

## Food and Drug Administration, HHS

## § 5.89

to physicians and the general public information the Director determines is useful in evaluating the performance of mammography facilities as provided by section 354(l) of the Public Health Service Act.

(m)(1) The following officials may authorize a State to carry out certification program requirements and implement quality standards under section 354(q)(1) and (q)(2) of the Public Health Service Act:

(i) The Director and Deputy Director for Regulations and Policy, CDRH.

(ii) The Director, Office of Health and Industry Programs, CDRH.

(2) The Director, CDRH, is authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the Public Health Service Act.

[60 FR 47268, Sept. 12, 1995]

### § 5.86 Variances from performance standards for electronic products.

The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

[52 FR 29664, Aug. 11, 1987, as amended at 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

### § 5.87 Exemption of electronic products from performance standards and prohibited acts.

The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 358(a)(5) of the Public Health Service Act (the act) and to exempt an electronic product or class of products from all or part of the provisions of section 360B(a) of the act under section 360B(b) of that act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

[52 FR 29664, Aug. 11, 1987, as amended at 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

### § 5.88 Testing programs and methods of certification and identification for electronic products.

The Director and Deputy Directors, Center for Devices and Radiological Health, (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act (the Act), and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the Act.

[62 FR 67272, Dec. 24, 1997]

### § 5.89 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs, relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 359 of the Public Health Service Act (the act) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance, CDRH, and

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the Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the act and under §1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in §1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in §1040.20(b) of this chapter.

[48 FR 56948, Dec. 27, 1983, as amended at 51 FR 32452, Sept. 12, 1986; 55 FR 47054, Nov. 9, 1990; 62 FR 15110, Mar. 31, 1997; 62 FR 67272, Dec. 24, 1997]

### **§5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

[62 FR 67273, Dec. 24, 1997]

### **§5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

[62 FR 67273, Dec. 24, 1997]

### **§5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.**

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities

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engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

[62 FR 67273, Dec. 24, 1997]

### **§5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.**

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the Federal Food, Drug and Cosmetic Act (the act) concerning the date of submission or the date or effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the act:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

[53 FR 18274, May 23, 1988, as amended at 55 FR 6247, Feb. 22, 1990; 62 FR 2558, Jan. 17, 1997; 64 FR 49383, Sept. 13, 1999]

### **§5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.**

The following officials are authorized to extend or stay an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(a) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Office of Biological Product Review, CBBER.

(3) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBBER.