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

CFR 5.1), chapter I of title 21 of the Code of Federal Regulations is amended as follows:

1. In part 182:

§ 182.4029 [Deleted]

a. By deleting § 182.4029 Cholic acid.

§ 182.4037 [Deleted]

b. By deleting § 182.4037 Desoxycholic acid.

§ 182.4053 [Deleted]

c. By deleting § 182.4053 Glycocholic acid.

§ 182.4105 [Deleted]

d. By deleting § 182.4105 Taurocholic acid.

§ 182.4560 [Deleted]

e. By deleting § 182.4560 Ox bile extract.

2. In Part 184, by adding new § 184.4560 to read as follows:

§ 184.4560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. MX 8008-63-7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.[1]

(c) The ingredient is used as a surfactant as defined in § 170.3 (o)(29) of this chapter.

(d) The ingredient is used in food in accordance with § 184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in § 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation shall be effective September 14, 1978.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: August 2, 1978.

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

[FR Doc. 78-22654 Filed 8-14-78; 8:45 am]

[1] Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Md. 20852.

[3210-01]

Title 22—Foreign Relations

CHAPTER VII—OVERSEAS PRIVATE INVESTMENT CORPORATION

PART 709—FOREIGN CORRUPT PRACTICES ACT OF 1977

Promulgation of Regulations

AGENCY: Overseas Private Investment Corporation.

ACTION: Final regulations.

SUMMARY: The purpose of these regulations is to prescribe the procedure and conditions under which individuals and companies may be disqualified from receiving the services of the Overseas Private Investment Corporation ("OPIC") because of their conviction under the Foreign Corrupt Pracitces Act of 1977. These regulations establish the criteria that will be followed in deciding whether an individual or company will be suspended from eligibility for OPIC services. Finally, the regulations outline the effect that a suspension will have on an individual or company and how such a suspension can be voided. These regulations implement provisions of section 237(1) of the Foreign Assistance Act of 1961, as amended.

EFFECTIVE DATE: August 15, 1978.

FOR FURTHER INFORMATION CONTACT:

Cecil Hunt, Acting General Counsel, Overseas Private Investment Corporation, 1129 20th Street NW., Washington, D.C. 20527, telephone 202-632-1766.

SUPPLEMENTARY INFORMATION: Legislation enacted April 24, 1978, requires OPIC to adopt regulations prescribing the procedure under which individuals and corporations may be disqualified from eligibility for OPIC services. The new section 237(1) of the Foreign Assistance Act of 1961, as amended by Pub. L. 95-268, requires that by August 22, 1978 regulations be adopted providing for suspension of certain persons convicted under the Foreign Corrupt Practices Act of 1977.

Accordingly, title 22, chapter VII of the Code of Federal Regulations is amended by the addition of a part 709 as set forth below.

Adopted by the Overseas Private Investment Corporation at its offices in Washington, D.C. on August 8, 1978.

RUTHERFORD M. POATS,
Acting President.

Title 22 is amended by adding Part 709 as follows:

Sec.
709.1 Authority and purpose.
709.2 Applicability.
709.3 Definitions.
709.4 Cause for suspension of entities from eligibility.
709.5 Procedure.
709.6 Suspension duration criteria.
709.7 Effect of suspension.
709.8 Procedure for voiding suspensions.

AUTHORITY: Section 237(1) of the Foreign Assistance Act of 1961, added by Pub. L. 95-268.

§ 709.1 Authority and purpose.

(a) These regulations are issued under the general powers of the Overseas Private Investment Corporation ("OPIC") and pursuant to section 237(1) of the Foreign Assistance Act of 1961, added by Pub. L. 95-268.* The Board of Directors of OPIC has authorized the President of OPIC to issue these regulations and to amend them as the President shall deem appropriate.

(b) These regulations prescribe the procedure under which individuals and companies may be suspended, as mandated by section 237(1) of the Foreign Assistance Act of 1961, as amended, from eligibility for OPIC services because of conviction under the Foreign Corrupt Practices Act of 1977 (Pub. L. 95-213) of an offense related to an OPIC-supported project.

(c) The purposes of the suspensions provided herein are to carry out the statutory requirements of Section 237(1) of the Foreign Assistance Act of 1961, as amended, to protect the interest of the United States and to foster full and free competition in international commerce.

(d) The specific provisions of law under which OPIC operates and the general powers conferred on OPIC give OPIC broad discretion in the conduct of its programs. The issuance of these regulations is not to be con-

*Section 237(1) of that Act states:

(1) No payment may be made under any insurance or reinsurance which is issued under this title on or after the date of enactment of this subsection for any loss occurring with respect to a project, if the preponderant cause of such loss was an act by the investor seeking payment under this title, by a person possessing majority ownership and control of the investor at the time of the act, or by any agent of such investor or controlling person, and a court of the United States has entered a final judgment that such act constituted a violation under the Foreign Corrupt Practices Act of 1977.

(2) Not later than 120 days after the date of enactment of this subsection, the Corporation shall adopt regulations setting forth appropriate conditions under which any person convicted under the Foreign Corrupt Practices Act of 1977 for an offense related to a project insured or otherwise supported by the Corporation shall be suspended, for a period of not more than 5 years, from eligibility to receive any insurance, reinsurance, guaranty, loan or other financial support authorized by this title.

strued as in any way limiting or derogating from the discretion of OPIC to determine whether or not to support the investment of a particular entity in a particular case.

§ 709.2 Applicability.

These regulations take effect on the date of publication in the FEDERAL REGISTER and govern eligibility for OPIC services for which OPIC has not previously obligated itself.

§ 709.3 Definitions

(a) The "Act" means the Foreign Corrupt Practices Act of 1977.

(b) "Entity" means any individual, association, company, corporation, concern, partnership, or person.

(c) "Offense" means any act or omission to act which has been found by a United States court of competent jurisdiction to constitute, with respect to a particular entity, a violation of the Act, of sections 13(b)(2), 13(b)(3) or 30A of the Securities Exchange Act of 1934 (which were added in 1977 by the Act), or of any other provision of law derived from the Act.

(d) "Suspension" means the designation of an entity as ineligible to receive OPIC services through a suspension determination.

(e) "Suspension determination" means a determination by the President of OPIC pursuant to these regulations that an entity is ineligible to receive OPIC services.

§ 709.4 Cause for suspension of entities from eligibility.

Any entity which has been convicted of an offense related to a project insured or otherwise supported by OPIC may be suspended from eligibility for additional OPIC services for a period of not more than 5 years pursuant to a suspension determination.

§ 709.5 Procedure.

(a) Upon receipt of an application for OPIC services from any entity which OPIC has reason to believe may have been convicted under the Act the OPIC General Counsel shall ascertain whether a conviction has been entered against such entity under the Act and, if so, whether it was entered for an offense related to a project insured or otherwise supported by OPIC. If such an offense is found, the General Counsel shall advise the President of such finding and any known circumstances indicating that suspension would not be in the national interest of the United States. If, after reviewing the submission from the General Counsel, the President determines that national interest considerations are not great enough to preclude suspension, OPIC shall furnish the subject entity with a written notice (1) specifying the offense and stating that suspension for the maximum duration is being considered and (2) inviting the subject entity to submit to OPIC any evidence of facts or circumstances which it deems appropriate to indicate that a suspension should not be imposed or that the duration of the suspension should be less than the maximum. Such notice shall further state that the subject entity must provide such evidence within 30 days of the date of such written notice or any extension of time granted in writing by OPIC. The Genral Counsel shall promptly review any evidence submitted by the subject entity and report his findings and recommendations to the President. The President shall determine whether the subject entity shall be suspended and, if so, the President shall issue a suspension determination specifying the duration of such suspension. Notice of such suspension determination shall be forwarded by registered mail to the subject entity and any entity so notified shall be advised that such suspension may be reduced as provided in section 5(b) or voided as provided in section 8.

(b) The duration of any suspension may be reduced by the President at any time for good cause, including the submission by the suspended entity of an application for relief, supported by evidence and setting forth appropriate grounds for granting such relief, such as the institution of measures designed to preclude the recurrence of the actions with respect to which the suspension was initially imposed. Notice of each such reduction shall be forwarded to the suspended entity by registered mail.

(c) The duration of any suspension may be increased by the President at any time for good cause, subject to providing the subject entity with notice and opportunity to submit evidence in accordance with section 5(a). In no event shall any such increase result in a period of suspension exceeding 5 years with respect to any single conviction.

§ 709.6 Suspension duration criteria.

Factors which the President may consider in setting or amending the duration of any suspension imposed pursuant to these regulations include, but are not limited to, the following:

(a) Whether the offense with respect to which suspension has been imposed or is being considered was committed with the knowledge or consent of the board of directors or other group or officer or individual responsible for the overall management of the subject entity;

(b) Whether or not such offense was committed under pressure of extortion, political intervention, or other duress exerted by the government, or any official of the government, of the country in which such offense was committed;

(c) Quantitative factors relating to the seriousness of the offense, such as the amounts of any improper payments and the frequency with which, and period of time over which, they were made;

(d) The purpose of any such offense;

(e) Whether such offense violated the laws of the country in which it was committed;

(f) The extent to which the offense was related to the establishment or operation of a project supported by OPIC; and

(g) Any factors relating to the effect of suspension on the national interest of the United States.

§ 709.7 Effect of suspension.

(a) Any entity suspended pursuant to a suspension determination shall not, for the duration of such suspension, and subject to the provisions of section 7(b), be eligible to receive any additional insurance, reinsurance, guaranty, loan, or other financial support from OPIC.

(b) Suspended entities:

(1) May be retained on the OPIC mailing list only for the purpose of receiving informational mailings;

(2) May register projects with OPIC but may not submit project applications to OPIC;

(3) May continue to deal with OPIC with respect to agreements entered with OPIC prior to the suspension and may amend or be granted modifications of such agreements, including loan reschedulings and refinancings;

(4) May not be invited to participate in OPIC-sponsored investment missions or other similar activities; and

(5) May not receive indirectly, or beneficially, whether through the purchase of project participations, the use of intermediary entities or other such devices, any OPIC services which they would not be entitled to receive directly, and may not be the beneficiary of financial support advanced by a third party where such support, in turn, is guaranteed or insured by OPIC; provided, however that such suspended entity shall be entitled to all benefits and payments accruing to holders of negotiable instruments guaranteed by OPIC and acquired by such suspended entity pursuant to a public offering thereof by the original or any subsequent holder thereof.

§ 709.8 Procedure for voiding suspensions.

Upon receipt by OPIC from the subject entity of notice of the entry of a final judgment of reversal of the conviction or convictions on which a suspension was based, and subject to verification thereof by the General Counsel and to a finding by the General Counsel that no other convictions

under the act are outstanding, the President shall void such suspension.

[FR Doc. 78-22707 Filed 8-14-78; 8:45 am]

[4210-01]

Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. FI 4374]

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Suspension of Community Eligibility

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: This rule lists communities where the sale of flood insurance, as authorized under the National Flood Insurance Program (NFIP), will be suspended because of noncompliance with the flood plain management requirements of the program.

EFFECTIVE DATES: The third date ("Susp.") listed in the fourth column.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), administered by the Federal Insurance Administration, enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (24 CFR Part 1909 et seq.). Accordingly, the communities are suspended on the effective date in the fifth column, so that as of that date subsidized flood insurance is no longer available in the community.

In addition, the Federal Insurance Administration has identified the special flood hazard areas in these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the sixth column of the table. Section 202(a) of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), as amended, provides that no direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP, with respect to which a year has elapsed since publication of a flood insurance map. This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Federal Insurance Administrator finds that delayed effective dates would be contrary to the public interest. The Administrator also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

In each entry, a complete chronology of effective dates appears for each listed community.

Section 1914.6 is amended by adding in alphabetical sequence new entries to the table.

§ 1914.6 List of suspended communities.

State	County	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Hazard area identified	Date[1]
California	Alameda	Berkeley, city of	06004-A	Oct. 22, 1971, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	Dec. 7, 1973	Sept. 1, 1978.
Do	Orange	Newport Beach, city of	060227-B	May 12, 1972, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	Mar. 15, 1974 July 9, 1976	Do.
Colorado	Douglas	Castle Rock, town of	080050-B	Apr. 22, 1975, emergency, Aug. 15, 1978, regular, Sept. 1, 1978, suspended.	Mar. 29, 1974	Do.
Do	Larimer	Loveland, city of	080103-B	Sept. 18, 1975, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	Mar. 1, 1974 Dec. 17, 1976	Do.
Do	San Juan	Unincorporated areas	080267-A	Oct. 25, 1974, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	Sept. 1, 1978	Do.
Do	....do	Silverton, town of	080165-B	Nov. 7, 1974, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	June 14, 1974 May 28, 1976	Do.
Delaware	Sussex	Millsboro, town of	100043-B	May 28, 1974, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	June 21, 1974	Do.
Florida	Levy	Yankeetown, town of	120147-A	Nov. 13, 1970, emergency, Nov. 13, 1970, regular, Sept. 15, 1972, suspended, June 30, 1975, reinstated, Sept. 1, 1978, suspended.	Aug. 20, 1971 Feb. 27, 1976	Do.
Kansas	Barton	Ellinwood, city of	200018-B	July 29, 1975, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	Mar. 15, 1974 Oct. 24, 1975	Do.
Do.	Allen	Humboldt, city of	200002-B	Dec. 24, 1974, emergency, Sept. 1, 1978, regular, Sept. 1, 1978, suspended.	Dec. 7, 1973 Sept. 5, 1975	Do.
Louisiana	St. Mary	Morgan City, city of	220196-A	Mar. 23, 1973, emergency, Aug. 15, 1978, regular, Sept. 1, 1978, suspended.	Oct. 5, 1973	Do.