

- 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 FDA believes that the number of requests for formal dispute resolution under the draft guidance would be higher because manufacturers have expressed reluctance to dispute with the agency scientific or technical issues raised in an investigation in the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 In addition, manufacturers have requested the formal mechanisms in the draft guidance to facilitate the review of such disagreements.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 BURDEN¹

	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.

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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 re-examine 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 re-examination 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