

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

JMB

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**Implantation or Injectable Dosage Form New Animal Drugs; Moxidectin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for veterinary prescription use of a sustained-release injectable moxidectin formulation for prevention of heartworm disease and treatment of existing hookworm infections in dogs.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141-189 that provides for veterinary prescription use of ProHeart® 6 (moxidectin) Sustained Release Injectable for Dogs for prevention of heartworm disease caused by *Dirofilaria immitis* and treatment of existing larval and adult hookworm (*Ancylostoma caninum*) infections. The NADA is approved as of June 6, 2001, and the regulations are amended in 21 CFR part 522 by adding new § 522.1451 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food