

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted pursuant to section 512(m) of the Federal Food, Drug, and Cosmetic Act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250).

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for animal use and feeds bearing or containing new animal drugs.

[49 FR 17936, Apr. 26, 1984, as amended at 63 FR 70650, Dec. 22, 1998]

§ 5.85 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to issue, renew, and extend certificates to mammography facilities under section 354(c) of the Public Health Service Act (42 U.S.C. 263b):

(1) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(b) The following officials are authorized to accept an application for a cer-

tificate under section 354(d)(1) of the Public Health Service Act:

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

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(c) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the Public Health Service Act:

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

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

(d) The following officials are authorized to ensure that accreditation bodies provide satisfactory assurances of compliance under section 354(e)(1)(C) of the Public Health Service Act:

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

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(e) The Director, CDRH, is authorized to promulgate regulations under which the Director may withdraw approval of accreditation bodies under section 354(e)(2) of the Public Health Service Act.

(f) The following officials are authorized to determine the applicable standards for a facility for accreditation under section 354(e)(3) of the Public Health Service Act:

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

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(g) The following officials are authorized to ensure that accreditation bodies make on site visits and to determine whether other measures are appropriate under section 354(e)(4)(A) and (e)(4)(B) of the Public Health Service Act:

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

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(h) The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the Public Health Service Act:

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

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(i) The following officials are authorized to determine the compliance of certified facilities with established standards through facility inspections as provided by section 354(g) of the Public Health Service Act:

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

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

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(j) The Director and Deputy Director for Regulations and Policy, CDRH, are authorized to impose sanctions under section 354(h)(1) and (h)(2) of the Public Health Service Act.

(k) The Director and Deputy Director for Regulations and Policy, CDRH, are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2)(A) of the Public Health Service Act.

(l) The Director and Deputy Director for Regulations Policy, CDRH, are authorized to compile and make available 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 sec-

tion 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]