§ 791.85

necessary, the Administrator may order the transcription of the stenographic record of the hearing, written briefs, oral arguments or any other reasonable aids to making an equitable decision.

(c) The final Agency order may be reviewed in federal court as provided by 26 U.S.C. 2603(c).

Subpart E—Final Order

§ 791.85 Availability of final Agency order.

The final Agency order shall be available to the public for inspection and copying pursuant to 5 U.S.C. 552(a)(2), subject to necessary confidentiality restrictions.

Subpart F—Prohibited Acts

§ 791.105 Prohibited acts.

Failure to provide information required by the Agency or to pay the amounts awarded under this rule within time allotted in the final order shall constitute a violation of 15 U.S.C. 2614(1) or 2614(3).

PART 792—GOOD LABORATORY PRACTICE STANDARDS

Subpart A—General Provisions

Sec.
792.1 Scope.
792.3 Definitions.
792.10 Applicability to studies performed under grants and contracts.
792.12 Statement of compliance or non-compliance.
792.15 Inspection of a testing facility.
792.17 Effects of non-compliance.

Subpart B—Organization and Personnel

792.29 Personnel.
792.31 Testing facility management.
792.33 Study director.
792.35 Quality assurance unit.

Subpart C—Facilities

792.41 General.
792.43 Test system care facilities.
792.45 Test system supply facilities.
792.47 Facilities for handling test, control, and reference substances.
792.49 Laboratory operation areas.
792.51 Specimen and data storage facilities.
If data are not developed in accordance with the provisions of this part, EPA will consider such data insufficient to evaluate the health and environmental effects of the chemical substances unless the submitter provides additional information demonstrating that the data are reliable and adequate.

§ 792.3 Definitions.

As used in this part the following terms shall have the meanings specified:

**Batch** means a specific quantity or lot of a test, control, or reference substance that has been characterized according to §792.105(a).

**Carrier** means any material, including but not limited to, feed, water, soil, and nutrient media, with which the test substance is combined for administration to a test system.

**Control substance** means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for chemical or biological measurements.

**EPA** means the U.S. Environmental Protection Agency.

**Experimental start date** means the first date the test substance is applied to the test system.

**Experimental termination date** means the last date on which data are collected directly from the study.

**FDA** means the U.S. Food and Drug Administration.

**Person** includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

**Quality assurance unit** means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.

**Raw data** means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. “Raw data” may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

**Reference substance** means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.

**Specimen** means any material derived from a test system for examination or analysis.

**Sponsor** means:

1. A person who initiates and supports, by provision of financial or other resources, a study;
2. A person who submits a study to the EPA in response to a TSCA section 4(a) test rule and/or a person who submits a study under a TSCA section 4 testing consent agreement or a TSCA section 5 rule or order to the extent the agreement, rule or order references this part; or
3. A testing facility, if it both initiates and actually conducts the study.

**Study** means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, environmental and chemical fate, persistence, or other characteristics in humans, other living organisms, or media. The term “study” does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

**Study completion date** means the date the final report is signed by the study director.

**Study director** means the individual responsible for the overall conduct of a study.