particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for ''2-methyl-4,6-bis-[(octylthio)methyl] phenol'' in item ''4.'' under the heading ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
2-Methyl-4,6-bis-[(octylthio)methyl] phenol (CAS Reg. No. 110553–27–0)	For use only: * * * 4. At levels not to exceed 1.7 percent by weight of the finished rubber products complying with § 177.2600 of this chapter.
* * *	* * * *

Dated: October 22, 1999.

L. Robert Lake,

Director, Office of Policy, Planning, and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–30569 Filed 11–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health. The supplemental NADA provides for oral use of moxidectin gel for horses and ponies for treatment and control of *Gasterophilus nasalis* (3rd instars) infections.

EFFECTIVE DATE: November 24, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 5th St. NW, P.O. Box 518, Fort Dodge, IA 50501, filed supplemental NADA 141–087 that provides for use of Quest™ moxidectin 2-percent equine oral gel in horses and ponies for treatment and control of horse stomach bot *G. nasalis* (3rd instars). The product is approved for treatment and control of infections of certain large strongyles, small strongyles (adult and larvae), encysted cyathostomes, ascarids, pinworms, hairworms, large-mouth stomach worms, and horse stomach bots (*G. intestinalis* (2nd and 3rd instars)), and for suppression of strongyle egg production for 84 days. The supplemental NADA is approved as of October 4, 1999, and the regulations are amended in 21 CFR 520.1452(d)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, § 520.1452 is amended in paragraph (d)(2) to state that the drug will suppress strongyle egg production for 84 days, and paragraph (d)(3) is amended to remove statements required elsewhere by the regulations or not required to be codified.

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 and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, except on Federal holidays.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for nonfood producing animals qualifies for 3 years of marketing exclusivity beginning October 4, 1999, because the application contains substantial evidence of the effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use for treatment and control of horse stomach bot *G. nasalis (3rd instars) infections.*

FDA has determined under 21 CFR 25.33(d) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an

environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1452 is amended by revising paragraphs (d)(2) and (d)(3) to read as follows:

§ 520.1452 Moxidectin gel.

* * * * *

(d) * * *

(2) *Indications for use.* Horses and ponies for treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated lumenal larvae); encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris equi* (adults and L4 larval stages)); hairworms (*Trichostrongylus axei* (adults)); large-mouth stomach worms (*Habronema muscae* (adults)); and horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars)). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* Not for use in horses and ponies intended for food.

Dated: November 12, 1999.

Melanie R. Berson,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–30571 Filed 11–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 805

[Docket No. 85N–0322]

Medical Devices; Revocation of Cardiac Pacemaker Registry

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revoke a regulation requiring a cardiac pacemaker registry. The registry, which was mandated by the Deficit Reduction Act of 1984, requires any physician and any provider of services who requests or receives Medicare payment for an implantation, removal, or replacement of permanent cardiac pacemaker devices and pacemaker leads to submit certain information to the registry. The information is used by FDA to track the performance of permanent cardiac pacemakers and pacemaker leads and by the Health Care Finance Administration (HCFA) to administer its Medicare payment program for these devices. This action is being taken to implement an act to Repeal An Unnecessary Medical Device Reporting Requirement passed by Congress in 1996 to remove the cardiac pacemaker registry to eliminate duplicative and unnecessary reporting.

DATES: This regulation is effective December 27, 1999.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 23, 1987 (52 FR 27756), FDA and HCFA jointly issued a final rule to establish a national cardiac pacemaker registry as mandated by the Deficit Reduction Act of 1984 (Public Law 98–369). The new law, which was enacted on July 18, 1984, amended title XVIII of the Social Security Act, by adding section 1862(h) (42 U.S.C. 1395y(h)) to the Social Security Act . FDA and HCFA jointly issued a proposed rule announcing the establishment of this registry in the **Federal Register** of May 6, 1986 (51 FR 16792).

The final rule for the cardiac pacemaker registry was codified in part 805 (21 CFR part 805). Briefly summarized, the scope of the regulation provides that FDA establish a nationwide registry for cardiac pacemakers and pacemaker leads. FDA used the information submitted to the registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analysis regarding the use of the devices. The agency transmitted data to the HCFA to administer its Medicare program and to other Federal components to carry out statutory responsibilities.

On October 2, 1996, an act to Repeal An Unnecessary Medical Device Reporting Requirement (Public Law 104–224), which amended title XVIII of the Social Security Act (42 U.S.C. 1395), became law. The purpose of the new law was to remove section 1862(h) (42 U.S.C. 1395y(h)) of the Social Security Act to eliminate duplicative and unnecessary reporting.

When section 1862(h) was added to the Social Security Act, there was a need to identify and keep track of defective pacemakers. In particular, there was a need to identify circumstances in which a defective pacemaker was surgically implanted in a patient, and then surgically removed, with both procedures being paid for by Medicare. One of the main reasons for this early pacemaker registry was that there was no good way to track defective implantable medical devices, and no viable way for HCFA to recover costs in those circumstances where a defective product was used. Congress enacted an act to repeal section 1862(h) of the Social Security Act because the SMDA of 1990 (Public Law 101–629) added section 519(e) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)), which requires among other things that manufacturers track and collect data for certain devices, including permanently implanted pacemakers and pacemaker leads from the manufacturer through the distribution chain to the patient using the device.

Notice and comment rulemaking on the revocation of part 805 is unnecessary. The statutory authority for this rule has been revoked. Therefore, FDA concludes under 5 U.S.C. 553(b)(8) and 21 CFR 10.40(e)(1), that there is a good cause for revoking part 805 without notice and comment rulemaking.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment