

(i) The committee has submitted its recommendation for the quantity of lemons it considers advisable to be handled during the specified week. The recommendation resulted from consideration of the factors covered in the order. The committee further reports the demand for lemons is similar to last week, with size 140's and smaller very good. Average f.o.b. price was \$6.44 per carton the week ended July 16, 1977, compared to \$6.31 per carton the previous week. Track and rolling supplies at 215 cars were up 50 cars from last week.

(ii) Having considered the recommendation and information submitted by the committee, and other available information, the Secretary finds that the quantity of lemons which may be handled should be established as provided in this regulation.

(3) It is further found that it is impracticable and is contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553), because the time intervening between the date when information upon which this regulation is based became available and the time when it must become effective to effectuate the declared policy of the act is insufficient. A reasonable time is permitted, for preparation for the effective time; and good cause exists for making the regulation effective as specified. The committee held an open meeting during the current week, after giving due notice, to consider supply and market conditions for lemons and the need for regulation. Interested persons were afforded an opportunity to submit information and views at this meeting. The recommendation and supporting information for regulation during the period specified were promptly submitted to the Secretary after the meeting was held, and information concerning the provisions and effective time has been provided to handlers of lemons. It is necessary, to effectuate the declared policy of the act, to make this regulation effective as specified. The committee meeting was held on July 19, 1977.

#### § 910.402 Lemon Regulation 102.

(b) *Order.*—(1) The quantity of lemons grown in California and Arizona which may be handled during the period July 24, 1977, through July 30, 1977, is established at 295,000 cartons.

(2) As used in this section, "handled" and "carton(s)" have the same meaning as when used in the amended marketing agreement and order.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.)

Dated: July 21, 1977.

CHARLES R. BRADER,  
Deputy Director, Fruit and  
Vegetable Division, Agricultural  
Marketing Service.

[FR Doc. 77-21408 Filed 7-21-77; 11:34 am]

### CHAPTER XIV—COMMODITY CREDIT CORPORATION, DEPARTMENT OF AGRICULTURE

#### SUBCHAPTER B—LOANS, PURCHASES, AND OTHER OPERATIONS

[CCC Grain Price Support Regulations, 1976 Crop Wheat Supplement, Amdt. 2]

#### PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

##### Subpart—1976 Crop Wheat Loan and Purchase Program

AGENCY: Agricultural Stabilization and Conservation Service, Department of Agriculture.

ACTION: Correction.

SUMMARY: This document corrects a final rule that appeared at page 4400 in the FEDERAL REGISTER of January 25, 1977 (FR Doc. 77-2172).

EFFECTIVE DATE: (Date of publication in FR) January 25, 1977.

FOR FURTHER INFORMATION CONTACT:

Merle Strawderman, (ASCS) (202-447-9223).

The following correction is made to § 1421.488(a): On page 4400, right column, under heading "Virginia" the entry that reads "all other counties \$2.24" is changed to read "all other counties \$2.26."

Signed at Washington, D.C., on July 14, 1977.

RAY FITZGERALD,  
Executive Vice President,  
Commodity Credit Corporation.

[FR Doc. 77-21061 Filed 7-21-77; 8:45 am]

### CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

#### SUBCHAPTER F—SECURITY SERVICING AND LIQUIDATION

[FmHA Instruction 462.1]

#### PART 1871—CHATTEL SECURITY

##### Subpart A—Servicing Chattel Security

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration amends its regulations concerning subordinations. The intended effect is to clarify the purposes for subordinating chattel liens securing emergency loans and to limit the amount of proposed subordinations.

EFFECTIVE DATE: July 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Thomas B. Baden, (202-447-2331).

SUPPLEMENTARY INFORMATION: The Farmers Home Administration published at page 45576 of the FEDERAL REGISTER for October 15, 1976, a proposal to amend § 1871.11 of Subpart A of Part 1871, Title 7 Code of Federal Regulations (36 FR 1110; 37 FR 17543; 41 FR 24700). No comments were received and there-

fore the proposal is adopted with only editorial changes. The amendment establishes that the amount of any new subordination plus any existing subordination does not exceed the operating or emergency loan approval authority of the loan official. The addition of paragraph (10) clarifies the purpose of subordinating chattel liens securing emergency loans.

As amended, § 1871.11(b) (10) (i), (ii), and (iii) and (c) read as follows:

§ 1871.11 Use of other credit and subordination of chattel security.

(b) *Purposes and limitations.*

(10) FmHA may subordinate chattel liens securing EM loans to another creditor or permit that creditor to loan for any authorized EM loan purpose including capital purchases, providing it is determined:

(i) The borrower needs the loan to continue his farming operation and it will be to his benefit to receive such a loan.

(ii) The loan will enhance the borrower's possibility of accomplishing the objectives of loans made by FmHA.

(iii) FmHA's financial interest will not be adversely affected.

(c) *Approval authorization.* Loan approval officials are authorized to approve subordinations and waivers of FmHA lien priority provided the amount of the proposed subordination or waiver, plus the principal balance of existing subordinations or waivers does not exceed their loan approval authority stated in Subpart A of Part 1901 of this chapter for the type of loan being subordinated.

When the lien priority for more than one type of loan is subordinated or waived, the total amount of the approval officials authority will be limited to the amount of the loan approval authority for the type of loan with the lowest approval authority for that official, as stated in Subpart A of Part 1901 of this chapter. However, the State Director may approve subordinations or waivers regardless of the amount, except as provided in paragraph (b) (9) of this section. State Directors may redelegate their authority for approving subordinations to qualified State Office personnel, including District Directors.

(7 U.S.C. 1989; 42 U.S.C. 1480; 42 U.S.C. 2942; 5 U.S.C. 301; Sec. 10 P.L. 93-357, 88 Stat 392; delegation of authority by the Sec. of Agri., 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development, 7 CFR 2.70; delegations of authority by Dir., OEO 29 FR 14764, 33 FR 9850.)

NOTE.—The Farmers Home Administration has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: July 15, 1977.

GORDON CAVANAUGH,  
Administrator,  
Farmers Home Administration.

[FR Doc. 77-21063 Filed 7-21-77; 8:45 am]

## Title 9—Animals and Animal Products

## CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

## SUBCHAPTER D—EXPORTATION AND IMPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

## PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCES AND SHIPPING CONTAINERS THEREON

## Importation of Cattle From Canada

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends importation requirements for cattle from Canada by deleting exceptions made in the current regulations for brucellosis testing of certain cattle originating in specified areas of that country, and amends importation requirements for calves of dairy and beef breeds with respect to the ages at which they must be vaccinated for brucellosis to qualify for importation without a negative brucellosis test. This action is required to prevent the introduction of diseases into the United States by cattle imported under exceptions presently appearing in the regulations and to make importation requirements for calves comparable with requirements for interstate movement. The intended effects of these amendments are to decrease the probability of introduction of disease through imported cattle and to make calves imported from Canada without brucellosis tests eligible for interstate movement following their importation.

EFFECTIVE DATE: July 18, 1977.

FOR FURTHER INFORMATION CONTACT:

Dr. D. E. Herrick, USDA, APHIS, VS, Federal Building, Room 815, Hyattsville, Maryland 20782. (301-436-8170).

SUPPLEMENTARY INFORMATION: Exceptions are now contained in the regulations concerning certain cattle originating in specified areas of Canada, and cattle from specified herds in Canada, which may be imported into the United States under less restrictive brucellosis testing requirements than other cattle from Canada. The Department has found that cattle imported under certain of these exceptions have introduced disease into the United States. Therefore, to protect the livestock of the United States, the exceptions now in effect which relate to brucellosis testing of cattle from specified areas are deleted. The effect of this deletion will be to remove the special considerations presently given to cattle originating in areas of Canada which have been designated by Canadian officials as having special brucellosis status, and to require that all cattle imported into the United States from Canada meet uniform brucellosis testing requirements. Therefore, the exemption presently found in § 92.20(c) (1) which allows the

importation of cattle from herds not known to be affected with brucellosis in certified areas in Canada on the basis of only one negative brucellosis test within 30 days of the date of entry is deleted. The effect of this deletion is to require that certain cattle imported from Canada meet the requirements of new § 92.20(c) (3) of these amendments. That section will require that certain cattle to be imported from herds other than brucellosis certified free herds shall be accompanied by a Canadian certificate showing that all the cattle are from a herd which has special brucellosis test status to qualify for export and that the cattle to be imported, with certain exceptions, must have been tested for brucellosis with negative results, within the 30 days prior to their date of entry. To maintain a brucellosis certified free status in Canada, a herd of cattle is required to be tested for brucellosis annually, with negative results. In addition, all cattle entering such herd must originate from herds which are also brucellosis certified free. All cattle to be imported from Canada shall be conveyed by direct movement to the port of entry without contact with cattle not eligible for certification.

The importation requirement for brucellosis-vaccinated female calves, presently found in § 92.20(c) (4) of the regulations, is amended to change the ages at which calves of dairy and beef breeds must be vaccinated and provides that, to qualify for importation without a negative brucellosis test, such vaccinated calves shall not be more than 18 months of age on the date of importation. The term "Bulls" has been deleted from the section because vaccination provisions of that section will not apply to male calves and they will have to meet the same importation test requirements as certain other cattle.

Accordingly, Part 92, Title 9, Code of Federal Regulations, is amended in the following respects:

1. In § 92.1, paragraph (r) is amended to read as follows:

§ 92.1 Definitions.

(r) *Brucellosis certified free herd.* A herd in which all eligible cattle in the herd proved negative to brucellosis tests under the Canadian requirements and which is officially certified by the Canadian Government.

2. In § 92.20(c), subparagraph (4) is redesignated subparagraph (5); new subparagraphs (4) and (6) are added; and the introductory paragraph, subparagraphs (1) and (3) and redesignated subparagraph (5) are amended to read:

§ 92.20 Cattle from Canada.

(c) *Brucellosis test or vaccination certificates.* Importations from Canada of cattle six months of age or older, except steers and all cattle for immediate slaughter, shall be in compliance with the following conditions and requirements:

(1) Cattle from herds designated as brucellosis certified free herds by the Canadian Government, except as provided in subparagraph (3) of this paragraph, shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government. This certificate shall show them to be from such herds and that the cattle to be imported have been tested for brucellosis with negative results within 30 days prior to their date of entry. If one or more reactors or suspects are disclosed in such a herd as a result of a brucellosis test at any time, cattle from the herd shall not be imported into the United States unless after such test the cattle to be imported and the herd are tested for brucellosis and found negative and such cattle are accompanied by a certificate in accordance with subparagraph (2) of this paragraph or the herd is officially certified by the Canadian Government as a brucellosis certified free herd under Canadian regulations.

(2) \* \* \*

(3) All other cattle to be imported from Canada, except as provided in subparagraph (5) of this section, shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing that the cattle originated from a herd which is officially certified by the Canadian Government as a brucellosis qualified for export herd. A brucellosis qualified for export herd is a herd which meets at least one of the following conditions:

(i) All of the cattle have been maintained as a herd unit for at least two years prior to importation and all of the cattle eligible for brucellosis testing (hereinafter referred to as eligible cattle) have been tested for brucellosis and found negative in accordance with Canadian requirements within 12 months of the date of importation; *Provided*, Such herd unit may include cattle which were born and raised within such herd unit during said period, or cattle which were moved directly from another herd unit of like status. *Provided, further*, Such herd unit may include any other cattle if: (a) Such other cattle have been tested for brucellosis and found negative within 30 days prior to entry into such herd unit and all eligible cattle in such herd unit have been tested for brucellosis and found negative not less than 90 days following the date when the last of such other cattle had been added to such herd unit or (b) all eligible cattle in the herd unit have been tested negative for brucellosis no less than 90 days nor more than 12 months prior to the date of importation.

(ii) All of the cattle are from herd units qualified under subparagraph (i) of this paragraph; *Provided*, That if all of the cattle are not from herd units qualified under paragraph (c) (3) (i) of this section, all eligible cattle have been tested for brucellosis and found negative to three laboratory tests administered at intervals of at least 90 days.

(4) All cattle from a brucellosis qualified for export herd offered for importation, except as described in para-

graph (c) (5) of this section, shall be tested negative for brucellosis within 30 days prior to the date of importation into the United States.

(5) Female cattle under 18 months of age that originate in herds in which cattle were tested as described in subparagraphs (c) (1) and (2) of this section are exempted from the test requirement for brucellosis. *Provided, however,* They are accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing that they were officially vaccinated against brucellosis as calves between the ages of 2-6 months (60-179 days old) for dairy breeds and from 2-10 months of age (60-299 days old) for beef breeds. The certificate accompanying such officially vaccinated cattle shall comply with paragraph (d) of this section except that it shall show, in lieu of the date and place of testing, the date of vaccination and the age of the animal at the time of vaccination.

(6) All cattle to be imported from Canada which originate from a brucellosis-free herd or a brucellosis-qualified for export herd shall move directly to the port of entry without contact with cattle which are not from a brucellosis-free herd or a brucellosis-qualified for export herd.

(Sec. 2, 32 Stat. 792, as amended; secs. 2, 3, 4, and 11, 76 Stat. 129, 130, 132 (21 U.S.C. 111, 134a, 134b, 134c, and 134f); 37 FR 28464, 28477; 38 FR 19141.)

These amendments impose additional restrictions on the importation of cattle from Canada. The amendments are of an emergency nature and should be placed in effect immediately in order to protect the livestock of the United States from the introduction and dissemination of disease.

Therefore, for such good cause the Department finds that notice and public comment are impracticable, unnecessary and contrary to the public interest and good cause is found for making the amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 15th day of July 1977.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement Under Executive Order 11821 and OMB Circular A-107.

PIERRE A. CHALOUX,  
Acting Deputy Administrator,  
Veterinary Services.

[FR Doc.77-20933 Filed 7-21-77;8:45 am]

#### Title 21—Food and Drugs

### CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

#### SUBCHAPTER A—GENERAL

[Docket No. 77C-0207]

#### PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

#### PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

##### Guanine

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations to "permanently" list guanine for use in externally applied drugs and in cosmetics generally, including drugs and cosmetics intended for use in the area of the eye. The Cosmetic, Toiletory, and Fragrance Association, Inc., filed a petition for such use: This rule will remove guanine from the provisional listing.

DATES: Effective August 22, 1977; objections by August 22, 1977.

ADDRESS: Written objections to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

#### FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, (202-472-5740).

#### SUPPLEMENTARY INFORMATION:

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21200), stated that a petition (CAP 8C0074) for the "permanent" listing of natural pearl essence (guanine) as a color additive for use in externally applied cosmetics, including lipsticks and those for use in the area of the eye, had been filed by the Cosmetic, Toiletory, and Fragrance Association, Inc. (1133 15th Street NW., Washington, D.C. 20005), c/o Hazleton Laboratories, P.O. Box 30, Falls Church, Va. 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376). A notice published in the FEDERAL REGISTER of March 5, 1976 (41 FR 9584), amended the filing of this petition to

include the additional use of natural pearl essence (guanine) in all types of cosmetics subject to ingestion. A notice published in the FEDERAL REGISTER of June 17, 1977 (42 FR 30893), amended the filing of this petition to include the additional use of guanine (pearl essence) in externally applied drugs.

This order "permanently" lists guanine for use in externally applied drugs and in cosmetics generally, including those for use in the area of the eye, under new § 73.1329 (21 CFR 73.1329) for drug use and new § 73.2329 (21 CFR 73.2329) for cosmetic use. The provisional listing of guanine (pearl essence) for use in cosmetics under § 81.1(g) (21 CFR 81.1(g)), which was extended to August 30, 1977, by regulation published in the FEDERAL REGISTER of July 1, 1977 (42 FR 33724), is being deleted because it will become obsolete when this order becomes effective on August 22, 1977, unless this order is stayed by the timely filing of objections.

The Commissioner, having evaluated the data in the petition and other relevant material, concludes that guanine is safe under the conditions set forth below for use in coloring cosmetics generally and in externally applied drugs, including cosmetics and drugs for use in the area of the eye, and that certification is not necessary for the protection of the public health.

The original filing notice for the petition identified the color additive as "natural pearl essence," although the color additive is provisionally listed as "guanine (pearl essence)." The Commissioner, in evaluating the data for this color additive concludes that both the term "natural pearl essence" and the parenthetical expression "(pearl essence)" are inappropriate for identifying this color additive because they are ambiguous and do not reflect the true nature of the color. The Commissioner further concludes that the name "guanine" would be more appropriate nomenclature, and he identifies the color by that name in the order set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1), Parts 73 and 81 are amended as follows:

1. Part 73 is amended:

a. By adding new § 73.1329 to Subpart B, to read as follows:

## § 73.1329 Guanine.

(a) *Identity.* (1) The color additive guanine is the crystalline material obtained from fish scales and consists principally of the two purines, guanine and hypoxanthine. The guanine content will vary from 75 to 97 percent, and the hypoxanthine will vary from 3 to 25 percent, depending on the particular fish and tissue from which the crystals are derived.

(2) Color additive mixtures for drug use made with guanine may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive guanine shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Guanine, not less than 75 percent.  
Hypoxanthine, not more than 25 percent.  
Ash (ignition at 800° C), not more than 2 percent.  
Lead (as Pb), not more than 20 parts per million.  
Arsenic (as As), not more than 3 parts per million.  
Assay, not less than 96 percent total purines.  
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Guanine is safe for use in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, batches thereof are exempt from certification pursuant to section 706(c) of the act.

b. By adding new § 73.2329 to Subpart C, to read as follows:

## § 73.2329 Guanine.

(a) *Identity and specifications.* (1) The color additive guanine shall conform in identity and specifications to the requirements of § 73.1329 (a) (1) and (b).

(2) Color additive mixtures of guanine may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001 (a) (1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001 (b) and, in addition, nitrocellulose.

(b) *Uses and restrictions.* The color additive guanine may be safely used in cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition

to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, batches thereof are exempt from certification pursuant to section 706(c) of the act.

## § 81.1 [Amended]

2. In § 81.1 *Provisional lists of color additives* by amending paragraph (g) by deleting the listing for "Guanine (pearl essence)."

Any person who will be adversely affected by the foregoing order may at any time on or before August 22, 1977, file with the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the Hearing Clerk's office, between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: August 22, 1977, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. note).)

Dated: July 14, 1977.

WILLIAM F. RANDOLPH,  
Acting Associate Commissioner  
for Compliance.

[FR Doc. 77-20783 Filed 7-21-77; 8:45 am]

[Docket No. 77C-0210]

## PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

## PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

## Zinc Oxide

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document "permanently" lists zinc oxide for use in ex-

ternally applied drugs and in cosmetics generally, including those intended for use in the area of the eye. The Cosmetic, Toiletry, and Fragrance Association, Inc., filed a petition for such use. The color additive will be removed from the provisional listing.

DATES: Effective August 22, 1977; objections by August 22, 1977.

ADDRESS: Written objection: Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

## FOR FURTHER INFORMATION CONTACT:

Gerald L. McCowin, Bureau of Foods (HFF-334), Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, (202-472-5740).

## SUPPLEMENTARY INFORMATION:

The Commissioner of Food and Drugs, having evaluated the data in a petition (CAP 6C0122) filed by the Cosmetic, Toiletry, and Fragrance Association, Inc. (1133 15th Street NW., Washington, D.C. 20005), and other relevant material, concludes that zinc oxide is safe and suitable for use, under the conditions prescribed in the regulations, in coloring externally applied drugs and in coloring cosmetics generally, including drugs and cosmetics intended for use in the area of the eye, and that certification is not necessary for the protection of the public health. This order "permanently" lists zinc oxide for use in externally applied drugs under new § 73.1991 (21 CFR 73.1991) and also "permanently" lists zinc oxide for use in cosmetics generally, including those for use in the area of the eye, under new § 73.2991 (21 CFR 73.2991).

The provisional listing of zinc oxide for use in cosmetics under § 81.1(g) (21 CFR 81.1(g)) will be deleted when this order becomes effective on August 22, 1977, unless this order is stayed by the timely filing of objections.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403, as amended (21 U.S.C. 376 (b), (c), and (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note)), and under authority delegated to the Commissioner (21 CFR 5.1), Parts 73 and 81 are amended as follows:

1. By amending Part 73:

a. By adding new § 73.1991 to Subpart B, to read as follows:

## § 73.1991 Zinc oxide.

(a) *Identity.* (1) The color additive zinc oxide is a white or yellow-white amorphous powder manufactured by the French process (described as the indirect process whereby zinc metal isolated from the zinc-containing ore is vaporized and then oxidized). It is principally composed of Zn.

(2) Color additive mixtures for drug use made with zinc oxide may contain only those diluents listed in this subpart as safe and suitable in color additive