Appendix I to Part 305—Heating Performance and Cost for Central Air Conditioners

1. Range Information:

Single package units	Range of HSPF's	
Manufacturer's rated heating capacity (Btu's/hr.)	Low	High
Heat Pumps (Heating Function): All capacities	6.60	8.20

Split system units	Range of HSPF's	
Manufacturer's rated heating capacity (Btu's/hr.)	Low	High
Heat Pumps (Heating Function): All capacities	6.80	10.20

The HSPF shall be the Region IV value based on the appropriate average design heat loss from the table below.

* * * * *

7. In section 2 of Appendix I of Part 305, the text and formulas are amended by removing the figure ''8.67¢'' wherever it appears and by adding, in its place, the figure ''8.6¢''. In addition, the text and formulas are amended by removing the figure ''13.01¢'' wherever it appears and by adding, in its place, the figure ''12.90¢''.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–23401 Filed 9–13–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 92F–0117]

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 provide for the safe use of a mixture of methylated 4,4′-bis(2-benzoxazolyl)stilbenes, with the major portion consisting of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl)stilbene and lesser portions consisting of 4,4′-bis(5-methyl-2-benzoxazolyl)stilbene and 4,4′-bis(2-benzoxazolyl) stilbene, as an optical brightener in all food-contact polymers. This action is in response to a petition filed by Hoechst Aktiengesellschaft.

DATES: Effective September 16, 1996; written objections and requests for a hearing by October 16, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–606–0202.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of April 8, 1992 (57 FR 11958), FDA announced that a food additive petition (FAP 2B4317) had been filed by Hoechst Aktiengesellschaft, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of a mixture of methylated 4,4′-bis(2-benzoxazolyl) stilbenes, with the major portion consisting of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl) stilbene and lesser portions consisting of 4,4′-bis(5-methyl-2-benzoxazolyl) stilbene and 4,4′-bis(2-benzoxazolyl) stilbene, as an optical brightener in all food-contact polymers. (Because of a printing error, 4,4′-bis(5-methyl-2-benzoxazolyl) stilbene was not listed in the filing notice summary as a lesser component of the proposed additive. However, the correct composition of the additive was given in the supplemental information section of the filing notice.)

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and that therefore, the regulations in § 178.3297 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 21 CFR 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 16, 1996 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 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 objection 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * * * * * *	
Mixed methylated 4,4′-bis(2-benzoxazolyl)stilbenes with the major portion consisting of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl)stilbene (CAS Registry No. 5242–49–9) and lesser portions consisting of 4,4′-bis(5-methyl-2-benzoxazolyl)stilbene (CAS Registry No. 2397–00–4) and 4,4′-bis(2-benzoxazolyl)stilbene (CAS Registry No. 1533–45–5).	For use as an optical brightener only at levels not to exceed 0.05 percent by weight of rigid and semirigid polyvinyl chloride and not to exceed 0.03 percent by weight in all other polymers. The finished food-contact articles shall be used only under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.
* * * * * * *	

Dated: August 28, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–23549 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Otic Solution

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 an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of gentamicin sulfate and betamethasone valerate otic solution to treat acute and chronic canine otitus externa and canine and feline superficial infected lesions caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: September 16, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, filed ANADA 200–183, which provides for use of gentamicin otic solution (gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin and betamethasone valerate equivalent to 1 mg betamethasone) topically to treat acute and chronic canine otitus externa and canine and feline superficial infected lesions caused by bacteria sensitive to gentamicin.

The ANADA is approved as a generic copy of Schering Plough's NADA 46–821 Gentocin Otic Solution (gentamicin sulfate with betamethasone valerate). ANADA 200–183 is approved as of July 31, 1996, and the regulations are amended in 21 CFR 524.1044b(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 524

Animal drugs.

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 524.1044b [Amended]

2. Section 524.1044b *Gentamicin sulfate, betamethasone valerate otic solution* is amended in paragraph (b) by removing ''No. 000061'' and adding in its place ''Nos. 000061 and 051259''.

Dated: September 4, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–23668 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F