an opportunity for public comment pursuant to 5 U.S.C. 553(b)(A), as it involves a matter relating to Board procedures and practice. Similarly, because this rule of procedure does not have a substantive effect on the public, it is not subject to a 30 day delay in effective date, as normally is required under 5 U.S.C. § 553(d). However, the Board is interested in receiving public comment and is, therefore, issuing this rule as interim final.

Regulatory Flexibility Act

Because this rule is not subject to a requirement to provide prior notice and an opportunity for public comment pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are inapplicable.

Congressional Review Act

This rule has been determined to be not major for purposes of the Congressional Review Act, 5 U.S.C. § 801 *et seq.*

Intergovernmental Review

No intergovernmental consultations with State and local officials is required because the rule is not subject to the provisions of Executive Order 12372 or Executive Order 12875.

Unfunded Mandate Reform Act of 1995

This rule contains no Federal mandates, as that term is defined in the Unfunded Mandates Reform Act, on State, local and tribal governments or the private sector.

Executive Order 13132

This rule does not contain policies having federalism implications requiring preparation of a Federalism Assessment.

Executive Order 12630

This rule does not contain policies that have takings implications.

List of Subjects in 13 CFR Part 500

Administrative practice and procedure, Loan Program—Oil and Gas, Reporting and recordkeeping requirements.

Charles E. Hall,

Executive director, Emergency Oil and Gas Guaranteed Loan Board.

For the reasons set forth in the preamble, the Emergency Oil and Gas Guaranteed Loan Board amends 13 CFR part 500 as follows:

1. The authority citation for part 500 continues to read as follows:

Authority: Pub. L. 106–51, 113 Stat. 255 (15 U.S.C. 1841 note).

2. Section 500.205 is amended by revising paragraphs (a) to read as follows:

§ 500.205 Application Process

(a) *Application process.* An original application and three copies must be received by the Board no later than 5 P.M. EST, February 28, 2000, in the U.S. Department of Commerce, 1401 Constitution Avenue, NW., room H–2500, Washington, DC 20230. Applications which have been provided to a delivery service on or before February 27, 2000, with ''delivery guaranteed'' before 5 P.M. on February 28, 2000, will be acceptabled for review if the Applicant can document that the application was provided to the delivery service with delivery to the address listed in this section guaranteed prior to the closing date and time. A postmark of February 27, 2000, is not sufficient to meet this deadline as the application must be received by the required date and time. Applications will not be accepted via facsimile machine transmission or electronic mail.

* * * * *

[FR Doc. 00–3291 Filed 2–10–00; 8:45 am]

BILLING CODE 3510–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F–0443]

Indirect Food Additives: Adhesives and Components of Coatings

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 1,2-dibromo-2,4-dicyanobutane (DBDCB) and a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one (CMI) and 2-methyl-4-isothiazolin-3-one (MI), optionally containing magnesium nitrate, as antimicrobial agents in emulsion-based silicone coating formulations. This action responds to a petition filed by Dow Corning Corp.

DATES: This regulation is effective February 11, 2000. Submit written objections and requests for a hearing by March 13, 2000.

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: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 12, 1993 (58 FR 8290), FDA announced that a petition (FAP 3B4346) had been filed by Dow Corning Corp., P.O. Box 994, Midland, MI 48686–0994. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), § 175.320 *Resinous and polymeric coatings for polyolefin films* (21 CFR 175.320), and § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst. It also proposed that the food additive regulations be amended to provide for the safe use of 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate and methylvinyl cyclosiloxane as optional polymerization inhibitors. Additionally, the petition proposed that the regulations be amended to provide for the safe use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, optionally containing magnesium nitrate, as an antimicrobial agent for emulsion-based silicone coating formulations.

However, subsequent to the filing of the petition, the petitioner requested that tetramethyltetravinylcyclotetrasiloxane be included in the petition. Therefore, in a notice published in the **Federal Register** of July 2, 1998 (63 FR 36246), FDA announced that it was amending the filing notice of February 12, 1993, to indicate that the petitioner was also proposing that the food additive regulations be amended to provide for the safe use of tetramethyltetravinylcyclotetrasiloxane as an optional polymerization inhibitor in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

Also, subsequent to the filing of the petition, the petitioner requested that 1,2-dibromo-2,4-dicyanobutane be included in the petition. Therefore, in a notice published in the **Federal Register** of December 24, 1998 (63 FR 71294), FDA announced that it was amending the filing notice of July 2, 1998, to indicate that the petitioner was also proposing that the food additive regulations be amended to provide for the safe use of 1,2-dibromo-2,4-dicyanobutane as an antimicrobial agent in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

A partial response to the petition published in the **Federal Register** of December 23, 1998 (63 FR 71016). That document responded to the petitioner's request to amend the food additive regulations to provide for the safe use of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen polysiloxane and dimethylmethylhydrogen polysiloxane using a platinum catalyst. In that document, FDA also amended the food additive regulations to provide for the safe use of 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate, methylvinyl cyclosiloxane, and tetramethyltetravinylcyclotetrasiloxane as optional polymerization inhibitors.

Also in the December 23, 1998, document, the agency stated that in 1996, Congress enacted the Food Quality Protection Act (the FQPA). As a result of that law, antimicrobial formulations used in or on food contact articles became subject to regulation as pesticide chemicals by the U.S. Environmental Protection Agency (EPA). Thus, the petitioned antimicrobial use of 1,2-dibromo-2,4-dicyanobutane (DBDCB) and of 5-chloro-2-methyl-4-isothiazolin-3-one (CMI) and 2-methyl-4-isothiazolin-3-one (MI) mixture, optionally containing magnesium nitrate were, at that time, subject to regulation by EPA. Subsequently, Congress passed the Antimicrobial Regulation Technical Corrections Act of 1998 (the ARTCA) (Public Law 105–324) that returned some of the regulatory authority for regulating antimicrobials in or on food contact articles to FDA. As a result of ARTCA, these petitioned antimicrobial uses are once again subject to regulation by FDA under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) and are not subject to regulation as pesticide chemicals under section 408 of the act (21 U.S.C. 346a). Although these antimicrobial uses are regulated under section 409 of the act as food additives, nevertheless, the intended uses may be subject to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, persons intending to market these food additives for such antimicrobial uses should contact the EPA to determine whether such uses require a pesticide registration under FIFRA.

In this document, the agency is responding to the petitioner's request to amend the food additive regulations to provide for the safe use of: (1) DBDCB, and (2) a mixture of CMI and MI, optionally containing magnesium nitrate, as antimicrobial agents in emulsion-based silicone coating formulations.

I. Evaluation of the Additive DBDCB

FDA has evaluated the data in the petition and other material relevant to the safety of DBDCB. The agency's conclusion on the safe use of DBDCB is contained in section III of this document.

II. Evaluation of the Mixture of CMI and MI

In its evaluation of the safety of the mixture of CMI and MI, optionally containing magnesium nitrate, FDA has reviewed the safety of each component of the mixture and the chemical impurities that may be present in the mixture resulting from its manufacturing process. Although the components themselves have not been shown to cause cancer, the mixture of CMI and MI, optionally containing magnesium nitrate, has been found to contain residual amounts of dimethylnitrosamine (DMNA), a carcinogenic impurity resulting from the manufacture of the mixture. Residual amounts of reactants and manufacturing aids, such as DMNA, are commonly found as contaminants in chemical products, including food additives.

A. Determination of Safety

Under the general safety standard of the act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348 (c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive. *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).

B. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the CMI and MI mixture, optionally containing magnesium nitrate, as an antimicrobial agent in emulsion-based silicone coatings, will result in exposure to no greater than 0.2 parts per billion of the mixture in the daily diet (3 kilogram (kg)) or an estimated daily intake (EDI) of 600 nanograms per person per day (ng/p/d) (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the mixture of CMI and MI and concludes that the estimated small dietary exposure resulting from the petitioned use of this mixture is safe.

FDA has evaluated the safety of the CMI and MI mixture under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by DMNA, the carcinogenic chemical that may be present as an impurity in the mixture. The risk evaluation of DMNA has two aspects: (1) Assessment of exposure to the impurity from the petitioned use of the mixture, and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

1. Dimethylnitrosamine

FDA has estimated the exposure to DMNA from the petitioned use of the mixture of CMI and MI, optionally containing magnesium nitrate, as an antimicrobial agent in emulsion-based silicone coating formulations, to be no more than 0.1 part per quintillion in the daily diet (3 kg), or 0.3 femtograms per

person per day (fg/p/d) (Ref. 1). The agency used data from a carcinogenesis bioassay on DMNA conducted by R. Peto et al. (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the mixture. The authors reported that DMNA was carcinogenic for male and female rats under the conditions of the study, causing liver tumors in the rats.

Based on the agency's estimate that exposure to DMNA will not exceed 0.3 fg/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of a mixture of CMI and MI, optionally containing magnesium nitrate, is 1×10^{-14} or 1 in 100 trillion (Refs. 1 and 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to DMNA is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to DMNA would result from the petitioned use of the mixture of CMI and MI, optionally containing magnesium nitrate.

2. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of DMNA present as an impurity in the mixture of CMI and MI. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which DMNA may be expected to remain as an impurity following production of the CMI and MI mixture, the agency would not expect this impurity to become a component of food at other than extremely low levels, and (2) the upper-bound limit of lifetime risk from exposure to this impurity from the petitioned use is very low, 1 in 100 trillion.

III. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed uses of DBDCB, and of the mixture of CMI and MI, optionally containing magnesium nitrate, as antimicrobial agents in silicone coating formulations are safe, (2) each additive will achieve its intended technical effect, and therefore, that the regulations in §§ 175.300 and 175.320 should be amended as set forth below.

In the previous response to this petition (63 FR 71016, December 23, 1998), the agency noted that the petition proposed to amend § 176.170 to list the two antimicrobials; however, because the petitioned additives will be listed under § 175.300(b)(3), by cross-reference they may be used under § 176.170(b)(1). Therefore, this action does not include an amendment that would establish a separate listing for the additives under § 176.170(b)(1). (FDA inadvertently referred to § 176.170(b)(2) in the earlier document.)

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.

IV. Environmental Impact

The agency has previously considered the environmental effects of this action as announced in the amended notices of filing for FAP 3B4346 published in the **Federal Register** of July 2, 1998 (63 FR 36246) and December 24, 1998 (63 FR 71294). 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.

V. Paperwork Reduction Act of 1995

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.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before March 13, 2000 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.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated March 10, 1999, from The Division of Product Manufacture and Use, Chemistry Review Team (HFS–246), to the Division of Petition Control (HFS–215) entitled ''FAP 3B4346 (MATS 675, 2.8.1)—Dow Corning Corporation (DC). Request dated 2–10–99 from Division of Petition Control (DPC) for an exposure estimate to nitrosamine impurities in 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one.''

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis; published by S. Karger, New York, NY, pp. 24–33, 1985.

3. Peto, R. et al., ''Nitrosamine Carcinogenesis In 5120 Rodents: Chronic Administration Of Sixteen Different Concentrations Of NDEA, NDMA, NPYR And NPIP In The Water of 4440 Inbred Rats, With Parallel Studies On NDEA Alone Of The Effect Of Age Of Starting (3, 6 or 20 Weeks) And Of Species (Rats, Mice or Hamsters),'' *IARC Science Publications*, 57:627–665, 1984.

4. Memorandum, dated March 25, 1999, from the Division of Petition Control (HFS–215), to Executive Secretary, Quantitative Risk Assessment Committee (QRAC), (HFS–308), entitled ''Estimation of upper-bound lifetime risk from dimethylnitrosamine, an impurity in 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, the subject of Food Additive Petition 3B4346 (Dow Corning Corporation).''

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

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

* * * * *

(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.

* * * * *

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.

* * * * *

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.

* * * * *

(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.

[FR Doc. 00–3195 Filed 2–10–00; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 00–3194 Filed 2–10–00; 8:45 am]

BILLING CODE 4160–01–F