

§ 160.312

with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter, or if otherwise required by law.

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution where noncompliance is indicated.* (1) If an investigation pursuant to §160.306 or a compliance review pursuant to §160.308 indicates a failure to comply, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

(2) If the Secretary finds the covered entity is not in compliance and determines that the matter cannot be resolved by informal means, the Secretary may issue to the covered entity and, if the matter arose from a complaint, to the complainant written findings documenting the non-compliance.

(b) *Resolution when no violation is found.* If, after an investigation or compliance review, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant in writing.

Subpart E—Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings

SOURCE: 68 FR 18902, Apr. 17, 2003, unless otherwise noted.

EFFECTIVE DATE NOTE: At 68 FR 18902, Apr. 17, 2003, and corrected at 68 FR 22453, Apr. 28, 2003, subpart E was added, effective May 19, 2003, to Sept. 16, 2004. At 69 FR 55515, Sept. 15, 2004, the expiration date was extended from Sept. 16, 2004, to Sept. 16, 2005.

§ 160.500 Applicability.

This subpart applies to investigations conducted, penalties imposed, hearings conducted, and subpoenas

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issued, under the authority of 42 U.S.C. 1320d-5, relating to the imposition of civil money penalties.

§ 160.502 Definitions.

For the purposes of this subpart:

ALJ means Administrative Law Judge.

Entity means a legal person.

Penalty means the amount calculated under 42 U.S.C. 1320d-5, as determined in accordance with this part, and includes the plural of that term.

Person means a natural or legal person.

Respondent means the person upon whom the Secretary has imposed, or proposes to impose, a penalty.

§ 160.504 Investigational subpoenas and inquiries.

(a) The provisions of this paragraph govern subpoenas issued by the Secretary in accordance with 42 U.S.C. 405(d) and (e), 1320a-7a(j), and 1320d-5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation pursuant to this part.

(1) A subpoena issued under this paragraph must—

(i) State the name of the person to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the named entity must designate one or more natural persons who will testify on its behalf, and must state as to each person so designated that person's name and address and the matters on which he or she will testify. The person so designated must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the