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and Control Act of 1970, 21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports to Congress.

[60 FR 54424, Oct. 24, 1995]

§5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in §314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in §314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989, as amended at 62 FR 2558, Jan. 17, 1997]

§5.83 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, 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