
GENERAL PROCEDURAL POLICIES

**APPROVAL OF NEW ANIMAL DRUG APPLICATIONS
AND THEIR SUPPLEMENTS**

The Federal Food, Drug, and Cosmetic Act (the Act) assigns the responsibility for the enforcement of the Act to the Secretary of Health and Human Services. Section 5.10 of Title 21 of the Code of Federal Regulations delegates to the Commissioner of Food and Drugs, with authority to redelegate except when specifically prohibited, all authority vested in the Secretary under the Act. Section 5.83 provides for the delegation of authority to perform the functions of the Commissioner with regard to the approval of new animal drug applications and supplements thereto, submitted pursuant to section 512 of the Act, to certain officials of the Center for Veterinary Medicine. Section 5.84 provides for the delegation of authority to issue notices, proposals, and orders relating to new animal drugs and feeds bearing or containing new animal drugs. Section 5.95 provides for the submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

1. **Purpose:**

The purpose of this guide is to identify those individuals who are authorized to perform the functions of the Commissioner with regard to the approval of new animal drug applications and supplements thereto, including medicated feed mill licenses.

2. **Delegation of Authority:**

a. The Director and Deputy Director of the Center for Veterinary Medicine 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 Act.

(1) The Director and Deputy Director, Office of New Animal Drug Evaluation, are authorized to perform the functions of the Commissioner with regard to the approval of supplements. (This does not apply to those involving new species and significant new claims, or a supplement providing for a change in Rx/OTC status.)

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

are authorized to perform the functions of the Commissioner with regard to the approval of all regulatory supplements. (Regulatory supplements are those submitted to or identified by the Division of Epidemiology and Surveillance as supplements intended to correct/address problems associated with an approved product.)

- (3) The Director, Division of Manufacturing Technologies, Office of NADE, and the Director, Division of Epidemiology and Surveillance, Office of S&C, are authorized to perform the functions of the Commissioner with regard to the approval of chemistry, manufacturing, and controls supplements.
 - (4) The Director and Deputy Director, Center for Veterinary Medicine, and the Director and Deputy Director, Office of New Animal Drug Evaluation, are authorized to perform all the functions of the Commissioner with regard to determinations made under 512(c)(2)(D)(iv) and (c)(2)(F) of the Act concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the Act, and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the Act. These determinations are an essential part of the calculation of exclusivity periods.
- b. The Director and Deputy Director, Division of Animal Feeds, Office of S&C, the Team Leader, Medicated Feeds Team, and the Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, S&C are authorized to perform the functions of the Commissioner with regard to the approval of applications for animal feeds containing new animal drugs.