chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new drug applications and supplements thereto which are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components and which have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

§ 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 and Deputy Director of the Bureau of Drugs 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 which are for drugs for human use and have been submitted pursuant to section 505 of the Federal Food, Drugs, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section, and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to issue notices of opportunity for hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto which are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components and which have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

§ 5.83 Approval of new animal drug applications and their supplements.

The Director of the Bureau of Veterinary Medicine is 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 Director of the Division of Animal Feeds of the Bureau of Veterinary Medicine is authorized to perform the functions of the Commissioner with regard to the approval of applications for animal feeds containing new animal drugs.

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

The Director of the Bureau of Veterinary Medicine is authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications and new animal drug application supplements for drugs for animal use submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

§ 5.86 Granting and withdrawing variances from performance standards for electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to grant and withdraw variances from the provisions of performance standards for electronic products established in Subchapter J of this chapter.

§ 5.87 Exemptions from performance standards for electronic products.

The Director of the Bureau of Radiological Health is authorized to exempt from performance standards any electronic product intended solely or predominantly for departments or agencies of the United States under section 358 (a)(5) of the Public Health Service Act.