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 ''2,4-Di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
2,4-Di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate (CAS Reg. No. 123968–25–2).	For use only: 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520 of this chapter in contact with food under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter, except that polypropylene containing the additive at levels not to exceed 0.075 percent by weight may contact food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 1.0 percent by weight of of styrene block polymers complying with § 177.1810 of this chapter. The additive is used under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 1.0 percent by weight of polystyrene and rubber modified polystyrene complying with § 177.1640 of this chapter in contact with food under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: September 21, 1999.

L. Robert Lake,

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

[FR Doc. 99–25790 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate

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 Pfizer, Inc. The supplemental NADA provides for revised feeding instructions for use of pyrantel tartrate Type A medicated articles to make Type C medicated horse feeds.

EFFECTIVE DATE: October 5, 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: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 140–819 that provides for revised feeding instructions for use of Pfizer's pyrantel tartrate Type A medicated articles (Strongid® 48 (48 grams of pyrantel tartrate per pound (g/lb))) to make Type C medicated horse feeds (Strongid® C (4.8 g/lb) and Strongid® C2x (9.6 g/lb)) used for the prevention of *Strongylus vulgaris* larval infections, and control of several types of adult and 4th stage larval large and small strongyle, pinworm, and ascarid infections. The supplement provides for use of a top-dressed Type C feed containing up to 20,000 g of pyrantel tartrate per ton to be fed at the currently approved rate of 1.2 milligrams per pound of body weight daily. The supplemental NADA is approved as of August 24, 1999, and § 558.485 (21 CFR 558.485) is amended to reflect the approval.

Also, § 558.485(e)(2)(i)(A) is amended to reflect that the organism *Triodontophorus* is now classified as a small strongyle.

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.

The agency has determined under 21 CFR 25.33(a)(3) 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 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.485 is amended by revising paragraphs (e)(2)(i) introductory text, (e)(2)(i)(A), and the first sentence of paragraph (e)(2)(i)(B), and by adding and reserving paragraph (e)(2)(ii) to read as follows:

§ 558.485 Pyrantel tartrate.

* * * * *

(e) * * *

(2) *Horses*—(i) *Amount.* Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use.* Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris,* and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).

(B) *Limitations.* Administer either as a top-dress (not to exceed 20,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal parasites. * * *

(ii) [Reserved]

Dated: September 9, 1999.

Melanie R. Berson,

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

[FR Doc. 99–25773 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 78N–2646]

General and Plastic Surgery Devices; Classification of the Nonresorbable Gauze/Sponge for External Use, the Hydrophilic Wound Dressing, the Occlusive Wound Dressing, and the Hydrogel Wound Dressing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing into class I (general controls). FDA is also exempting these devices from premarket notification procedures. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: November 4, 1999.

FOR FURTHER INFORMATION CONTACT: Gail G. Gantt, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 1989 (54 FR 38600) (hereinafter referred to as the September 19, 1989 proposal), FDA issued a proposed rule to classify the following 11 devices: The nonabsorbable gauze surgical sponge for external use, the hydrophilic wound and burn dressing, the interactive wound and burn dressing, the porcine burn dressing, the intravascular catheter securement device, the medical adhesive tape, the medical adhesive bandage, the adhesive wound closure, the occlusive wound and burn dressing, the burn sheet, and the hydrogel wound and burn dressing. Four of the eleven devices (the liquid bandage, the intravascular catheter securement device, the medical adhesive tape and bandage, and the burn sheet) were already classified as general hospital and personal use devices (45 FR 1739, October 21, 1980).

In the September 19, 1989 proposal, FDA proposed that: (1) The four general hospital and personal use devices, identified above, be recodified in the Code of Federal Regulations (CFR) with the general and plastic surgery devices; (2) the medical adhesive tape and bandage be divided into four generic devices; (3) the liquid bandage be divided into two generic devices; and (4) the porcine burn dressing for short-term use be classified into class I and the porcine burn dressing for long-term use be classified into class III as the interactive wound and burn dressing. The proposals were not finalized. Based on the comments of the September 19, 1989 proposed rule, the General and Plastic Surgery Devices Panel's (the panel) recommendations, and current wound care and product use, FDA is finalizing the classification of the following four wound care devices: The nonresorbable gauze/sponge for external use, the hydrophilic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing.

These final rules do not address wound dressings that contain added drugs such as antimicrobial agents, added biologics such as growth factors, or are composed of materials derived from animal sources. These are preamendments devices that FDA intends to classify in the future.

II. Comments and FDA's Responses

Interested persons were given until November 20, 1989, to comment on the September 19, 1989 proposed rule. During the comment period, FDA received following comments.

1. Two comments requested that an additional classification category be added for the nonsterile hydrogel wound and burn dressing. The nonsterile device would be for conditions such as minor cuts, scrapes, burns, and sunburn. The comment stated that components of this type of hydrogel wound and burn dressing cannot withstand sterilization.

FDA agrees that the hydrogel wound and burn dressing may be either sterile or nonsterile and has revised the final rule accordingly.

2. One comment requested that the health risk information be printed on the wrappings of the devices.

FDA believes that it is adequate that the health risk information be provided in the outer labeling of the device.

3. One comment stressed the need for price control because low-income persons generally have little or no health insurance coverage.

FDA notes that the agency has no control over the price of medical