

§ 1003.20

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comply with the applicable Federal standard;

(2) The Secretary's findings, with references to the tests, inspections, studies, or reports upon which such findings are based;

(3) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

The manufacturer shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) Every manufacturer who receives a notice under paragraph (a) of this section shall immediately advise the Secretary in writing of the total number of such product units produced and the approximate number of such product units which have left the place of manufacture.

(c) If, after the expiration of the period of time specified in the notice, the Secretary determines that the product has a defect or does not comply with an applicable Federal standard and the manufacturer has not applied for an exemption, he shall direct the manufacturer to furnish the notification to the persons specified in §1003.10(b) in the manner specified in §1003.21. The manufacturer shall within 14 days from the date of receipt of such directive furnish the required notification.

[38 FR 28628, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977]

Subpart C—Notification

§1003.20 Notification by the manufacturer to the Secretary.

The notification to the Secretary required by §1003.10(a) shall be confirmed in writing and, in addition to other relevant information which the Secretary may require, shall include the following:

(a) Identification of the product or products involved;

(b) The total number of such product units so produced, and the approximate number of such product units which have left the place of manufacture;

(c) The expected usage for the product if known to the manufacturer;

(d) A description of the defect in the product or the manner in which the product fails to comply with an applicable Federal standard;

(e) An evaluation of the hazards reasonably related to defect or the failure to comply with the Federal standard;

(f) A statement of the measures to be taken to repair such defect or to bring the product into compliance with the Federal standard;

(g) The date and circumstances under which the defect was discovered; and

(h) The identification of any trade secret information which the manufacturer desires kept confidential.

§1003.21 Notification by the manufacturer to affected persons.

(a) The notification to the persons specified in §1003.10(b) shall be in writing and, in addition to other relevant information which the Secretary may require, shall include:

(1) The information prescribed by §1003.20 (a), (d), and instructions with respect to the use of the product pending the correction of the defect;

(2) A clear evaluation in nontechnical terms of the hazards reasonably related to any defect or failure to comply; and

(3) The following statement:

The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you.

Provided, That if at the time the notification is sent, the Secretary has approved a plan for the repair, replacement or refund of the product, the notification may include the details of the approved plan in lieu of the above statement.

(b) The envelope containing the notice shall not contain advertising or other extraneous material, and such mailings will be made in accordance with this section.

(1) No. 10 white envelopes shall be used, and the name and address of the manufacturer shall appear in the upper left corner of the envelope.