REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS—Continued

[Amendment 418; Effective Date: November 4, 1999]

From	To	MEA
*4500–MOCA DICKINSON, ND VORTAC	MINOTA, ND VORTAC	*6000 *4300–MOCA

§ 95.6532 VOR FEDERAL AIRWAY 532 Is Amended to Read in Part

LITTLE ROCK, AR VOTAC	*PARDON, AR FIX	2600 *3500–MRA
PARON, AR FIX	GATZY, AR FIX	*3700 *3100–MOCA
GATZY, AR FIX	BLURB, AR FIX	*5500 *3200–MOCA
BLURB, AR FIX	BLIMP, AR FIX	*4100 *3600–MOCA
BLIMP, AR FIX	FORTH SMITH, AR VOTAC	*2900 *2400–MOCA

§ 95.8003 VOR Federal Airway Changeover Points

From	To	Changeover Points	
		Distance	From
Airway Segment V–12 is Amended to Modify Changeover Point			
EMPORIA, KS VORTAC	JOHNSON COUNTY, KS VOR/DME	49	EMPORIA

[FR Doc. 99–30660 Filed 11–23–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–1170]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the safe use of 2-methyl-4,6-bis-[(octylthio)methyl] phenol as a stabilizer for repeat use rubber articles. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

DATES: This regulation is effective November 24, 1999. Submit written objections and requests for a hearing by December 27, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 6, 1999 (64 FR 24407), FDA announced that a food additive petition (FAP 9B4660) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., P.O. Box 2005, Tarrytown, NY 10591–9005. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-methyl-4,6-bis-[(octylthio)methyl] phenol as a stabilizer for repeat use rubber articles.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive as a stabilizer for repeat use rubber articles is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4660 (64 FR 24407, May 6, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before December 27, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any

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