

PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

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AUTHORITY: 21 U.S.C. 346a, 348, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50291, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 178.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator delegates the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of the Agency's Office of Prevention, Pesticides and Toxic Substances to whom the Assistant Administrator delegates the authority to perform functions under this part.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301-392.

[55 FR 50291, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

Subpart B—Procedures for Filing Objections and Requests for Hearing

§ 178.20 Right to submit objections and requests for a hearing.

(a) On or before the 30th day after the date of publication in the FEDERAL REGISTER of an order under part 177 or part 180 of this chapter establishing, modifying, or revoking a regulation, or an order under part 177 of this chapter denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

(b) A person may include with any such objection a written request for an evidentiary hearing on such objection in accordance with § 178.27

(c) A person who submits objections need not request a hearing. For instance, if the person's objections are of a purely legal or policy nature, a hearing request would be inappropriate; the purpose of an evidentiary hearing is to resolve factual disputes. The Administrator will rule on the objections, whether or not a hearing is requested.

(d) As a matter of discretion, the Administrator may order a hearing on an objection even though no person has requested a hearing.

§ 178.25 Form and manner of submission of objections.

(a) To be considered by the Administrator, an objection must:

- (1) Be in writing.
- (2) Specify with particularity the provision(s) of the order, regulation, or denial objected to, the basis for the objection(s), and the relief sought.
- (3) Be signed by the objector.
- (4) State the objector's name and mailing address.
- (5) Be accompanied by the fee prescribed by § 180.33(i) of this chapter, if the objection is to an order or regulation issued under part 180 of this chapter.
- (6) Be submitted to the hearing clerk.
- (7) Be received by the hearing clerk not later than the close of business of the 30th day following the date of the publication in the FEDERAL REGISTER