

Food and Drug Administration, HHS

§ 5.85

and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act:

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to new animal drug applications that are described by § 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs pursuant to section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of

Animal Feeds, Office of Surveillance and Compliance, CVM.

[49 FR 14937, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 53 FR 2225, Jan. 27, 1988; 53 FR 17186, May 16, 1988; 53 FR 40055, Oct. 13, 1988; 63 FR 70650, Dec. 22, 1998; 64 FR 23184, Apr. 30, 1999]

§ 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 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