 25 manufacturers will submit approximately 25 requests annually for a tier-one dispute resolution. FDA also estimates that approximately five manufacturers will appeal approximately five of these requests to the DR Panel (request for tier-two dispute resolution).

Based on the time it currently takes manufacturers to prepare responses to FDA concerning issues raised in a Form FDA 483, FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one dispute resolution and approximately 8 hours to prepare and submit each request for a tier-two dispute resolution.

Based on the methodology and assumptions in the previous paragraphs, table 1 of this document provides an estimate of the annual reporting burden for requests for a tier-one dispute resolution and requests for a tier-two dispute resolution under the draft guidance. FDA requests comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Requests for Tier-One Dispute Resolution	25	1	25	30	750
Requests for Tier-Two Dispute Resolution	5	1	5	8	40
Total					790

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm* or*http://www.fda.gov/cber/guidelines.htm*

Dated: August 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–22575 Filed 9–3–03; 10:00 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003D–0060]

Guidance for Industry on ''Part 11, Electronic Records; Electronic Signatures—Scope and Application;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application.'' The guidance explains FDA's current thinking regarding the requirements and application of part 11 (21 CFR part 11). FDA has begun to reexamine part 11 as it applies to all FDA regulated products. This guidance explains that we will narrowly interpret the scope of part 11. While the reexamination of part 11 is under way, we intend to exercise enforcement discretion with respect to certain part 11 requirements. With respect to systems that were operational before August 20, 1997, the effective date of the final rule establishing part 11, we intend to exercise enforcement discretion with respect to all part 11 requirements under certain circumstances.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and