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