and eating. Such room or building shall be provided with: (1) Stoves or hot plates, with a minimum equivalent of two burners, in a ratio of 1 stove or hot plate to 10 persons, or 1 stove or hot plate to 2 families; and (2) adequate food storage shelves and a counter for food preparation; and (3) mechanical refrigeration for food at a temperature of not more than 45° F.; and (4) tables and chairs or equivalent seating adequate for the intended use of the facility; and (5) adequate sinks with hot and cold water under pressure; and (6) adequate lighting and ventilation; and (7) floors shall be of nonabsorbent, easily cleaned materials.

(c) When central mess facilities are provided, the kitchen and mess hall shall be in proper proportion to the capacity of the housing and shall be separate from the sleeping quarters. The physical facilities, equipment and operation shall be in accordance with provisions of applicable State codes.

(d) Wall surface adjacent to all food preparation and cooking areas shall be of nonabsorbent, easily cleaned material. In addition, the wall surface adjacent to cooking areas shall be of fire-resistant material.

§ 620.14 Garbage and other refuse.

(a) Durable, fly-tight, clean containers in good condition of a minimum capacity of 20 gallons, shall be provided adjacent to each housing unit for the storage of garbage and other refuse. Such containers shall be provided in a minimum ratio of 1 per 15 persons.

(b) Provisions shall be made for collection of refuse at least twice a week, or more often if necessary. The disposal of refuse, which includes garbage, shall be in accordance with State and local law.

§ 620.15 Insect and rodent control.

Housing and facilities shall be free of insects, rodents, and other vermin.

§ 620.16 Sleeping facilities.

(a) Sleeping facilities shall be provided for each person. Such facilities shall consist of comfortable beds, cots, or bunks, provided with clean mattresses.

(b) Any bedding provided by the housing operator shall be clean and sanitary.

(c) Triple deck bunks shall not be provided.

(d) The clear space above the top of the lower mattress of a double deck bunk and the bottom of the upper bunk shall be a minimum of 27 inches. The distance from the top of the upper mattress to the ceiling shall be a minimum of 36 inches.

(e) Beds used for double occupancy may be provided only in family accommodations.

§ 620.17 Fire, safety, and first aid.

(a) All buildings in which people sleep or eat shall be constructed and maintained in accordance with applicable State or local fire and safety laws.

(b) In family housing and housing units for less than 10 persons, of one story construction, two means of escape shall be provided. One of the two required means of escape may be a readily accessible window with an openable space of not less than 24 x 24 inches.

(c) All sleeping quarters intended for use by 10 or more persons, central dining facilities, and common assembly rooms shall have at least two doors remotely separated so as to provide alternate means of escape to the outside or to an interior hall.

(d) Sleeping quarters and common assembly rooms on the second story shall have a stairway, and a permanent, affixed exterior ladder or a second stairway.

(e) Sleeping and common assembly rooms located above the second story shall comply with the State and local fire and building codes relative to multiple story dwellings.

(f) Fire extinguishing equipment shall be provided in a readily accessible place located not more than 100 feet from each housing unit. Such equipment shall provide protection equal to a 2½ gallon stored pressure or 5-gallon pump-type water extinguisher.

(g) First aid facilities shall be provided and readily accessible for use at all time. Such facilities shall be equivalent to the 16 unit first aid kit recommended by the American Red Cross, and provided in a ratio of 1 per 50 persons.

(h) No flammable or volatile liquids or materials shall be stored in or adjacent to rooms used for living purposes, except for those needed for current household use.

(i) Agricultural pesticides and toxic chemicals shall not be stored in the housing area.

Signed at Washington, D.C., this 3rd day of August 1978.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

[FR Doc. 78-22735 Filed 8-14-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

BIOLOGICS

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations setting forth delegations of authority to certain officials in the Bureau of Biologics in order to change the title "Associate Director" to "Associate Director for Compliance." These amendments are editorial in nature and do not reflect a change in bureau operating policies or procedures.

EFFECTIVE DATE: August 15, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting," or unless it is not legally permissible. Further redelegation of the authority delegated is not authorized.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and the Public Health Service Act (sec. 351, 58 Stat. 702 (42 U.S.C. 262)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), part 5 is amended as follows:

1. Section 5.30(b) is revised to read as follows:

§ 5.30 Hearings and review boards.

* * * * *

(b) The Director and Deputy Director of the Bureau of Biologics and the Associate Director for Compliance of

that Bureau are authorized to appoint review boards as provided by § 601.41 of this chapter.

* * * * *

2. Section 5.37(a)(5) is revised to read as follows:

§ 5.37 Issuance of reports of minor violations.

(a) * * *

(5) The Director and Deputy Director of the Bureau of Biologics, and the Associate Director for Compliance and Director of the Division of Compliance of that Bureau.

* * * * *

3. Section 5.68 is revised to read as follows:

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The Director and Deputy Director of the Bureau of Biologics and the Associate Director for Compliance of that Bureau are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request.

4. Section 5.71(b) is revised to read as follows:

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings or in animals.

* * * * *

(b) The Director and Deputy Director of the Bureau of Biologics and the Associate Director for Compliance of that Bureau are authorized to perform all the functions of the Commissioner of Food and Drugs regarding the termination of exemptions for new drugs for investigational use in human beings under § 312.1 and in animals under § 312.9 of this chapter pertaining to nonradioactive biological products subject to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262), nonradioactive urokinase products, and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components.

* * * * *

5. Section 5.80(b) is revised to read as follows:

§ 5.80 Approval of new drug applications and their supplements.

* * * * *

(b) The Director and Deputy Director of the Bureau of Biologics and the Associate Director for Compliance of that Bureau are authorized to perform all the functions of the Commissioner of Food and Drugs regarding the approval of new drug applications and supplements thereto submitted under section 505 of the Federal Food, Drug, and Cosmetic Act that are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components.

6. Section 5.82(b) is amended to read as follows:

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

* * * * *

(b) The Director and Deputy Director of the Bureau of Biologics and the Associate Director for Compliance of that Bureau are authorized to issue notices of opportunity for hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto, submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, that are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components, and to issue notices refusing or withdrawing approval when opportunity for hearing has been waived.

Effective date. This regulation shall be effective August 15, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: August 8, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-22653 Filed 8-14-78; 8:45 am]

[4110-03]

[Docket No. 77C-0208]

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

Ferric Ferrocyanide (Iron Blue)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document restores ferric ferrocyanide (iron blue) to the color additive provisional list under § 81.1(g) (21 CFR 81.1(g)) until November 30, 1978, for use in externally applied cosmetics, including those used in the area of the eye. This action is in partial response to two citizen petitions filed by Mearl Corp. (CAP's 8CP0138 and 8CP0139). This reinstatement will permit the marketing of cosmetics containing ferric ferrocyanide (iron blue) as a color additive.

DATE: Effective August 15, 1978.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: Ferric ferrocyanide (iron blue) was provisionally listed under § 81.1(g) (21 CFR 81.1(g)) for use in cosmetics on the basis of its use in cosmetics before 1960. A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21200), stated that a petition (CAP 8C0082) for the permanent listing of ferric ferrocyanide as a color additive for use in externally applied cosmetics, including those for use in the area of the eye, had been filed by the Cosmetic, Toiletry & Fragrance Association, Inc. (1133 15th Street NW., Washington, D.C. 20005), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, Va. 22046. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376). 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 ferric ferrocyanide in externally applied drugs, including those intended for use in the area of the eye.

On the basis of CAP 8C0082, the Food and Drug Administration (FDA) published a regulation on July 29, 1977 (42 FR 38562), permanently listing ferric ammonium ferrocyanide for use in externally applied drugs and cosmetics, including those drugs and cosmetics intended for use in the area of the eye. The same document removed ferric ferrocyanide (iron blue) from the provisional list of color additives on the basis that provisional listing of ferric ferrocyanide became obsolete with the permanent listing of ferric ammonium ferrocyanide. The permanent listing of the color additive as ferric ammonium ferrocyanide in lieu of ferric ferrocyanide was based on the description of the color additive contained in CAP 8C0082. The removal from provisional listing was based on the fact that with completion of action on the petition for ferric ammo-

nium ferrocyanide, there were no petitions or indications of studies being conducted to support listing of ferric ferrocyanide (iron blue). This is a basic requirement for provisional listing.

Two objections to the listing of the color additive as ferric ammonium ferrocyanide instead of ferric ferrocyanide were received. One of these was sent after expiration of the objection period for the order. Receipt of these objections was the first indication to FDA that an iron blue color other than ferric ammonium ferrocyanide was being used in cosmetics. These objections were dismissed in the confirmation of effective date notice for ferric ammonium ferrocyanide which published in the FEDERAL REGISTER of February 17, 1978 (43 FR 6938). The basis for rejection of the objections was that the manufacturers did not submit the data about iron blue when requested during the petition review process. The data in the petition had described the compound ferric ammonium ferrocyanide as being the color that should be listed. Although similar, ferric ferrocyanide is a different chemical compound that is manufactured by a different method. In the February 17, 1978, order, the manufacturers were advised to submit petitions to amend the listing to include their products.

On March 17, 1978, Kleinfeld, Kaplan & Becker filed citizen petitions on behalf of Mearl Corp. to stay the confirmation of effective date order (CAP 8CP0139) and to request that the Commissioner of Food and Drugs reconsider the rejection of the objections published on February 17, 1978 (43 FR 6938) (CAP 8CP0138). CAP 8CP0138 specifically requested that the Commissioner: (1) Reinstate the color ferric ferrocyanide (iron blue) as a provisionally listed color; (2) recognize the "objections" filed by Mearl to the regulation published on July 29, 1977, as what they legally were, a request for hearing, and grant Mearl a hearing in accordance with section 701(e) of the act on the issues of fact raised by Mearl's objections; and (3) modify the permanent listing of "ferric ammonium ferrocyanide" to change the specification for soluble cyanide to 10 ppm.

The Commissioner has reevaluated the decision to confirm the effective date of the listing of ferric ammonium ferrocyanide and to remove ferric ferrocyanide (iron blue) from the provisional list of color additives. On the basis of this review of the objections as supplemented by the citizen petitions, the Commissioner concludes that the petitions are meritorious.

Regarding 8CP0139, the Commissioner sees no basis for staying the existing regulation for ferric ammonium ferrocyanide. Reinstatement of ferric ferrocyanide (iron blue) to the provisional list of color additives will accomplish the objective sought in the petition for a stay of the permanent listing of ferric ammonium ferrocyanide.

Regarding the three actions requested in 8CP0138, the Commissioner comments as follows:

1. *Reinstate the color ferric ferrocyanide (iron blue) to the provisional list.* This document accomplishes the requested action on the following basis:

The Food and Drug Administration records show that the identity of the color additive that had previously been provisionally listed as ferric ferrocyanide (iron blue) is ambiguous, and, therefore, a basis for restoring ferric ferrocyanide (iron blue) to the provisional list exists without the additional burden of establishing prior use history by a manufacturer for its particular iron blue pigment. The Commissioner has reviewed the data on hand that indicates that ferric ammonium ferrocyanide and ferric ferrocyanide are simply different salts of the same compound and would be expected to have similar structures. With the submission of additional information regarding the manufacturing processes used for ferric ferrocyanide and analytical data establishing specifications for ferric ferrocyanide, the data on hand would most likely be sufficient to list ferric ferrocyanide for use in externally applied drugs and cosmetics, including those intended for use in the area of the eye.

Under the provisions of title II of the Color Additive Amendments of 1960 (sec. 203(a)(2), Pub. L. 86-618, 74 Stat. 404 (21 U.S.C. 376 note)) and under authority delegated to him (21 CFR 12.38), the Commissioner is authorized to postpone the closing date of a provisional listing of a color additive on his own initiative or upon application by an interested person. He is also authorized to promulgate and keep current a list or lists of the color additives and of their particular uses, whenever in his judgment such action is consistent with the protection of the public health. The citizen petitions submitted by Mearl Corp. are requests by an interested person to reinstate ferric ferrocyanide (iron blue) to the provisional list.

The Commissioner finds that restoration to the provisional list of ferric ferrocyanide (iron blue) for use in externally applied cosmetics, including those intended for use in the area of the eye, for the short period of time required to provide the necessary data to support permanent listing is consistent with the protection of the public health.

The new closing date for ferric ferrocyanide (iron blue) will be November 30, 1978. The necessary manufacturing and chemistry data are required to be submitted to FDA by September 14, 1978. This is a short time period, but because relatively little data is required, the petitioner should be able to comply with the deadline. In addition, the petitioner and the Cosmetic, Toiletry and Fragrance Association have already been advised of the type of data that would be necessary. In a letter of August 23, 1977, Mearl Corp. stated that it would obtain any additional data necessary to support permanent listing of ferric ferrocyanide.

2. *Recognize Mearl's objections as a request for a hearing and grant Mearl a hearing.* No purpose would be served by holding such a hearing. The restoration of ferric ferrocyanide (iron blue) to the provisional list responds to the petitioner's stated concerns and obviates the need for a hearing. Furthermore, the Commissioner disagrees with the petitioner's contention that an objection is implicitly a request for hearing. Section 12.22(a)(4) of FDA's regulations (21 CFR 12.22(a)(4)) clearly requires a specific statement requesting a hearing to be submitted along with each objection if a hearing is desired on the issue.

3. *Modify the permanent listing for ferric ammonium ferrocyanide to change the specification for soluble cyanide to 10 parts per million (ppm).* A proposed rule is published elsewhere in this issue of the FEDERAL REGISTER concerning specifications for water soluble cyanide and cobalt and nickel.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 203 (a)(2) and (d)(1), Pub. L. 86-618; 74 Stat. 404-405 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 12.38), part 81 of the color additive regulations is amended as follows:

1. In § 81.1(g) by alphabetically inseting "ferric ferrocyanide (iron blue)" in the list of substances in the table to read as follows:

§ 81.1 Provisional lists of color additives.

* * * * *

(g) * * *

Color additive	Closing date	Restrictions
* * * * * * *		
Ferric ferrocyanide (iron blue)	Nov. 30, 1978	External use only, including use in area of the eye.
* * * * * * *		

2. In § 81.27 by revising paragraph (c) to read as follows:

§ 81.27 Conditions of provisional listing of additives.

* * * * *

(c) The closing date for D&C Red No. 6, D&C Red No. 7, and D&C Red No. 30 is postponed until October 31, 1978, and for ferric ferrocyanide (iron blue) until November 30, 1978, while chemistry data and analytical methods to establish specifications are developed and evaluated and subject to compliance with the requirements of this paragraph.

(1) At least one petitioner for D&C Red No. 6, D&C Red No. 7, and D&C Red No. 30 shall agree in writing by March 7, 1977, to undertake and develop the necessary chemistry data and analytical methods for the color additives.

(2) The required chemistry data and analytical methods shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204, by July 31, 1978, for D&C Red No. 6, D&C Red No. 7, and D&C Red No. 30 and by September 14, 1978, for ferric ferrocyanide (iron blue).

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

* * * * *

Notice and public procedure and delayed effective date are not prerequisites to the promulgation of this order, since section 203(a)(2) of Pub. L. 86-618 provides for this issuance.

Effective date: This regulation shall be effective August 15, 1978.

(Sec. 203 (a)(2) and (d)(1), Pub. L. 86-618, 74 Stat. 404-405 (21 U.S.C. 376 note).)

Dated: August 8, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-22656 Filed 8-14-78; 8:45 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77N-0311]

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Bile Salts and Ox Bile Extract

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency affirms the generally recognized as safe (GRAS) status of ox bile extract as a direct human food ingredient and removes cholic acid, desoxycholic acid, glycocholic acid, taurocholic acid, and the sodium salt of taurocholic acid from GRAS status. The safety of these ingredients has been evaluated under the agency's comprehensive safety review of substances considered to be GRAS or subject to a prior sanction.

EFFECTIVE DATE: September 14, 1978.

ADDRESS: Written objections to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of January 31, 1978 (43 FR 4062), the Commissioner of Food and Drugs proposed to affirm the GRAS status of ox bile extract for use as a direct human food ingredient and to remove the bile salts cholic acid desoxycholic acid, glycocholic acid, taurocholic acid and the sodium salt of taurocholic acid from GRAS status. The proposal was based on safety information developed by the select committee on GRAS substances and was published as part of the Food and Drug Administration (FDA) review of the safety of GRAS and Prior-sanctioned food ingredients.

Under § 170.35 (21 CFR 170.35), relating to the affirmation of GRAS food ingredients, copies of the Scientific Literature Review on cholic acid and derivatives and the report of the select committee on GRAS substances on bile salts and ox bile extract have been made available for public review in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Copies of these documents have also been made available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing to affirm the GRAS status of ox bile extract, the Commissioner advised in the January 1978 proposal that he was unaware of any prior-sanctioned food ingredient use for this ingredient other than for the proposed conditions of use. Persons asserting additional or extended uses under approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of such sanctions so that the safety of prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of bile salts or ox bile extract approved by issuing appropriate regulations under part 181—Prior-Sanctioned Food Ingredients (21 CFR part 181), provided prior-sanctioned use could be affirmed as safe on the basis of currently available data. Notice was also given that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert sanction at any future time.

No reports of a prior-sanctioned use for bile salts or ox bile extract were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of bile salts and ox bile extract under conditions different from those set forth in this regulation has been waived.

No comments were received in response to the Commissioner's proposal and supporting data and information on bile salts and ox bile extract. The Commissioner therefore concludes that no change in the proposal to affirm the GRAS status of ox bile extract is warranted, and it is being promulgated without change. Additionally, no information was received in opposition to the proposal to remove the bile salts from GRAS status and, accordingly, they are removed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner (21