(1) Retain all current options available regarding the search and inspection of any and all passengers, cargo and conveyances; and

(2) Provide training to carrier personnel to assist the development of proper operational procedures.

§ 122.175 Exemption from penalties.

Should a controlled substance be introduced into the United States or discovered aboard an aircraft owned or operated by a participating carrier, or in cargo carried by a participating carrier, the participating air carrier shall be considered to have met the test of highest degree of care and diligence required under law, and shall not be subject to the penalty or seizure provisions of the Tariff Act of 1930, as amended, if the carrier establishes at an oral presentation before the district director or his designee, that the carrier was not grossly negligent nor engaged in willful misconduct, and that it had complied with all the provisions of these regulations.

§ 122.176 Removal from ACSPP.

(a) *Grounds for removal and suspension from ACSPP.* (1) The Assistant Commissioner, Inspection and Control, shall revoke the privilege of operating as a member of the ACSPP if:

(i) Acceptance into the program was gained through fraud or the misstatement of a material fact; or

(ii) An officer of the carrier or corporation which has been accepted into the program is convicted of a felony, or is convicted of a misdemeanor involving theft, smuggling, or theft-connected or Customs related crime.

(2) The Assistant Commissioner, Inspection and Control, may revoke or suspend the privilege of operating as a member of the ACSPP if the carrier has been notified in writing that it has been found in noncompliance with a provision of the program and after having been given a reasonable opportunity, has failed to correct the noncompliance. Examples of noncompliance include:

(i) Refusing or neglecting to obey a proper order of a Customs officer or any Customs order, rule, or regulation relative to the carrier's cooperation within the program;

(ii) Failing to retain merchandise which has been designated for examination by Customs;

(iii) Failing to provide secure facilities or properly safeguard merchandise within the carrier's area of control; and

(iv) Failing to observe any of the procedures which the carrier had set forth in the SOP which served as the basis for its acceptance into the program.

(b) *Notice and appeal.* The Assistant Commissioner, Office of Inspection and Control, shall suspend or remove participants from the ACSPP by serving notice of the proposed action upon the carrier in writing. The notice shall be in the form of a statement specifically setting forth the grounds for suspension or removal and shall provide the carrier with notice that it may file a written notice of appeal from suspension or revocation within 10 days following receipt of the notice of revocation or suspension. The notice of appeal shall be filed in duplicate with the office of the Assistant Commissioner, Inspection and Control, and shall set forth the response of the carrier to the statement of the Assistant Commissioner.

(c) *Notice of decision.* The Assistant Commissioner, Inspection and Control, shall notify the participating carrier in writing of the decision concerning continued participation in the program.

Michael H. Lane,

Acting Commissioner of Customs.

Approved: October 26, 1989.

John P. Simpson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 89-27025 Filed 11-16-89; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 89F-0107]

Indirect Food Additives; Adhesives and Components of Coatings

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of bentonite, modified with benzyl (hydrogenated tallow alkyl) dimethyl ammonium chloride as a modifier in resinous and polymeric coatings for use in contact with food. This action is in response to a petition filed by United Catalysts, Inc.

DATES: Effective November 17, 1989; written objections and requests for a hearing by December 18, 1989.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 2, 1989 (54 FR 18700), FDA announced that a food additive petition (FAP 8B4112) had been filed by United Catalysts, Inc., P.O. Box 32370, Louisville, KY 40232, proposing that § 175.300 Resinous and polymeric coatings (21 CFR 175.300) be amended to provide for the safe use of bentonite, modified with benzyl (hydrogenated tallow alkyl) dimethyl ammonium chloride, as a rheological modifier in resinous and polymeric coatings for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that 21 CFR 175.300 should be amended in paragraph (b)(3)(xxxiii) 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 December 18, 1989, 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 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

§ 175.300 [Amended]

2. Section 175.300 is amended in paragraph (b)(3)(xxxiii) by alphabetically adding a new entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(xxxiii) * * *

Bentonite, modified by reaction with benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 71011-24-0). For use only as a rheological agent in coatings intended to contact food under repeated use conditions.	

* * * * *

Dated: November 8, 1989.

Richard J. Ronk,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-26987 Filed 11-16-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 175

[Docket No. 88F-0227]

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 bentonite, modified by reaction with sodium stearate and benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow; and for the safe use of hectorite, modified by reaction with a mixture of benzyl methyl dialkyl ammonium chloride and dimethyl dialkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow, for use as rheological agents in resinous and polymeric coatings complying with 21 CFR 175.300 when used on repeated-use containers. This action is in response to a petition filed by N. L. Industries, Inc.

DATES: Effective November 17, 1989; written objections and requests for a hearing by December 18, 1989.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gillian Robert-Baldo, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 26, 1988 (53 FR 28069), FDA announced that a food additive petition (FAP 8B4082) had been filed by N. L. Industries, Inc., P.O. Box 1090, Hightstown, NJ 08520, proposing that § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) be amended to provide for the safe use of bentonite clay modified by reaction with benzyl dimethyl hydrogenated tallow alkyl ammonium chloride and sodium stearate, and for the safe use of hectorite clay modified by reaction with a mixture of benzyl methyl bis(hydrogenated tallow alkyl) ammonium chloride and dimethyl bis(hydrogenated tallow alkyl) ammonium chloride as pigments in resinous and polymeric coatings for use on repeated-use bulk food containers.

FDA has evaluated data in the petition and other relevant material. During the course of its evaluation, FDA determined that the additives would be more accurately described as "bentonite, modified by reaction with sodium stearate and benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow;" and as "hectorite, modified by reaction with a mixture of benzyl methyl dialkyl ammonium chloride and dimethyl dialkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow." Therefore, the agency is using these names in this final rule.

The agency has also determined in its review that the additives are not pigments but instead are rheological agents used in coatings to control flow, viscosity, and pigment suspension, and that it would be more appropriate to regulate the proposed use of the additives in § 175.300(b)(3)(xxxiii) as rheological additives rather than in § 175.300(b)(3)(xxvi). The petitioner agrees with this finding. The agency further concludes that the proposed use of these additives is safe.

Therefore, the agency is amending § 175.300(b)(3)(xxxiii) to include two new entries which identify the two substances and prescribe limitations for their safe use as rheological agents in resinous and polymeric coatings.

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 December 18, 1989, 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 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 175.300 is amended in paragraph (b)(3)(xxxiii) by alphabetically adding two new entries to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(xxxiii) * * *

Bentonite, modified by reaction with sodium stearate and benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 121888-68-4). For use as a rheological agent only in coatings intended to contact dry food under repeated-use conditions.

* * * * *

Hectorite, modified by reaction with a mixture of benzyl methyl dialkyl ammonium chloride and dimethyl dialkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 121888-67-3). For use as a rheological agent only in coatings intended to contact dry food under repeated-use conditions.

* * * * *

Dated: November 8, 1989.

Richard J. Ronk,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-27055 Filed 11-16-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Clindamycin Hydrochloride Liquid

AGENCY: Food and Drug Administration.

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 The Upjohn Co., providing for use of clindamycin hydrochloride liquid for dogs for treatment of dental infections caused by susceptible strains of *Staphylococcus aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis, B. melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens.*

EFFECTIVE DATE: November 17, 1989.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, filed a supplement to NADA 135-940 providing for use of Antirobe® Aquadrops Liquid (clindamycin hydrochloride) in dogs for treatment of dental infections caused by susceptible strains of *S. aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis, B. melaninogenicus, F. necrophorum,* and *C. perfringens,* in addition to the current approval for treatment of canine wound infections, abscesses, and osteomyelitis caused by *S. aureus.* The supplement is approved and the regulations are amended in 21 CFR 520.447(c) to reflect the approval. The basis of 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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.447 is amended by revising paragraph (c) to read as follows:

§ 520.447 Clindamycin hydrochloride liquid.

* * * * *

(c) *Conditions of use in dogs*—(1) *Amount.* Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use.* For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis, Bacteroides melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens.*