

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

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

2. Section 175.300 is amended in paragraph (b)(3)(xxxiii), under the heading "Miscellaneous materials" by alphabetically adding two entries to read as follows:

§ 175.300 Resinous and polymeric coatings

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(b) * * *

(3) * * *

(xxxiii) * * *

5-Chloro-2-methyl-4-isothiazolin-3-

one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2628-20-4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2) and optionally containing magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight). For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulations.

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1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7). For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coatings.

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3. Section 175.320 is amended in the table in paragraph (b)(3) by alphabetically adding two entries in item (iii) under the headings "List of Substances" and "Limitations" to read as follows:

§ 175.320 Resinous and polymeric coatings for polyolefin films.

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(b) * * *

(3) * * *

List of substances	Limitations
(iii) * * *	
5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2628-20-4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2) and optionally containing magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation.
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7)	For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coating.
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Dated: January 24, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Bayer Corp., Agriculture Division,

Animal Health to Schering-Plough Animal Health Corp.

DATES: This rule is effective February 11, 2000.

FOR FURTHER INFORMATION CONTACT:

Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201 has informed FDA that it has transferred ownership of, and all rights and interests in NADA 113-645 (cloprostenol sodium) to Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083. Accordingly, the agency is amending the regulations in 21 CFR 522.460 to reflect the transfer of ownership.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.460 [Amended]

4. Section 522.460 *Cloprostenol sodium* is amended in paragraphs (a)(2) and (b)(2) by removing "000859" and adding in its place "000061".

Dated: January 24, 2000.

Claire M. Lathers,

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

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