boarding occurs, a written statement explaining the terms, conditions and limitations of the denied boarding compensation provided by this part. Each carrier shall, prior to furnishing passengers with such written statement or any revision thereof, file three copies of such statement, or revision, with the Chief, Passenger and Cargo Rates Division, Bureau of Economics. The language of the statement, or revision, to be filed must have the prior approval of the Board, unless the wording thereof is as prescribed hereinbelow.

* * * * *

(Secs. 102, 204(a), 403, 404, 411, 416(a), Federal Aviation Act of 1958, as amended, 72 Stat. 240, 743, 758, 760, 769, 771; 49 U.S.C. 1302, 1324, 1373, 1374, 1381, 1386; secs. 3, 4, Administrative Procedure Act, 81 Stat. 54, 80 Stat. 383; 5 U.S.C. 552, 553)

By the Civil Aeronautics Board.

[SEAL] HARRY J. ZINK, *Secretary.*

[FR Doc.72-5303 Filed 4-5-72;8:49 am]

SUBCHAPTER E—ORGANIZATION REGULATIONS

[Reg. OR-60; Amdt. 25]

PART 385—DELEGATIONS AND REVIEW OF ACTION UNDER DELEGATION; NONHEARING MATTERS

Miscellaneous Amendments

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 3d day of April 1972.

Concurrently herewith, the Board is adopting ER-727, amending Part 250 (Priority Rules, Denied Boarding Compensation Tariffs and Reports of Unaccommodated Passengers), to designate the Chief, Passenger and Cargo Rates Division, Bureau of Economics, as the Board official with whom copies of a carrier's written statements under § 250.9 are to be filed. As stated in ER-727, supra, the Board has also determined to designate concurrently the Chief, Passenger and Cargo Rates Division, Bureau of Economics, as the official to whom it delegates the authority to approve or disapprove the language of written statements filed under § 250.9. This amendment gives effect to such determination.

Since this amendment is a rule of internal agency organization and procedure, notice and public procedure are not required, and the rule may be made effective on less than 30 days' notice.

Accordingly, the Civil Aeronautics Board hereby amends Part 385 of its Organization Regulations (14 CFR Part 385), effective April 7, 1972, to read as follows:

1. Amend § 385.13 by deleting and reserving paragraph (u) as follows:

§ 385.13 Delegation to the Director, Bureau of Operating Rights.

The Board hereby delegates to the Director, Bureau of Operating Rights, the authority to:

* * * * *

(u) [Reserved]

* * * * *

2. Amend § 385.14 by adding paragraph (j) to read as follows:

§ 385.14 Delegation to the Chief, Passenger and Cargo Rates Division, Bureau of Economics.

The Board hereby delegates to the Chief, Passenger and Cargo Rates Division, Bureau of Economics, the authority to:

* * * * *

(j) Approve or disapprove written statements filed by air carriers pursuant to § 250.9 of this chapter (Economic Regulations) explaining the terms, conditions, and limitations of denied boarding compensation provided by Part 250 of this chapter.

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743; 49 U.S.C. 1324; Reorg. Plan No. 3 of 1961, 75 Stat. 837, 26 F.R. 5989)

By the Civil Aeronautics Board.

[SEAL] HARRY J. ZINK, *Secretary.*

[FR Doc.72-5304 Filed 4-5-72;8:49 am]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS

The Commissioner of Food and Drugs, having evaluated the data in a petition (FAP 1B2697) filed by Monsanto Co., 800 North Lindbergh Boulevard, St. Louis, MO 63166, and other relevant material, concludes that the food additive regulations should be amended to provide for the safe use, as set forth below, of polyamine-epichlorohydrin resin as a wet strength agent and/or retention aid in the manufacture of paper and paperboard for food-contact use.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 2.120), § 121.2526 is amended in paragraph (a)(5) by adding alphabetically a new item to the list of substances, as follows:

§ 121.2526 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	*Limitations*
* * *	* * *
Polyamine - epichlorohydrin resin produced by the reaction of bis (hexamethylene) triamine and higher homologues with epichlorophydrin such that the finished resin has a nitrogen content of 7.4–8.9 percent and chlorine content of 18–21 percent on a dry basis, and a minimum viscosity in 20 percent by weight aqueous solution of 30 centipoises at 25° C., as determined by Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet - strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
* * *	* * *

* * * * *

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective on its date of publication in the FEDERAL REGISTER (4-6-72).

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348 (c)(1))

Dated: March 30, 1972.

SAM D. FINE, *Associate Commissioner for Compliance.*

[FR Doc.72-5290 Filed 4-5-72;8:48 am]

SUBCHAPTER C—DRUGS

PART 135a—NEW ANIMAL DRUGS FOR OPHTHALMIC AND TOPICAL USE

Gentamicin Sulfate, Betamethasone Valerate

The Commissioner of Food and Drugs has evaluated a new animal drug application (46-821V) filed by Schering Corp., 86 Orange Street, Bloomfield, NJ 07003, proposing the safe and effective use of a combination drug containing gentamicin sulfate and betamethasone valerate for the treatment of dogs. The application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), Part 135a is amended by adding the following new section:

§ 135a.22 Gentamicin sulfate, betamethasone valerate otic solution.

(a) *Specifications*. Each cubic centimeter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone alcohol.

(b) *Sponsor*. See code No. 032 in § 135.501(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used or intended for use in dogs for the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin.

(2) It is used by instillation of 3 to 8 drops of solution into the ear canal twice daily for 7 to 14 days. Duration of treatment will depend upon the severity of the condition and the response obtained. The duration of treatment and/or frequency of the dosage may be reduced but care should be taken not to discontinue therapy prematurely. The external ear and ear canal should be properly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area of the external ear.

(3) If hypersensitivity to any of the components occurs treatment with this product should be discontinued and appropriate therapy instituted. Concomitant use with other drugs known to induce ototoxicity is not recommended. This preparation should not be used in conditions where corticosteroids are contraindicated. Do not administer parenteral corticosteroids during treatment with this drug. The antibiotic sensitivity of the pathogenic organism should be determined prior to use of this preparation.

(4) For use by or on the order of a licensed veterinarian.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (4-6-72).

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i))

Dated: March 28, 1972.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc.72-5291 Filed 4-5-72;8:48 am]

PART 146—ANTIBIOTIC DRUGS; PROCEDURAL AND INTERPRETIVE REGULATIONS

Fee for Gas Chromatography Test

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), Part 146 is amended in § 146.8(b)(1) by revising the chargeable fee for the gas chromatography test to read as follows:

§ 146.8 Fees.

* * * * *

(b) * * *

(1) * * *

Test	*Chargeable fee per test*
* * *	* * *
Gas chromatography	18
* * *	* * *

* * * * *

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (4-6-72).

(Sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357)

Dated: March 28, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-5292 Filed 4-5-72;8:48 am]

Title 33—NAVIGATION AND NAVIGABLE WATERS

Chapter I—Coast Guard, Department of Transportation

[CGFR 71-107a]

PART 117—DRAWBRIDGE OPERATION REGULATIONS

Willamette River, Oreg.

This amendment changes the regulations for the Oregon State Highway Department across the Willamette River, mile 132.1 at Corvallis to require that the draw open on signal if at least 7 days notice has been given. Further, the draw need not open on Saturdays, Sundays, and legal holidays. This amendment was circulated as a public notice dated 26 October 1971 by the Commander, Thirteenth Coast Guard District and was published in the FEDERAL REGISTER as a notice of proposed rule making (CGFR 71-107) on October 14, 1971 (36 F.R. 19981). Six comments were received, four had no objection to the proposal. One objection was withdrawn after clarifying information had been given to the objector. One objected to the 6-month period, stating that this was not reasonable. In a subsequent meeting between the bridge owners and the objector it was agreed that 7 days notice would be adequate, this change is incorporated in this amendment. Another change in the proposed amendment is in the name of this bridge because this was transferred from county to state ownership. This amendment was originally proposed to be included in § 117.755 however these regulations more appropriately are codified under § 117.759b(f)(7).

Accordingly, Part 117 of Title 33 of the Code of Federal Regulations is amended by revising subparagraph (7) of paragraph (f) of § 117.759b to read as follows:

§ 117.759b Drawbridges in the State of Oregon where constant attendance is not required.

* * * * *

(f) * * *

(7) *Oregon State Highway Department bridge, Van Buren Street, Corvallis*. The draw shall open on signal if at least 7 days' notice has been given, however, the draw need not open on Saturdays, Sundays, and legal holidays.

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937; 33 U.S.C. 499, 49 U.S.C. 1655(g)(2); 49 CFR 1.46(c)(5), 33 CFR 1.05-1(c)(4))

Effective date. This revision shall become effective on May 8, 1972.

W. M. BENKERT,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.

MARCH 31, 1972.

[FR Doc.72-5289 Filed 4-5-72;8:47 am]

Proposed Rule Making

DEPARTMENT OF AGRICULTURE

Consumer and Marketing Service

[7 CFR Part 946]

[AO-200-A1]

IRISH POTATOES GROWN IN STATE OF WASHINGTON

Decision With Respect to Proposed Amendment of Marketing Agreement and Order; Referendum Order

Pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674), and the applicable rules of practice and procedure, as amended, governing proceedings to formulate marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held in Quincy, Wash., October 28, 1971, pursuant to notice thereof published in the September 24, 1971, issue of the FEDERAL REGISTER (36 F.R. 18956), upon a proposed amendment of Marketing Agreement No. 113 and Order No. 946 (7 CFR Part 946) hereinafter referred to collectively as the "order," regulating the handling of Irish potatoes grown in the State of Washington.

Based on evidence adduced at the hearing and the record thereof, the Deputy Administrator, Consumer and Marketing Service, on February 29, 1972, filed with the Hearing Clerk, U.S. Department of Agriculture, a recommended decision (including a proposed amendment of the order) which was published in the FEDERAL REGISTER March 3, 1972 (37 F.R. 4444). It offered opportunity to file written exceptions thereto until March 23, 1972. None was filed.

Material issues, findings, and conclusions. The material issues, findings, and conclusions of the recommended decision set forth in the FEDERAL REGISTER (F.R. Doc. 72-3241; 37 F.R. 4444), are hereby approved and adopted as the material issues, findings, and conclusions of this decision as if set forth in full herein.

Amendment of the Marketing Agreement and Order. Annexed hereto, and made a part hereof are two documents entitled, respectively, "Marketing Agreement as Amended Regulating the Handling of Irish Potatoes Grown in the State of Washington" and "Order Amending the Order Regulating the Handling of Irish Potatoes Grown in the State of Washington" which have been decided upon as the detailed means of effectuating the foregoing conclusions. These documents shall not become effective unless and until the requirements of § 900.14 of the aforesaid rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

Referendum order. Pursuant to the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), it is hereby directed that a referendum be conducted among producers who during the period April 16, 1971, through April 15, 1972 (which is hereby determined to be the representative period for the purpose of such referendum) have been engaged within the production area as defined in the order annexed to this decision and referendum order, in the production of potatoes for market, to determine whether such producers approve or favor the issuance of the annexed amendatory order. William C. Knope and John C. Rhine of the Fruit and Vegetable Division, Consumer and Marketing Service, U.S. Department of Agriculture, are hereby designated referendum agents of the Secretary of Agriculture to conduct said referendum severally or jointly.

The procedure applicable to the referendum shall be the "Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agriculture Marketing Agreement Act of 1937, as Amended" (7 CFR Part 900).

The ballots used in the referendum shall contain a summary describing the terms and conditions of the proposed amendatory order.

A copy of the aforesaid annexed order and of the aforesaid referendum procedure may be examined in the Northwest Marketing Field Office, U.S. Department of Agriculture, 1218 Southwest Washington Street, Portland, OR 97205.

It is hereby ordered, That this decision and referendum order, except the annexed marketing agreement, as amended, be published in the FEDERAL REGISTER. The regulatory provisions of the said marketing agreement, as amended, are identical with those contained in the order as amended by the annexed order which will be published with this decision.

Dated: March 31, 1972.

RICHARD E. LYNG,
Acting Secretary.

Order[1] Amending the order regulating the handling of Irish potatoes grown in the State of Washington

§ 946.0 Findings and determinations.

The findings and determinations hereinafter set forth are supplementary, and in addition to the previous findings and determinations which were made in connection with the issuance of the marketing agreement and order; and all of the said previous findings and determinations are hereby ratified and affirmed except insofar as such previous findings and determinations may be in conflict with the findings and determinations set forth herein (for prior findings and determinations see 14 F.R. 5860);

(a) Findings upon the basis of the hearing record: Pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674) and the applicable rules of practice and procedure effective thereunder (7 CFR Part 900), a public hearing was held in Quincy, Wash., on October 28, 1971, upon a proposed amendment of Marketing Agreement No. 113 and Order No. 946 (7 CFR Part 946) regulating the handling of Irish potatoes grown in the State of Washington. Upon the basis of the evidence introduced at such hearing and the record thereof, it is hereby found that:

(1) The order, as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The order, as hereby amended, regulates the handling of potatoes grown in the State of Washington in the same manner as, and is applicable only to persons in the respective classes of industrial and commercial activity specified in, the marketing order upon which hearings have been held;

(3) The order, as hereby amended, is limited in application to the smallest regional production area which is practicable, consistently with carrying out the declared policy of the act; and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the act;

(4) There are no differences in the production and marketing of potatoes the production area covered by the order, as hereby amended, which require different terms applicable to different parts of such area; and

(5) All handling of potatoes grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

(b) *It is therefore ordered,* That, on and after the effective date hereof, all handling of potatoes grown in the production area shall be in conformity to, and in compliance with, the terms and conditions of the said order as hereby amended, as follows:

1. Section 946.6 is revised to read as follows:

§ 946.6 Handler.

"Handler" is synonymous with "shipper" and means any person (except a common or contract carrier of potatoes

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure, as amended, governing proceedings to formulate marketing agreements and marketing orders have been met.

owned by another person) who handles potatoes or causes potatoes to be handled.

2. Section 946.7 is revised to read as follows:

§ 946.7 Handle.

"Handle" is synonymous with "ship" and means to transport, sell, or in any other way to place potatoes grown in the State of Washington, or cause such potatoes to be placed, in the current of commerce within the production area or between the production area and any point outside thereof, or from any point in the adjoining States of Oregon and Idaho to any other point: *Provided*, That, the definition of "handle" shall not include the transportation of ungraded potatoes within the production area for the purpose of having such potatoes prepared for market, or stored, except that the committee may impose safeguards pursuant to § 946.55 with respect to such potatoes.

3. Section 946.9 is revised to read as follows:

§ 946.9 Fiscal period.

"Fiscal period" means the period beginning on July 1 of each year and ending June 30 of the following year, or such other period as the Secretary may establish pursuant to recommendation of the committee.

§§ 946.13, 946.14, and 946.15 [Deleted]

4. Sections 946.13, 946.14, and 946.15 are deleted.

5. Section 946.16 is renumbered as § 946.13 and revised to read as follows:

§ 946.13 Grade and size.

"Grade" means any one of the officially established grades of potatoes, and "size" means any one of the officially established sizes of potatoes as defined and set forth in:

(a) The U.S. Standards for Potatoes issued by the U.S. Department of Agriculture (§§ 51.1540 to 51.1566 of this title), or amendments thereto or modifications thereof, or variations based thereon;

(b) U.S. Standards for Grades of Potatoes for Processing as issued by the U.S. Department of Agriculture (§§ 51.3410 to 51.3424 of this title), or amendments thereto, or modifications thereof, or variations based thereon;

(c) U.S. Standards for Grades of Peeled Potatoes (§§ 52.2421 to 52.2433 of this title), or amendments thereto or modifications thereof, or variations based thereon; and

(d) State of Washington Standards for Potatoes issued by the State of Washington Director of Agriculture, or amendments thereto, or modifications thereof, or variations based thereon.

6. Section 946.14 is added to read as follows:

§ 946.14 Grading.

"Grading" is synonymous with "preparing for market" which means the sorting or separating of potatoes into grades and sizes for market purposes.

7. Section 946.17 is renumbered as § 946.15 and revised to read as follows:

§ 946.15 Export.

"Export" means shipment of potatoes beyond the boundaries of the 48 contiguous States of the United States, or the District of Columbia.

§ 946.16 [Renumbered]

8. Section 946.18 is renumbered as § 946.16.

9. Paragraph (a) of § 946.25 is amended to read as follows:

§ 946.25 Selection.

(a) Persons selected as committee members or alternates to represent producers shall be individuals who are producers in the respective district for which selected, or officers or employees of a corporate producer in such district.

* * * * *

10. Paragraph (a) of § 946.27 is amended to read as follows:

§ 946.27 Term of office.

(a) The term of office of committee members and alternates shall be for 3 years beginning on the 1st day of July and continuing until their successors are selected and have qualified: *Provided, however*, That the terms of office of the initial committee under the amended order shall be determined by the Secretary so that the terms of office of one-third of the initial members and alternates shall be for 1 year, one-third for 2 years, and one-third for 3 years.

* * * * *

11. Section 946.30 is revised to read as follows:

§ 946.30 Expenses and compensation.

Committee members and their respective alternates when acting on committee business shall be reimbursed for reasonable expenses necessarily incurred by them in the performance of their duties and in the exercise of their powers under this subpart. In addition, they may receive reasonable compensation at a rate recommended by the committee and approved by the Secretary.

12. Section 946.32 is revised to read as follows:

§ 946.32 Nomination.

The Secretary may select the members of the State of Washington Potato Committee and their respective alternates from nominations which may be made in the following manner, or from among such other qualified persons:

(a) A meeting or meetings of producers and handlers shall be held by the committee in each district for which nominees are to be selected not later than May 1 of each year to designate nominees for members and alternates to the committee; or the committee may conduct nominations by mail in a manner recommended by the committee and approved by the Secretary; and, in arranging for such meetings, the committee may, if it deems desirable, utilize the services and facilities of other existing organizations;

(b) At least one nominee shall be designated for each position as member and for each position as alternate member on the committee which is vacant, or which is to become vacant the following July 1;

(c) The names of nominees shall be supplied to the Secretary in such manner and form as he may prescribe, not later than June 1 of each year, or by such other date as may be specified by the Secretary;

(d) Only producers may participate in designating producer nominees, and only handlers may participate in designating handler nominees. Any person who operates in more than one district or is engaged in producing and handling potatoes, shall elect the classification (i.e., producer or handler), and the district within which he desires to participate in designating nominees;

(e) Regardless of the number of districts in which a person produces or handles potatoes, each such person is entitled to cast only one vote on behalf of himself, his agents, subsidiaries, affiliates, and representatives in designating nominees for committee members and alternates. An eligible voter's privilege of casting only one vote as aforesaid shall be construed to permit a voter to cast one vote for each position to be filled in the district in which he elects to vote; and

(f) If nominations are not made within the time and in the manner specified in this section, the Secretary may, without regard to nominations, select the committee members and alternates on the basis of the representation provided for in this subpart.

§ 946.33 [Deleted]

13. Section 946.33 is deleted.

§ 946.33 [Renumbered]

14. Section 946.34 is renumbered as § 946.33.

15. Section 946.40 is revised to read as follows:

§ 946.40 Expenses.

The committee is authorized to incur such expenses as the Secretary finds are reasonable and likely to be incurred by it during each fiscal period for its maintenance and functioning, and for such other purposes as the Secretary, pursuant to this subpart, determines to be appropriate. The committee shall submit to the Secretary a budget for each fiscal period, including an explanation of the items appearing therein, and a recommendation as to the rate of assessment for such fiscal period.

16. Section 946.41 is revised to read as follows:

§ 946.41 Assessments.

Each handler shall pay to the committee upon demand, his pro rata share of the expenses authorized by the Secretary for each fiscal period. Each handler's pro rata share shall be the rate of assessment per hundredweight fixed by the Secretary times the quantity of potatoes which he handles as the first handler thereof. At any time during or after a fiscal period, the Secretary may increase the rate of assessment as necessary to cover authorized expenses. Such increase shall be applicable to all potatoes handled during the given fiscal period. The payment of expenses for the maintenance and functioning of the committee may be required during periods when no regulations are in effect. If a handler does not pay his assessment within the time prescribed by the committee, the assessment may be increased by a late payment charge or an interest charge, or both, at rates prescribed by the committee with the approval of the Secretary.

17. Section 946.42 is revised to read as follows:

§ 946.42 Accounting.

(a) *Excess funds.* At the end of a fiscal period, funds in excess of the year's expenses shall be placed in an operating reserve not to exceed approximately two fiscal periods' operational expenses or such lower limits as the committee, with the approval of the Secretary, may establish. Funds in such reserve shall be available for use by the committee for expenses authorized pursuant to § 946.40. Funds in excess of those placed in the operating reserve shall be refunded to handlers. Each handler's share of such excess shall be the amount of assessments he paid in excess of his pro rata share of the actual expenses of the committee and the addition, if any, to the operating reserve.

(b) *Accounting of funds upon termination of order.* Any money collected as assessments pursuant to this subpart and remaining unexpended in the possession of the committee after termination of this part shall be distributed in such manner as the Secretary may direct: *Provided,* That to the extent practical, such funds shall be returned pro rata to the persons from whom such funds were collected.

18. Section 946.46 is renumbered as § 946.50 and revised to read as follows:

§ 946.50 Marketing policy.

(a) Prior to each marketing season, the committee shall consider and prepare a policy statement for the marketing of potatoes. In developing its marketing policy, the committee shall investigate relevant supply and demand conditions for potatoes. In such investigations, the committee shall give appropriate considerations to the following:

(1) Market prices of potatoes, including prices by grade, size, quality, and maturity in different packs of fresh potatoes and of the various forms of processed potatoes;

(2) Supplies of potatoes by grade, size, quality, and maturity in the production area and in other production areas, of fresh potatoes, and the supplies of various forms of processed potatoes;

(3) The trend and level of consumer income;

(4) Establishing and maintaining orderly marketing conditions for potatoes;

(5) Orderly marketing of potatoes as will be in the public interest; and

(6) Other relevant factors.

(b) In the event it becomes advisable to deviate from such marketing policy because of changed supply and demand conditions, the committee shall formulate a revised marketing policy statement in accordance with the appropriate considerations in paragraph (a) of this section.

(c) The committee shall submit a report to the Secretary setting forth such marketing policy. Notice of each such marketing policy and any revision thereof shall be given to producers, handlers, and other interested parties by bulletins, newspapers, or other appropriate media, and copies thereof shall be available for examination at the committee office to all interested parties.

19. Section 946.47 is renumbered as § 946.51 and revised to read as follows:

§ 946.51 Recommendation for regulation.

The committee shall recommend to the Secretary regulations, or amendments, modifications, suspension, or termination thereof, whenever it finds that such regulations as provided in § 946.52 are in accordance with the marketing policy established pursuant to § 946.50 and that such regulations will tend to effectuate the declared policy of the act.

20. Section 946.48 is renumbered as § 946.52 and revised to read as follows:

§ 946.52 Issuance of regulations.

(a) The Secretary shall limit the shipment of potatoes as set forth in this subpart whenever he finds from the recommendation and information submitted by the committee, or from other available information, that it would tend to effectuate the declared policy of the act:

(1) To regulate, in any or all portions of the production area the handling of particular grades, sizes, qualities or maturity of any or all varieties of potatoes during any period;

(2) To regulate the handling of particular grades, sizes, qualities or maturities of any or all varieties of potatoes, or for any combination of the foregoing during any period in the States of Oregon and Idaho which have been shipped from the production area to specified locations therein for grading or storage pursuant to § 946.54;

(3) To regulate the handling of particular grades, sizes, qualities or maturities of any or all varieties differently for: Different portions of the production area, different uses or outlets, different packs or for any combination of the foregoing, during any period;

(4) To regulate the handling of potatoes by establishing in terms of grades, sizes, or both, minimum standards of quality and maturity.

(b) The Secretary may amend any regulation issued under this subpart whenever he finds that such amendment would tend to effectuate the declared policy of the act. The Secretary may also terminate or suspend any regulation whenever he finds that such regulation obstructs or no longer tends to effectuate the declared policy of the act.

(c) The Secretary shall notify the committee of any such regulation issued pursuant to this section and the committee shall give reasonable notice thereof to handlers.

21. Section 946.49 is renumbered as § 946.53 and revised to read as follows:

§ 946.53 Minimum quantities.

The committee, with the approval of the Secretary, may establish, for any or all portions of the production area, minimum quantities below which shipments will be free from regulations issued pursuant to this part.

22. Section 946.50 is renumbered as § 946.54 and revised to read as follows:

§ 946.54 Shipments for specified purposes.

(a) Whenever the Secretary finds, upon the basis of the recommendations and information submitted by the committee, or from other available information, that it will tend to effectuate the declared policy of the act, he shall modify, suspend, or terminate any or all regulations issued pursuant to this part in order to facilitate shipments of potatoes for the following purposes:

(1) Livestock feed;

(2) Charity;

(3) Export;

(4) Seed;

(5) Prepeeling;

(6) Such other purposes as may be specified by the committee with the approval of the Secretary; and

(7) Grading or storing between the districts within the production area or to and within specified locations in the adjoining States of Idaho and Oregon.

(b) The Secretary shall give prompt notice to the committee of any modification, suspension, or termination of regulations pursuant to this section, or of any approval issued by him under the provisions of this section.

23. Section 946.55 is added to read as follows:

§ 946.55 Safeguards.

(a) The committee, with the approval of the Secretary, may prescribe adequate safeguards to prevent shipments pursuant to § 946.54 from entering channels of trade and other outlets for other than the specific purposes authorized therefor, and the transportation of potatoes for grading and storing to points outside the production area.

(b) Safeguards provided by this section may include, but shall not be limited to, requirements that handlers:

(1) Shall obtain the inspection required by § 946.60 or pay the assessment provided by § 946.41, or both, in connection with the potato shipments effected in accordance with § 946.54, and

(2) shall obtain a special purpose certificate from the committee for shipments of potatoes effected or to be effected under provisions of § 946.54.

(c) The committee, with the approval of the Secretary, shall prescribe rules governing the issuance and the contents of the special purpose certificate.

(d) The committee may rescind, or deny to any handler the special purpose certificate if proof satisfactory to the committee is obtained that potatoes shipped by him for the purpose stated in § 946.54 were handled contrary to the provisions of this section.

(e) The committee shall make reports to the Secretary, as requested, showing the number of applications for such certificates, the quantity of potatoes covered by such applications for such certificates, the number of such applications denied, and certificates granted, the quantity of potatoes shipped under duly issued certificates, and such other information as may be requested by the Secretary.

24. Section 946.53 is renumbered as § 946.60 and paragraph (a) is amended to read as follows:

§ 946.60 **Inspection and certification.**

(a) During any period in which the Secretary regulates the shipment of potatoes pursuant to the provisions of this subpart, each handler who first ships potatoes shall, prior to making shipment, cause each shipment to be inspected by an authorized representative of the Federal-State inspection service or such other inspection service as the Secretary shall designate. The committee may, with the approval of the Secretary, prescribe rules and regulations modifying the inspection requirements of this section in circumstances under which such requirements would create an undue hardship on growers or shippers: *Provided*, That all such shipments shall comply with all regulations in effect: *And provided further*, That proper safeguards to assure compliance are adopted.

* * * * *

§§ 946.56, 946.57, 946.58, and 946.59 [Deleted]

25. Sections 946.56, 946.57, 946.58, and 946.59 are deleted.

26. Section 946.70 is revised to read as follows:

§ 946.70 **Reports and records.**

(a) Upon the request of the committee, with the approval of the Secretary, every handler shall furnish to the committee in such manner and at such time as may be prescribed, such information as will enable the committee to exercise its duties under this subpart.

(b) Each handler shall establish and maintain for at least 2 succeeding years such records and documents with respect to potatoes received and potatoes disposed of by him as will substantiate the required reports.

(c) For the purpose of assuring compliance with the recordkeeping requirements and verifying reports filed by handlers, the Secretary and the committee through its duly authorized employees, shall have access to such records.

(d) All reports and records furnished or submitted by handlers to, or obtained by the employees of, the committee which contain data for information constituting a trade secret or disclosing the trade position, financial condition, or business operations of the particular handler from whom received, shall be treated as confidential, and the reports and all information obtained from records shall at all times be kept in the custody and under the control of one or more employees of the committee who shall disclose such information to no person other than the Secretary, or his authorized agents. Compilations of general reports from data and information submitted by handlers is authorized subject to the prohibition of disclosure of individual handlers' identity or operations.

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Farmers Home Administration

[7 CFR Part 1861]

[FHA Instruction 451.5]

SERVICING OF COMMUNITY PROGRAM LOANS AND GRANTS

Proposed Policies, Authorizations and Procedures

Notice is hereby given that the Farmers Home Administration has under consideration a proposed new Subpart F, "Servicing of Community Program Loans and Grants," which prescribes the policies, authorizations, and procedures for servicing association loans.

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed amendment to the Assistant Administrator for Management, Farmers Home Administration, U.S. Department of Agriculture, Room 5013, South Building, Washington, D.C. 20250, within 30 days after date of publication of this notice in the FEDERAL REGISTER. All written submissions made pursuant to this notice will be made available for public inspection at the Office of the Assistant Administrator for Management during regular business hours. (8:15 a.m.–4:45 p.m.)

As proposed, the new Subpart F will read as follows:

Sec.
1861.81 Purpose.
1861.82 Loan servicing.
1861.83 Sale or exchange of security property.
1861.84 Liquidation of security.
1861.85 Transfer of security and assumption of loans.
1861.86 Voluntary conveyance of security to FHA.
1861.87 Foreclosure.
1861.88 Mergers.
1861.89 Special provisions applicable to Economic Opportunity (EO) Cooperative loans.
1861.90 Care, management, and disposal of acquired property.
1861.91 Water and waste disposal systems which have become part of an urban area.
1861.92 Determining present market value.
1861.93 Development grants.
1861.94 Comprehensive planning grants.
1861.95 Servicing planning advances.
1861.96 Additional State Director's authorizations.
1861.97 Payment in full.
1861.98 State requirements.
1861.99 Redelegation of authority.
Sec.
1861.100 Reports and recommendations.
1861.101 Servicing public bodies.

AUTHORITY: The provisions of this Subpart F issued under sec. 339, 75 Stat. 318, 7 U.S.C. 1989; sec. 602, 78 Stat. 528, 42 U.S.C. 2942; sec. 301, 80 Stat. 379, 5 U.S.C. 301; Order of Act. Sec. of Agr., 36 F.R. 21529; Order of Asst. Sec. of Agr. for Rural Development and Conservation, 36 F.R. 21529; Order of Dir., OEO, 29 F.R. 14764.

Subpart F—Servicing of Community Program Loans and Grants

§ 1861.81 **Purpose.**

This subpart prescribes the policies, authorizations, and procedures for servicing the following: Community water and waste disposal system loans and grants, comprehensive water and sewer planning grants, loans for grazing and other shift-in-land use projects, community recreation facility loans, community irrigation and drainage loans, watershed loans and advances, resource conservation and development loans, economic opportunity cooperative loans, loans to Indian tribes and tribal corporations, and loans to timber development organizations. Servicing will be directed toward assisting the borrower to meet the objectives of the loan, repaying loans on schedule, complying with agreements, and protecting the Farmers Home Administration's (FHA's) financial interest.

§ 1861.82 **Loan servicing.**

(a) *Regular payments.* Regular payments are: All payments other than extra payments and refunds; revenue from mineral lease bonuses and delay rentals; proceeds from the sale of timber harvested on a selective cutting basis that does not deplete the Government's security; proceeds from the sale of gravel, rock, fill dirt, or sand when such sale does not reduce the value of the Government's security; and similar transactions which do not reduce the value of the Government's security.

(1) *Order of application.* Regular payments will be applied to accounts in accordance with § 1861.5(a) except as otherwise established by the note or bond.

(b) *Extra payments.* Extra payments are those derived from: the sale of basic chattel or real estate security, including rental or lease of real estate security of a depreciating or depleting nature; mineral royalties and timber other than referred to in paragraph (a)(1) of this section; cash proceeds of real property insurance as provided in § 1806.5(b) of this chapter; and a refund of unused loan funds.

(1) *Application.* Extra payments will be applied in accordance with § 1861.5 (b) except where otherwise established in accordance with the note or bond.

(c) *Collections.* Collections will be processed in accordance with Part 1862 of this chapter.

(d) *Actions by FHA for account of borrower including advances for protection of security or lien.* (1) Property insurance will be serviced in accordance with Part 1806 of this chapter in real estate mortgage cases and in accordance with the loan agreement in other cases.

(2) Borrower's real property taxes will be serviced in accordance with Part 1863 of this chapter. If State statutes permit a personal property tax lien to have priority over FHA's lien, personal property taxes will be serviced in accordance with §§ 1863.3 and 1863.4 of this chapter.

(3) The State Director is authorized to approve vouchers to pay costs, other than taxes and insurance, necessary to protect FHA's interest. Vouchers will be prepared using standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," in an original and two copies. The name and address of the party to whom payment is due will be inserted in the heading. The amount of the vouchered items will be inserted in the appropriate spaces. The notation inserted in the space for description of the services will include the purpose of the payment, the location and a simple description of the property, the name and case number of the borrower, and the fact that the amount will be charged to the borrower's account. A sample notation could be as follows:

For payment of water rights of real property in (community), (State), (case No.), (loan type code) for the period of July 15, 1971, through August 1971 to be charged to the borrower's loan account.

(4) After the voucher has been approved by the State Director, the original with any attached reports will be sent to the Finance Office, St. Louis, Mo. One copy will be held in the borrower's county office loan docket, and one copy will be given to the borrower.

(i) After the voucher has been processed in the Finance Office, a U.S. Treasury check will be issued to the appropriate payee and mailed to the State Director for delivery. The purpose of the payment will be stated on each check. Any amount advanced will be entered as a recoverable charge on the borrower's account in the Finance Office. The advance will bear interest at the rate specified in the most recent debt instrument under which the advance is authorized to be made. After the check is issued, Form FHA 451-26, "Transaction Record," will be prepared by the Finance Office and sent to the appropriate county office, showing the amount of the recoverable charge and the applicable rate of interest.

(e) *Subordination of security*—(1) *Request for subordination.* When a borrower requests FHA to subordinate a security instrument so that another creditor or lender can refinance, extend, reamortize, or increase the amount of a prior lien, or place a lien ahead of the FHA lien, it will submit a written request. This request should contain the purpose of the subordination, exact amount of money or property involved, description of security property to be subordinated, type of security instrument, name, address, line of business, and other general information pertaining to the party in favor of which subordination will be given, and other pertinent information which will be of assistance in determining need for subordination. The State Director is authorized to execute subordination on Form FHA 460-2, "Subordination by the Government," provided all the following requirements and conditions are met:

(i) The amount of the subordination does not exceed the State Director's loan approval authorization as set forth in Part 1810, Subpart B of this chapter.

(ii) The borrower is unable to refinance the FHA mortgage on terms which it can reasonably be expected to meet.

(iii) The transaction will either further the objectives for which the FHA loan was made or improve the borrower's debt-paying ability and, in either case, result in the FHA debt being adequately or no less well secured.

(iv) The terms and conditions of the prior lien will be such that the borrower can reasonably be expected to meet them as well as all other debts.

(v) Any proposed development work will be planned and performed in accordance with Subpart A of Part 1823 of this chapter or in a manner directed by the creditor which reasonably attains the objectives of Subpart A of Part 1823 of this chapter.

(vi) In case of land purchase, the FHA will obtain a mortgage on such purchased land.

(vii) When the transaction involves more than $1,000 and the State Director considers it necessary, a present market value appraisal report will be obtained. However, a current appraisal report need not be obtained if there is an appraisal report not over 2 years old in the file which will permit the proper determination as to the present market value of the total property after the transaction.

(viii) The subordination is for a specific amount.

(ix) All contracts, pay estimates, and change orders will be reviewed and approved by the FHA State Director.

(x) The proposed action will not so change the nature of the borrower's activities as to make it ineligible for FHA loan assistance.

(2) *Processing.* All subordinations pertaining to other than chattel liens will be closed in accordance with instructions from the Office of the General Counsel (OGC). When national office approval is required or the State Director desires advice pertaining to a requested subordination, the borrower's loan docket together with a current operating budget, financial statement, copy of proposed lien, appraisal report, borrower's written request, OGC opinion, and other necessary supporting information, will be sent to the national office.

(f) *Loan reamortization.* (1) The State Director is authorized to approve reamortization of loans for borrowers having a delinquency which cannot be brought current within 1 year while maintaining a reasonable reserve when all of the following conditions exist:

(i) The debt(s) to be reamortized does not exceed the State Director's loan approval authorization.

(ii) The borrower has demonstrated for at least 1 year by actual performance or has presented a budget which clearly indicates that it is able to meet the proposed payment schedule.

(iii) There is no extension of the final maturity date.

(2) Proposals for reamortization exceeding the limits set in subparagraph (1) of this paragraph, and those evidenced by notes which are not delinquent may be reamortized with prior approval of the national office. Requests for such reamortization will be forwarded to the national office along with the loan docket, a current budget and financial statement, and the State Director's statement of essential facts and recommendation.

(3) Processing will be handled as follows:

(i) Borrowers other than public bodies requesting reamortization will complete Form FHA 451-30, "Reamortization Agreement." All of the note, including principal and interest, will be reamortized. Reamortization will be accomplished through the use of a new note unless the OGC recommends that the terms of the existing note be modified through the use of Form FHA 451-30, or if that is legally inadequate through the use of other appropriate form.

(ii) Public body borrowers may effect reamortization by any procedure which in the opinion of their counsel and OGC is legally permissible under State law and acceptable to the State Director. Appendix 3 of Part 1823, Subpart A of this chapter would not apply to the new bonds.

(4) The properly executed new instrument(s) or endorsement, as appropriate, will be forwarded to the Finance Office together with the original existing note or bond attached thereto. The copy of the new note or bond or endorsement will be retained by the Finance Office until the account is paid in full or otherwise satisfied.

(g) *Consent to borrower's granting lease of security*—(1) *State Director's consent.* The State Director may consent to the leasing of all or a portion of security property, when:

(i) The lease will not adversely affect the repayment of the loan or the Government's rights under the security instrument.

(ii) Leasing is not an alternative to, or means of, delaying liquidation action.

(iii) The lease and use of any proceeds from such lease will further the objectives of the loan.

(iv) Rental income is assigned to FHA in an amount sufficient to make regular payments on the loan, and operate and maintain the facility, unless such payments are otherwise adequately assured.

(v) The lease is advantageous to the borrower and is not to the Government's disadvantage.

(vi) If foreclosure action has been approved and the case has been submitted to OGC, consent to lease and use of proceeds will be granted only with the concurrence of the OGC.

(vii) The lease shall not exceed a 1-year period. The property may not be under lease more than 2 consecutive years without authorization from the national office.

(2) *Mineral leases.* The State Director, unless liquidation is pending, is authorized to approve mineral leases when:

(i) The lessee agrees in the lease or elsewhere, or is liable without any agreement, to pay adequate compensation for any damage to the real estate surface and improvements. Damage compensation will be assigned to FHA by the use of Form FHA 443-16, "Assignment of Income from Real Estate Security," or other appropriate instrument, or to the prior lienholder.

(ii) Royalty payments are adequate and are assigned to FHA on Form FHA 443-16.

(iii) All or a portion of delay rentals and bonus payments may be assigned on Form FHA 443-16 if needed for protection of the Government's interests.

(iv) The lease, subordination, or consent form is acceptable to the OGC.

(3) *Processing.* When FHA's consent to a lease is required, the borrower will complete and submit Form FHA 465-1, "Application for Partial Release, Subordination, or Consent." This form will show the terms of the proposed lease and will specify the use of proceeds including any proceeds to be released to the borrower. When another lienholder's mortgage requires consent to lease, his consent will be obtained. When the approval of the national office is required or if the State Director wishes a lease transaction reviewed prior to approval, he will forward the loan docket, a copy of the proposed lease, and any other pertinent information along with his recommendations to the national office.

(h) *Membership liability.* As a loan approval requirement, some borrowers may have special agreements with members for the purchase of shares of stock or for the payment of a pro rata share of the loan in event of default, or they may have in their corporate instruments authority to make special assessments in such event. Such agreements may be referred to as individual liability agreements and may be assigned to and held by the FHA as additional security for the loan. In other cases the borrower's note may be endorsed by individuals. Such liability instruments will be serviced in a manner indicated by their contents so as to adequately protect the interest of the FHA.

(i) *Other security.* Other security such as collateral assignments, water stock certificates, notices of lienholder interest (Bureau of Land Management grazing permits), and waivers of grazing privileges (Forest Service grazing permits), will be serviced so as to protect the interest of FHA, and pursuant to any special servicing actions developed by the State Director with the assistance of the OGC. Evidence of such security will be filed in the loan docket in the county office. A notation will be made on Form FHA 405-10, "Management System Card—Association," showing necessary servicing action.

(j) *Correcting errors in security instruments.* Land, buildings, or chattels included in the mortgage through mutual mistake when substantiated by the factual situation may be released from the mortgage by the State Director. The release is contingent on the State Director with the advice of the OGC determining that a mutual error existed at the time such property was included in the Government's mortgage.

§ 1861.83 Sale or exchange of security property.

(a) *Authority.* Approval to a cash sale of a portion of the borrower's assets or an exchange of security property may be given when the approving official determines:

(1) The consideration is adequate.

(2) The release will not prevent carrying out the purpose of the loan.

(3) The remaining property is adequate security for the loan, or the transaction will not adversely effect FHA's security position.

(4) The proceeds are used for one or more of the following purposes:

(i) To pay on FHA debts in accordance with paragraphs (a) and (b) of § 1861.82, on debts secured by a prior lien, and on debts secured by a subsequent lien if it is to FHA's advantage.

(ii) To purchase or to acquire through exchange property more suitable to the borrower's needs, provided the FHA secured debt will be as well secured after the transaction as before.

(iii) To develop or enlarge the facility provided that such action is necessary to improve the borrower's debt-paying ability, place his operation on a more sound basis, or otherwise further the objectives of the loan.

(5) The FHA liens are not released until receipt of the appropriate sale proceeds for application on the Government's claim. In any State in which it is necessary to obtain the insured note from the lender to present to the recorder before a release of a portion of the land from the mortgage, the borrower must pay any cost for postage and insurance of the note while in transit. The county supervisor will advise the borrower when it requests a partial release that it must pay such costs. If the borrower is unable to pay the costs from personal funds, they may be deducted from the sale proceeds. The amount of the charge will be based on the statement of actual cost furnishd by the insured lender.

(b) *Processing.* When a borrower requests permission to sell or exchange a portion of FHA's security property, Form FHA 465-1, will be completed for real estate, or Form FHA 462-2, "Statement of Conditions on Which Lien Will be Released," will be completed for chattels. The county supervisor will forward Form FHA 465-1 or Form FHA 462-2, an appraisal report, as appropriate, the county office docket, his recommendation, and all other pertinent information to the State Director.

(c) *Releasing security*—(1) *Chattel security.* The county supervisor is authorized to satisfy or terminate chattel security instruments when paragraph (a) of this section and § 1871.8 of this chapter have been complied with. Satisfaction or termination of chattel security instruments will be accomplished in accordance with § 1871.13 of this chapter. Partial releases may be made by using Form FHA 460-1, "Partial Release," or Form FHA 460-6, "Partial Release (UCC States)." Form FHA 460-4, "Satisfaction," will be used when a debt has been paid in full or satisfied by debt settlement action.

(2) *Real estate.* Subject to paragraph (a) of this section, the State Director is authorized to consent to disposition of part of an interest in real estate security by approving Form FHA 465-1. Upon request for such consent, the county supervisor will forward Form FHA 465-1, the borrower's loan file, and any other pertinent information to the State Director. Partial release of real estate security may be made by use of Form FHA 460-1 or any other form approved by OGC. Form FHA 460-4 will be used when a debt has been paid in full or satisfied by debt settlement action.

(d) *Release of liability.* (1) When the FHA debt is paid in full from the sale of proceeds, the borrower will be released from liability by use of Form FHA 465-8, "Release from Personal Liability."

(2) When sale proceeds are not sufficient to pay the FHA debt in full and all security property has been disposed of, the remaining debt will be accelerated and the case reclassified to collection-only.

§ 1861.84 Liquidation of security.

When the county supervisor believes that continued servicing will not accomplish the objectives of the loan he will complete the form, "Report on Association Problem Case (Association-Type Projects)," available in all FHA offices, and submit it along with the county office file to the State office. If the State Director determines the account should be liquidated he will encourage the borrower to voluntarily sell the property and remit the proceeds to FHA. He will give the borrower a specified period of time not to exceed 180 days to accomplish such action. If the voluntary sale cannot be accomplished the loan will be liquidated in accordance with § 1861.85, 1861.86, or 1861.87.

§ 1861.85 Transfer of security and assumption of loans.

(a) *General.* Transfer and assumption may be approved subject to the following conditions:

(1) Transfers to eligible applicants will receive preference over transfers to ineligible applicants, provided recovery to FHA from the sale price is not less than it would be if the transfer were to an ineligible applicant.

(2) The present borrower is unable or unwilling to accomplish the objectives of the loan and the transfer will be to the Government's advantage.

(3) If the debt(s) exceeds the present market value of the security, the transferee will assume an amount at least equal to the present market value.

(4) If the FHA debt is less than the present market value, the transferee will assume an amount at least equal to the debt owed the FHA.

(5) The transfer will not adversely affect the FHA program in the area.

(6) FHA concurs in the plans for disposition of funds in the transferor's debt service, reserve and operation, and maintenance account.

(7) The county committee recommends the transfer.

(b) *Transfers to eligible applicants.* (1) The State Director is authorized to approve transfers of security property to and assumptions of FHA debts by transferees who would be eligible for the type of loan being transferred.

(2) If the interest rate or terms of the loan are changed, Form FHA 460-5, "Assumption Agreement (New Terms)," will be executed by the transferee. The new repayment period may not exceed the repayment period for a new loan of the type involved. If the current interest rate for such loans is higher than the rate specified in the note(s) being assumed, the current rate will apply except in cases of transfers from nonpublic to public bodies and mergers.

(3) If the full debt is assumed and the same interest rate and terms prevail, Form FHA 460-9, "Assumption Agreement (Same Terms—Eligible Transferee)," will be executed by the transferee.

(4) A loan for which the transferee is eligible may be made in connection with a transfer subject to the policies and procedures governing the kind of loan being made.

(5) If the transferor is to receive a payment for its equity, the total FHA debt must be assumed.

(6) Release of liability will be considered in accordance with the following:

(i) When all FHA security is transferred to an eligible applicant and the total outstanding debt is assumed, it will be the policy to release the transferor from liability.

(ii) In those cases where the transfer is for less than the full amount of the FHA debt, the transferor may be released from liability provided the State Director determines that the transferor has no reasonable debt-paying ability considering its assets and income at the time of the transfer and the county committee certifies that the transferor has cooperated in good faith, used due diligence to maintain the security property against loss, and has otherwise fulfilled the covenants incident to the loan to the best of its ability. If the county committee recommends a release of liability, such recommendation will be made on Form FHA 440-2, "County Committee Certification or Recommendation," in the blank space following item 10 similar to the following:

__________, in our opinion does not have reasonable debt-paying ability to pay the balance of the debt not assumed after considering its assets and income at the time of the transfer. Transferors have cooperated in good faith, used due diligence to maintain the security against loss, and otherwise fulfilled the covenants incident to the loan to the best of its ability. Therefore, we recommend that the transferor be released of personal liability upon the transferee's assumption of that portion of the indebtedness equal to the present market value of the security.

(c) *Transfers to ineligible applicants.* Transfer of an FHA loan to an ineligible applicant is considered only when needed as a method for servicing problem cases in which objectives of the original loan cannot be realized but not for providing a means by which members can obtain an equity, and not as a method of providing a source of credit for purchasers. The State Director is authorized to approve a transfer of indebtedness to and assumption of the loan by an applicant who does not meet the eligibility requirements for the kind of loan being assumed when the transferee will make a downpayment of at least 20 percent of the amount of the debt to be assumed and the remaining balance is scheduled for repayment in not to exceed five equal annual installments with interest to the transferee at the rate set forth in Part 1810, Subpart A of this chapter, plus .125 percent at the time of transfer approval and in accordance with the following:

(1) Transferees must have the ability to pay the FHA debt in accordance with the assumption agreement and the legal capacity to enter into the contract. The applicant will submit a complete financial statement using Form FHA 442-12, "Financial Statement," or similar form. This information should be supplemented by a credit report from an independent source such as Dunn and Bradstreet or verified by an independent certified public accountant. When the transferee is a new corporation, consideration will be given to obtaining individual liability agreements from its members.

(2) Form FHA 465-5, "Transfer of Real Estate Security," modified as appropriate, will be executed by the transferee.

(3) This subpart does not preclude the transferor from receiving equity payments when the full amount of the FHA debt is assumed. However, such equity payments will not be made on more favorable terms than those on which the balance of the FHA debt will be paid.

(4) In cases involving transfers to ineligible applicants for the full amount of the FHA debt, the State Director may release the transferor from liability.

(d) *Submission to the national office.* All proposed transfers involving the following will be submitted to the national office for review and approval authorization:

(1) Those to be made on more liberal rates and terms than is set forth in paragraph (c) of this section. There will be no release of liability in connection with transfers involving a repayment period in excess of 5 years.

(2) Those proposing a cash downpayment to the present borrower in an amount which exceeds actual sales expenses.

(3) Water and waste disposal loans representing indebtedness for projects financed in part by FHA development grants.

(e) *Processing transfers.* (1) Form FHA 465-5, will be completed to reflect the agreement between the transferor and the transferee. The form will be prepared so as to show agreements on items such as the prorating of taxes and insurance, title, legal and filing fees, equity and method of payment, and other appropriate items.

(2) The effective date of the transfer will be the actual date the transfer is closed. This is the date on which Form FHA 460-5 or FHA 460-9 is signed. In connection with the use of either form, the unpaid principal balance and the accrued interest will be shown in table 1 and the accrued interest will be computed from Form FHA 451-26, or Form FHA 451-11, "Statement of Account," or Form 451-25, "Status of Account." If Form FHA 460-9 is used, the transferee will be informed of the amount of principal and interest owed as shown on the latest Transaction Record or Statement of Account. He will also be advised as to the amount that would be required to place the account on schedule as of the previous installment due date and any amounts that must be paid to bring any payments up to date. If Form FHA 460-5 is used, he should be advised of the amount needed to be on schedule by the next installment due date.

(3) The transferor will convey title of all assets to the transferee, unless other arrangements are agreed upon by all parties concerned, including FHA.

(4) There must be no lien judgment or other claims of parties other than FHA against the security being transferred unless the transferee is willing to accept such claims and the FHA approving official determines that such claims will not affect the transferee's ability to repay FHA's debt, meet all operating and maintenance costs, and to maintain the required reserves. The written consent of any other lienor will be obtained where required.

(5) The county supervisor will forward the loan docket to the State office including forms and documents listed in instructions available in all FHA offices.

(6) If the transfer is not within the State Director's approval authority, the State Director will forward the loan docket along with his recommendation to OGC for review and comments. Upon receipt of OGC's comments, the State Director will forward the complete file along with his recommendation to the national office. The form, "Report on Association Problem Case (Association-Type Projects)," available in all FHA offices, will be used to record the borrower's present situation and will be forwarded with the docket.

(7) If an insured loan is involved, the Finance Office will have the insured note assigned to the fund when the Assumption Agreement changes the terms of note or bond.

(8) The transferee will obtain insurance in accordance with the requirements for the outstanding loan(s) involved unless the approval official requires additional insurance as a condition of approval. If insurance is required, it may be obtained either by transfer of the existing coverage by the transferor or by acquisition of a new policy by the transferee. When the full amount of the FHA debt is being assumed and an amount

has been advanced for insurance premiums or any other purposes the transfer will not be completed until the Finance Office has charged the advance to the transferor's account.

(9) The parties to the transfer will be responsible for obtaining the legal services necessary to accomplish the transfer. Transfer closing will be accomplished in accordance with OGC's instructions.

(10) When the transferee will be an eligible applicant, any development funds not to be refunded remaining in the transferor's supervised bank account will be transferred to the transferee's supervised bank account simultaneously with the closing of the transfer for use in completing planned development. All funds remaining in the supervised bank account will be refunded to FHA as a condition of transfer to an ineligible applicant.

(f) *Debt assumption or release from personal liability.* In each case where the full amount of the debt is assumed, or a release from personal liability is otherwise approved under this subpart, and all of the security is being transferred, Forms FHA 460-5, FHA 460-9, FHA 451-1, "Receipt for Payment," and FHA 465-8 will be completed and executed simultaneously with the closing of the transaction. The original of Forms FHA 460-5 or FHA 460-9 (including a signed copy for insured loan), Form FHA 451-1 when applicable, and a signed copy of Form FHA 465-8 will be transmitted immediately to the Finance Office. If a loan is involved, Form FHA 440-3, "Record of Actions," also will be sent to the Finance Office.

(g) *Transfer not completed.* If for any reason the transfer is not completed after approval, the Finance Office will be notified to resume servicing the account in the name of the transferor.

§ 1861.86 Voluntary conveyance of security to FHA.

(a) *General.* Voluntary conveyance should be considered only after the borrower has exhausted all reasonable efforts to liquidate the loan either through sale of its property or transfer and assumption.

(1) The State Director, subject to the policies outlined in this paragraph, is authorized to approve a voluntary conveyance with or without release of liability when the present market values of the property to be conveyed to the Government does not exceed $250,000.

(2) The borrower will complete and properly execute Form FHA 465-4, "Offer to Convey Security." A warranty deed using a State-approved form or a deed meeting the requirements of § 1807.2(e)(2) of this chapter and approved by OGC will be required and, whenever possible, completed and signed simultaneously with Form FHA 465-4; however, it will not be recorded until closing of the transaction. Any water rights not fully conveyed in the deed, any necessary assignments or transfers of water stock or membership certificates, or other water right title documents required will be obtained simultaneously with the execution of Form FHA 465-4 whenever possible, and in no case later than the closing of the transaction. Proposed bill of sale listing personal property items will be included.

(3) When the borrower's offer provides for less than full satisfaction of the account but is equal to the present market value of the security less any liens that are to remain outstanding, the State Director may accept the offer subject to the conditions outlined in Form FHA 465-4. If the offer provides for full satisfaction of all FHA debts, it may be accepted provided the value of the security less any liens to remain outstanding is sufficient to satisfy the FHA debt. If the offer to convey in full satisfaction of FHA debts is not acceptable, it will be returned to the county supervisor who will attempt to obtain an offer which will convey the security for its value as determined by the FHA.

(4) When an insured loan not held by the insurance fund is involved and the State Director decides to accept the offer to convey, he will request the Director, Finance Office, to have the insured loan assigned to the Agriculture Credit Insurance Fund (ACIF).

(5) Any funds remaining in the borrower's debt service, reserve or operation and maintenance accounts will be paid to FHA prior to closing the conveyance.

(6) Any funds remaining in the supervised bank account will be applied as a refund prior to assembling the voluntary conveyance docket.

(7) When a prior lien(s) exists, such lien(s) will be paid by standard Form 1034 only if it is determined that a substantially greater recovery on the Government's investment can be obtained from the sale of the real estate without the lien(s) than could be otherwise obtained, or the property is suitable for sale to an eligible applicant subject to the terms of the prior lien(s) and the holder of the prior lien(s), where his permission is necessary, will not agree for the Government to acquire the property and resell it subject to his lien(s). If the property is acquired subject to prior lien(s), any required payments on the prior lien(s) may be made while title of the property is held by the Government. All junior liens on the property except taxes and assessments which are or will become a lien on the property must be satisfied by the borrower without FHA assistance, unless in special circumstances it is clearly advantageous to FHA to make advances for the payment of such liens.

(b) *Release of liability.* Release of liability will be in accordance with the following:

(1) When the present market value of the security being conveyed less the amount of the prior lien(s) is equal to or exceeds the total FHA debt, it will be the policy to release the borrower from liability.

(2) When the present market value of the security is less than the total FHA debt, the State Director will determine whether the borrower is to be released from liability. This determination will be based upon the reasonable debt-paying ability of the borrower and recommendation of the county committee. In arriving at a determination of the reasonable debt-paying ability of the borrower, the State Director will consider its assets and income at the time of the proposed conveyance. If the county committee recommends a release of liability, a recommendation similar to the following will be recorded on Form FHA 440-2 in the blank space after item No. 10:

In our opinion (Name of Borrower(s)) has no reasonable debt-paying ability taking into consideration its assets and income at the time of the conveyance. The borrower has cooperated in good faith, used due diligence to maintain the security property against loss, and otherwise fulfilled the covenants incident to the loan to the best of its ability. Therefore, we recommend that the borrower be released from personal liability for any balance due on the secured indebtedness upon conveyance of the property to the Government.

(c) *Processing*—(1) *Docket submission.* When the State Director determines that voluntary conveyance to FHA is appropriate, he will instruct the county supervisor to assemble a voluntary conveyance docket and submit it to the State office along with the borrower's county office case folder(s).

(2) *Amount.* If the amount to be conveyed is more than $250,000, the voluntary conveyance docket and other pertinent information along with the State Director's recommendation will be submitted to the national office for review and authorization to approve.

(3) *Voluntary conveyance docket.* The voluntary conveyance docket will include the forms and documents listed in instructions available in all FHA offices.

(4) *Taxes.* When Form FHA 465-4 is submitted to the State Director, standard Form 1034 will be attached thereto for the payment of any taxes and assessments which are a lien or will become a lien on the property, or water assessments, or charges to protect the right to receive water, which are due and payable and which the borrower is not required to pay by the terms of Form FHA 465-4.

(5) *Title examination and closing instructions.* When a decision to accept the borrower's offer is made, title examination will be accomplished in accordance with advice of OGC. Title defects and encumbrances will be removed by the borrower except those recited in the FHA mortgage or subsequently approved by the FHA. When title defects and encumbrances have been removed, the voluntary conveyance docket including the title examination information will be submitted to OGC for review and issuance of closing instructions. The State Director's transmittal memorandum will include information as to items of expense incident to conveyance of title which have been paid by the FHA but are not shown on the statement of account, items of expense which are to be paid by the FHA, a statement as to whether the account is to be fully satisfied, and a request for preparation of

necessary legal instruments not required to be prepared by the borrower's attorney.

(6) *Closing of conveyance.* The conveyance transaction will be closed in accordance with closing instructions issued by OGC. Expenses incident to closing the transaction to be paid by FHA will be handled in accordance with prescribed requirements. After the transaction is closed, all appropriate items will be returned to OGC for review. After OGC determines that the transaction has been properly closed, all documents will be returned to the State Director together with the advice as to the date when title to the properly was vested in the Government. A copy of OGC's memorandum to the State Director will be forwarded to the Finance Office. Property insurance will be handled in accordance with § 1806.4(b) (3) of this chapter. All other insurance such as personal liability or workmen's compensation will be canceled. Ordinarily, the fidelity bond coverage will also be dropped. However, in individual cases such as when a caretaker will continue to operate the facility and will be handling a substantial amount of revenue, the State Director may require continuance of fidelity bond coverage.

(7) *Credit of value of property on indebtedness.* The credit to be allowed on the account will be either the value of the security to be conveyed less the amount of any prior liens as determined by a present market value appraisal, or the total amount of the indebtedness owed on the account after all expense items referred to in subparagraph (6) of this paragraph have been charged thereto, whichever is less. After the transaction is closed and the amount of the credit to be allowed on the account is determined by the State Director, Form FHA 465-6, "Advice of Mortgaged Real Estate Acquired," and where applicable, Form FHA 465-8 will be completed and transmitted to the Finance Office by the State Director. The county supervisor will inventory and appraise personal property and submit list of items to the Finance Office.

(8) *Satisfied account.* The Finance Office will stamp the borrower's note "satisfied by surrender of security and release from liability" when the account is fully satisfied or the borrower is released from personal liability for any deficiency. The Finance Office will forward the stamped note to the county supervisor for delivery to the borrower.

(9) *Unsatisfied account.* When the account is not fully satisfied by surrender of the security and the borrower is not released from personal liability, the State Director will reclassify the account as collection-only by submitting Forms FHA 404-1, "Case Reclassification," FHA 450-10, "Advice of Borrower's Change of Address or Name," and FHA 465-6 to the Finance Office. He will accelerate the unpaid indebtedness by written notice to the borrower with a copy to the Finance Office. The Finance Office will retain the note(s) and send the county office a current Form FHA 451-11. Upon receipt of Form FHA 451-11, the county supervisor will reconcile the loan record card with the statement of account and service the loan as collection-only in accordance with Subpart A of this part.

§ 1861.87 Foreclosure.

Foreclosure action will be initiated when liquidation has been decided upon and all reasonable attempts to liquidate the loan through voluntary sale, transfer, or voluntary conveyance have been exhausted, and a substantial net recovery can be obtained on the FHA account(s).

(a) *National office authorization.* Foreclosure will not be initiated without prior authorization of the national office. The State Director will forward the docket, a report completed in accordance with the form, "Report on Association Problem Case (Association-Type Projects)," a statement of essential facts, and his recommendation to the national office requesting authority to proceed with foreclosure.

(b) *Processing foreclosure.* Upon receipt of national office authorization, the State Director will forward the docket to OGC requesting necessary instructions. The State Director, with the assistance of OGC, will be guided by the following:

(1) *Prior lienholders.* Prior lienholders will be provided an opportunity to institute the foreclosure proceedings with the FHA taking the action necessary to protect the interest of the Government. If the prior lienholder is unable or unwilling to foreclose, FHA will institute foreclosure proceedings, subject to the prior lien. Whether foreclosure of the FHA mortgage will be subject to the prior lien will depend upon such factors as the State law, the action or inaction of the prior lienholder, the condition of the prior lien account, and the amount of the prior lien debt in relation to the FHA debt. When a prior lien foreclosure sale is to be held, the State Director will immediately forward the docket, a copy of the OGC's opinion, a statement of all facts essential to a decision, and his recommendations to the national office for a review and advice as to further handling.

(2) *Existing leases or other agreements.* If the foreclosure is made subject to a lease or other agreement in which the lessor's interest is acquired by FHA through the foreclosure sale, the original or a copy of the lease will be submitted to the Finance Office along with Form FHA 465-6 for processing. Any oral lease in effect at the time the Government acquires the property will be reduced to writing in a form approved by the State Director with the concurrence of OGC, and its execution by the lessee will be obtained if possible. The lessee will be notified in writing that the Government has acquired the lessor's rights under the lease and directed to remit all payments to the county office. Payments to FHA under a lease which by its terms were due and payable prior to the date of the foreclosure sale will be applied first on any deficiency claim resulting from the foreclosure and then on any other FHA claim against the borrower. Any surplus remaining will be remitted to the borrower. Payments due and payable to the FHA after the date of acquisition pursuant to foreclosure will be collected and forwarded to the Finance Office as miscellaneous income. Receipts for collection made in accordance with this paragraph will be issued to: "Lease proceeds from property formerly owned by (borrower's name and case number) and leased to (name of lessee)." After a foreclosure sale is held, if a redemption period is involved and the borrower has possession of the property during such period or a right to lease proceeds during the redemption period, a lease will not be obtained by the Government or be sent to the Finance Office until the redemption period has expired and the Government has a right to such proceeds.

(3) *FHA debt acceleration.* Unpaid FHA debts will be accelerated unless OGC advises such action is unnecessary. Form FHA 455-21, "Notice for Acceleration and Demand for Payment," may be used as a guide for preparing the notice. After issuance of the acceleration notice, account and security servicing actions, including payment of insurance and taxes, debt acceleration will be taken only with the advice of OGC. Expenses incident to the foreclosure action which are approved by OGC for payment by FHA will be paid in accordance with prescribed requirements available in all FHA offices. If the OGC advises that a credit to the borrower's account or a standard form 1034 will not be acceptable for payment of the FHA bid, the State Director will obtain a check from the Finance Office for making the payment. Standard Form 1034 will be used for this purpose.

(4) *Obtaining notes from Finance Office.* For a direct loan or an insured loan held in ACIF, the State Director will request the Finance Office to send the original or conformed copy of the note to the county office. For an insured loan not held in ACIF, the State Director will request the Finance Office to have the loan assigned to the ACIF in accordance with Part 1873 of this chapter, and provide him with the original or conformed copy of the note.

(5) *Certified statements of account.* Form FHA 451-10, "Request for Statement of Account," will be forwarded to the Finance Office to obtain a statement of account for each account to be included in the foreclosure and to request the Finance Office not to issue any statements of account to the borrower until further notice.

(6) *Funds remaining in supervised bank account.* The State Director will prepare an order to the appropriate bank for withdrawal of any funds remaining in the supervised bank account. These funds will be applied as an extra payment.

(7) *Title evidence.* OGC will inform the State Director regarding title evidence requirements.

(8) *Title defects.* Ordinarily, no curative action will be taken with respect to title defects before foreclosure sale. However, where for special reason the State

Director, with the advice of OGC, determines it would be in the best interest of FHA to cure certain defects before the foreclosure sale, the State Director may authorize the necessary curative action.

(9) *Deficiency judgments*. If it appears that the recovery to FHA from a sale by foreclosure will be insufficient to fully satisfy the FHA debt, the foreclosure action does not automatically result in a deficiency judgment, and if there are other assets from which recovery can likely be made, a deficiency judgment will be obtained if legally permissible. When a judgment is obtained, the account will be classified as a judgment case and the county supervisor will send Form FHA 455-20, "Notice of Judgment," to the Finance Office and the account will be serviced in accordance with § 1871.35(d) of this chapter. When action to obtain a deficiency judgment is pending at the time Form FHA 465-6 is sent to the Finance Office, the fact that it is pending will be indicated on Form FHA 465-6. When a deficiency judgment is not obtained, the borrower will be classified as collection-only, if appropriate, and Forms FHA 404-1 and FHA 450-10 will be sent immediately to the Finance Office and the account will be serviced accordingly.

(10) *Bidding*. The State Director will establish the maximum amount of the FHA bid and he or an employee designated by him is authorized to bid on behalf of the FHA. The FHA employee will make only one bid which will be for the authorized maximum bid. Such bid will be the estimated resale value of the security or gross investment, whichever is less.

(i) The estimated resale value means the amount for which the FHA could expect to resell the property in its present condition, on terms of 20 percent down with the balance payable in five equal annual installments with interest calculated in accordance with § 1861.85(c) and subject to any prior liens that will remain outstanding after the foreclosure sale. In establishing the estimated resale value, the State Director will consider the effect that any outstanding mineral rights, easements, other interest, or title defects will have on the resale of the property, and any other pertinent information affecting or indicating the resale price including an appraisal report showing present market value.

(ii) Gross investment means the total amount of the FHA debt plus all advances to be made by the FHA and charged to the mortgage debt before the foreclosure sale, plus the amount of any prior liens or other costs which the OGC advises must be paid from proceeds of the foreclosure sale.

(11) *Report on sale*. Immediately after a foreclosure sale the State Director will furnish OGC a report giving complete information relative to the sale, including a copy of Form FHA 465-6. The OGC will provide a final opinion regarding the foreclosure including any necessary additional instructions. If the FHA is the successful bidder at the foreclosure sale, Form FHA 465-6 will be completed and forwarded to the Finance Office by the county supervisor as soon as all information necessary for completion of the form is available without waiting for the final opinion of OGC. The Finance Office will be advised by memorandum of the date the Government actually acquires title to the property if different from the date of the foreclosure sale and any other pertinent information relating to redemption rights. The form will be dated the date of the sale.

(12) *Cancellation of foreclosure action*. When the State Director determines that foreclosure is unnecessary, he with the concurrence of OGC will notify the Finance Office and the county supervisor. The loan account will be reinstated. Any expenses incurred prior to cancellation of foreclosure action will be paid by the borrower.

(13) *Additional information*. The county supervisor will complete Form FHA 455-22, "Information for Litigation," as additional information when legal action is recommended which will involve the U.S. Attorney.

§ 1861.88 Mergers.

(a) *General*. State Directors are authorized to approve mergers or consolidations (which are herein referred to as mergers) when the resulting association will be eligible for an FHA loan and assumes all liabilities and acquires all assets of the merged borrowers. Mergers may be accomplished when:

(1) The merger is in the best interest of the Government and the merging borrower.

(2) The resulting borrower can meet all required operating and maintenance expenses, debt repayment, and maintain required reserves.

(3) All security property can be legally transferred to the resulting borrower.

(4) The membership of each organization involved is made aware of the proposed merger and a majority of the members of each is in favor of the proposal.

(5) If the merger involves assumption of less than the full amount of the debt and the merging borrower (transferor) is to be released of liability, the county committee recommendation must contain the statement contained in § 1861.85 (b)(6)(iii).

(6) The merger will not result in an outstanding FHA debt in excess of $4 million less the amount of any grants advanced to the merging borrowers.

(b) *Partial assumption*. Mergers which will involve assumption of less than the full amount of the FHA debt will be submitted to the national office along with the loan docket, comments of the OGC, and the State Director's recommendations for review and approval authorization.

(c) *Release of liability*. When all of the assets and liabilities of a merged borrower have been assumed by the resulting body, it will be the policy to release the merged borrower from liability.

(d) *Processing*. (1) When reamortization of one or more notes is being proposed in connection with the merger, § 1861.82 (f) will be followed.

(2) Forms FHA 460-5 and 460-9 will be executed as applicable by the resulting body.

(3) A loan for which the resulting body is eligible may be made in connection with a merger subject to the policies and procedures governing the kind of loan being made.

(4) The closing date of the merger will be the actual date the documents are prepared and the merger is effective.

(5) The county supervisor will submit the county office docket and other necessary forms and documents to the State Director for approval.

(e) *Insured loan*. If an insured loan is involved, the Finance Office will have the insured note assigned to the ACIF if the assumption agreement will change the terms of the note.

(f) *Merger not completed*. If for any reason the merger is not completed after the statement of the account has been received, the Finance Office will be notified to resume servicing the account in the names of the existing borrowers.

§ 1861.89 Special provisions applicable to Economic Opportunity (EO) cooperative loans.

(a) *Withdrawal of member and transfer to and assumption by new members of unincorporated cooperatives*. (1) Withdrawal of a member who is no longer utilizing the services of an association and transfer of his interest in the association to a new member who will assume the entire unpaid balance of the indebtedness of the withdrawing member may be permitted, provided the remaining members agree to accept the new member, and the transfer will not adversely affect the collection of the loan. The county supervisor will submit to the State office the county office file and the following:

(i) Form FHA 460-9, executed by the proposed new member.

(ii) County supervisor's statement of the current amount of the indebtedness involved.

(iii) A description and statement of the value of the security property.

(iv) Form FHA 442-15, "Membership Survey for Cooperative Association," for the proposed new member.

(v) A memorandum to justify the transaction.

(vi) Form FHA 440-2.

(vii) Form FHA 450-12, "Bill of Sale (Transfer by Withdrawing Member)," executed by the withdrawing member.

(viii) The form, "Agreement for New Member (With or Without Withdrawing Member)," as executed by the remaining members of the association, the proposed new member and the withdrawing member.

(2) If after review of the above information the State Director determines that the proposed new member is an eligible applicant and that there is justification for the transfer, he may approve the transfer and assumption by executing Form FHA 460-9.

(3) Upon completion of the above actions, the State Director may release the outgoing member from personal liability.

Form FHA 465-8 will be used for this purpose.

(4) Form FHA 460-9 and if applicable, Form FHA 465-8 should be forwarded immediately to the Finance Office by memorandum with the advice that these forms are intended only to establish liability for a new member and to release an old member from liability.

(b) *Withdrawal of members from unincorporated cooperatives*—(1) *Withdrawal when new member not available.* Withdrawal of a member who is no longer utilizing the services of an association may be permitted even though a new member is not available, provided:

(i) The State Director determines that:

(*a*) The remaining members have sufficient need for the property, and

(*b*) The withdrawal of the member will not adversely affect the collection of the loan.

(ii) The remaining members obtain from the outgoing member an agreement conveying the outgoing member's interest in the cooperative property to them. They may also wish to agree to protect the outgoing member against liability on the debt owed to FHA as well as any other debts. The form, "Agreement for Withdrawal of Member (Without New Member)," available in all FHA offices, may be used by the cooperative for the preparation of such agreement. The agreement will be between the withdrawing member and the remaining members of the cooperative, and FHA will not be a party to it. Upon execution of such an agreement, the State Director may release the outgoing member from personal liability. Form FHA 465-8 will be used for this purpose.

(iii) Form FHA 465-8 should be forwarded immediately to the Finance Office by memorandum with the advice that the form is intended only to release a withdrawing member from liability.

(c) *Addition of new members (no withdrawing member or transfer involved) for both incorporated and unincorporated cooperatives.* (1) A new member may be admitted to the association even though there is no withdrawing member, provided:

(i) The members of the association agree to accept the proposed new member, and

(ii) The State Director determines that the association owns adequate facilities to provide service to the new member.

(2) The county supervisor will submit to the State office the county office file and the following:

(i) Form FHA 460-9 executed by the proposed new member.

(ii) County supervisor's statement of the current amount of the indebtedness involved.

(iii) A description and statement of the value of the security property.

(iv) Form FHA 442-15 for the proposed new member.

(v) A memorandum to justify the transaction.

(vi) Form FHA 440-2.

(vii) The form, "Agreement for New Member (With or Without Withdrawing Member)," available in all FHA offices, as executed by the members of the association and the proposed new member.

(3) If after review of the above information the State Director determines that the proposed new member is an eligible applicant and that there is justification for the transaction, he may approve the transaction by executing Form FHA 460-9.

(4) Form FHA 460-9 should be forwarded immediately to the Finance Office by memorandum with the advice that the form is intended only to establish liability for a new member.

(d) *Deceased members of unincorporated associations.* Paragraph 10 of Form FHA 442-24, "Operating Agreement," provides that in case of the death of any member, the heirs or personal representative of the deceased member shall take his place in the association; this provision also covers sale of the decedent's interest in the association in case such sale is necessary for the payment of the debts of the estate.

(1) If the widow or other heirs do not wish to continue membership in the association, the remaining members may be permitted to continue to operate the property provided it is determined that FHA's financial interest will not be jeopardized. The remaining members should obtain from the deceased member's estate an agreement conveying the estate's interest in the cooperative property to them. They may wish to agree to protect the estate against liability on the debt to FHA as well as any other debts of the cooperative. If an agreement is obtained transferring the estate's interest in the cooperative property to the remaining members, and if such agreement protects the estate against liability on the debt to FHA, the State Director may release the outgoing member from personal liability. Form FHA 465-8 will be used for this purpose and should be forwarded immediately to the Finance Office by memorandum with the advice that the form is intended only to release the deceased member's estate interest from liability.

(2) The requirement of § 1871.39(f) of this chapter will be followed.

(e) *Action which affects individual members of unincorporated EO cooperative security.* The borrower will be expected to protect his own interest in condemnation, trespass, quiet title, and other cases affecting the security. The county supervisor will immediately furnish the complete facts concerning any action taken against individual members of unincorporated cooperatives to the State Director together with the county office case file.

§ 1861.90 Care, management, and disposal of acquired property.

Property acquired by FHA will be handled in accordance with Subpart C of Part 1872 of this chapter.

§ 1861.91 Water and waste disposal systems which have become part of an urban area.

(a) Water and/or waste disposal systems serving what were formerly rural areas but have now become a part of an urban area due to the growth of an urban community will be serviced as follows:

(1) If it is not practical for the urban community to immediately purchase the facility by paying FHA's debt in full or accept a transfer of the debt on an ineligible applicant basis, and if both the borrower and the urban community desire that the urban community operate and maintain the borrower facilities, the FHA borrower may, with prior approval of the national office, enter into a lease-purchase type arrangement with the urban community which will include:

(i) The urban community agreeing to:

(*a*) Assume responsibility for operation and maintenance of the facility, subject to nondiscrimination requirements and other requirements, to be specified in the agreement between the parties, which are applicable to the borrower, and

(*b*) Pay the association annually an amount necessary to enable it to meet all its obligations including reserve account requirements.

(ii) The FHA borrower agreeing to:

(*a*) Retain its corporate existence until FHA has been paid in full, and if the parties desire;

(*b*) Convey title of the facility to the urban community when the FHA debt has been paid in full.

(2) The State Director, with advice and guidance of OGC, will review the proposed agreement drafted by the borrower or the urban community. This draft agreement with the docket, any additional pertinent information, the State Director's recommendation, and OGC's comments will be forwarded to the national office for review and approval authorization.

§ 1861.92 Determining present market value.

(a) The value of security to be subordinated, sold, transferred, voluntarily conveyed, or foreclosed under this subpart will be determined by the State Director as follows:

(1) Where real estate and/or chattels are being disposed of which represent a relatively small portion of the total value of the security property, the State Director will determine that they are being disposed of at a reasonable price. He may require a current appraisal report.

(2) Where real estate or chattels are being disposed of represent a relatively large portion of the total value of the security property, the sale price will be at least the present market value.

(3) The State Director will require a current appraisal report completed in accordance with Subpart A of Part 1809 of this chapter.

§ 1861.93 Development grants.

In any case where it appears that the terms of the grant agreement may have been violated, the State Director will forward the docket to OGC for review and comments. After receipt of OGC's comments, the State Director will forward the docket, a copy of OGC's comments, and a statement of essential facts along with his recommendations to the national office.

§ 1861.94 Comprehensive planning grants.

Servicing problems with comprehensive planning grant recipients will be reviewed by the State Director with advice of OGC. The State Director will forward the grant docket, a copy of OGC's comments, and a statement of essential facts along with his recommendations to the national office.

§ 1861.95 Servicing planning advances.

Obligations incurred by recipients of planning advances may be declared nonreimbursable by the Administrator when the planned facility is not to be constructed, and the borrower does not have, nor can be reasonably expected to raise, the funds to repay such advances. In such cases the State Director will forward to the national office the following:

(a) A statement of essential facts including reasons why the borrower cannot repay the advance and his recommendation regarding declaration of all or part of the advance as nonreimbursable, and

(1) In the case involving the failure to locate an adequate water supply, copies of all well logs, survey reports, and other pertinent material supporting his recommendation, or

(2) In the case where the advance was based on particularly distressed economic conditions, the loan docket will be submitted. No commitment will be made to the borrower concerning cancellation of any obligations until written authorization has been received from the national office.

(b) In all cases where advances are not paid in full, plans, reports, well logs, and all other data assembled during investigation financed by the advance will be delivered to the county supervisor by the borrower.

§ 1861.96 Additional State Director's authorizations.

(a) State Directors are authorized to perform the following functions when they determine that such action likely will promote the loan or grant purposes without jeopardizing collectability of the loan or impairing the adequacy of the security, or will strengthen the security, or will facilitate, improve, or maintain the orderly collectability of the loan:

(1) Approve requests for permission to make changes in rules and regulations of associations, whether included in bylaws or resolutions or ordinances, including changes in rate schedules and fees.

(2) Approve association incurring additional indebtedness.

(3) Renew existing security instruments.

(4) Approve, with the concurrence of OGC, changes in a borrower's legal organization including revisions of articles of incorporation or charter and bylaws.

(5) Approve the extension or expansion of facilities and services.

(6) Require additional security when existing security is inadequate and the loan or security instruments obligate the borrower to give additional security, or in cases where the loan is in default and additional security is acceptable in lieu of other servicing actions.

(7) Release from mortgages securing Rural Renewal (RN) loan properties being sold by the borrower, provided the notes and mortgages given by the purchaser to the borrower are equal to the present market value and are assigned and pledged to the FHA and any money payable to the borrower is applied as an extra payment on the RN loan.

(b) All proposed servicing actions which the State Director is not authorized by this subpart to approve will be referred to the national office.

§ 1861.97 Payment in full.

Payment in full of a loan will be handled in accordance with Part 1866 of this chapter. The county supervisor will notify the bonding company in writing that the Government no longer has an interest in the fidelity bond and will release the FHA's interest in insurance policies in accordance with the applicable provisions of Part 1806 of this chapter. The county supervisor will release the FHA's interest in any other security in the manner prescribed by the State Director.

§ 1861.98 State requirements.

State requirements will be prepared with the advice and guidance of OGC, as necessary, to carry out this subpart. Each State requirement will include any and all particular information necessary to comply with appropriate State laws and regulations.

§ 1861.99 Redelegation of authority.

The State Director is authorized to redelegate in writing to the chief, community programs any authority to the State Director in this subpart.

§ 1861.100 Reports and recommendations.

Reports for association problem cases referred to in this subpart on certain forms available in all FHA offices, may have to be modified to provide for corporate execution, if appropriate, rather than the individual execution for which they were designed.

§ 1861.101 Servicing public bodies.

Servicing actions involving public bodies will be processed insofar as feasible in accordance with the other provisions of this subpart. The State Director is authorized to vary from such provisions to any extent that he with the advice and concurrence of OGC, determines reasonably appropriate to accomplish the servicing action.

Dated: March 31, 1972.

JOSEPH HASPRAY,
Deputy Administrator,
Farmers Home Administration.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1]

NUTRITION LABELING

Proposed Criteria for Food Label Information Panel

Correction

In F.R. Doc. 72-4948 appearing at page 6493 in the issue of Thursday, March 30, 1972, in § 1.16(a) the word "must" in the second line should read "may".

[21 CFR Part 121]

AMINO ACIDS IN FOOD FOR HUMAN CONSUMPTION

Proposed Conditions of Safe Use in Food and Deletion From GRAS List

The Food and Drug Administration is conducting a comprehensive study of the individual substances listed in § 121.101 *Substances that are generally recognized as safe* of the food additive regulations (21 CFR 121.101).

In the FEDERAL REGISTER of June 25, 1971 (36 F.R. 12093), criteria were promulgated by which substances henceforth are to be judged for possible classification as generally recognized as safe (GRAS). Section 121.3(c) thereof provides that substances intended for human consumption for which limitations are necessary to assure safe use are not eligible for GRAS status. Accordingly, such substances must be removed from the existing GRAS list (21 CFR 121.101).

A number of amino acids are listed in § 121.101(d)(5) under "Nutrients and/or Dietary Supplements" as GRAS without further limitation. As provided in § 121.3(b), the mere natural presence of an amino acid in unprocessed foods in free or combined (as protein) form does not qualify it as safe for addition in a pure form as a component of a formulated or processed food. A risk to health exists when a free amino acid produces toxic or other adverse effects. A potential risk to health also exists when a free amino acid is added at a level that produces an "unbalanced" protein (one used inefficiently for growth), or that produces an amino acid-imbalanced diet, which affects the body's quantitative need for an amino acid.

Experimental animal studies have shown that the adverse effects of these imbalances are suboptimal food intake, growth retardation, and degeneration of certain organs which can lead to the animal's early death. Excessive intakes of most of the nutritionally essential amino acids (for example, histidine and methionine) and several of the nutritionally nonessential amino acids (for example, tyrosine and glycine) will produce undesirable biochemical and pathological effects in animals. This indicates a potential health risk for man if use is not limited.

The individual amino acids in whole egg protein are in such quantity and proportion that they comprise an ideal pattern for high quality protein. The content of a specific amino acid in this protein is exceptionally uniform when expressed as percent of the protein. It is therefore reasonable to conclude that the limit for safe addition of an amino acid to a food should be the difference between the amount of that amino acid present in whole egg protein (expressed as the percent of the total protein) and the amount present in the original protein to which the amino is being added. It is reasonable to conclude also that such addition of one or more amino acids is justifiable only to provide significant improvement in the nutritional quality of the original protein.

Accordingly, the Commissioner of Food and Drugs concludes:

(1) That the amino acids for nutritive purposes listed in § 121.101(d)(5) for human use should be revoked,

(2) That since the D-forms of these amino acids (except for methionine) are not metabolized as efficiently as the L-forms and the conversion of the D- to the L-form takes place only to a limited extent in the body, the safety of the D-forms is uncertain, thus limiting positive action to the L-forms (except for methionine);

(3) That a new food additive regulation ($121.1002 proposed below) should be established prescribing limitations for the safe and nutritionally significant use in human food of amino acids of specified stereochemical configuration for nutritive purposes only;

(4) That the addition of amino acids for nutritive purposes should be limited to those situations where the original protein has a protein efficiency ratio (PER) of less than 2.50, the addition of the additive(s) results in a PER of 2.50 or more for the finished food, and each individual additive included results in an increase of 0.25 or more in the PER;

(5) That exceptions can be made to the requirement of a PER of 2.50 or more for the finished food proposed in paragraph (c)(3) of § 121.1002. The Food and Drug Administration will consider petitions submitted by any interested person requesting this exception. Such petitions must include scientific data which establish the specific nutritional value (relative to human requirements) of protein in finished foods with PER values of less than 2.50 in which the biological quality of the original protein has been improved by adding an amino acid(s) in accord with all the other provisions of the proposed section.

(6) That, in lieu of requiring specific food additive approval for each use of an amino acid proposed below in order to show that it will significantly improve the biological quality of the protein, § 121.1002 should provide that it will be sufficient for the necessary test information to be retained in the user's files and to be made available upon request by representatives of FDA;

(7) That individual uses of the same or other amino acids for technological purposes other than nutritive will be authorized only by separate actions based on food additive petitions submitted to FDA; and

(8) That this action does not cover the inclusion of amino acids in foods which do not contain original intact protein; such uses will be the subject of separate actions.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409(d), 701(a), 52 Stat. 1055, 72 Stat. 1784, 1787; 21 U.S.C. 321(s), 348(d), 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 121 be amended:

1. By revoking from § 121.101(d)(5) all amino acids for use in food for humans.

2. By adding to Subpart D a new section as follows:

§ 121.1002 Amino acids.

The food additive amino acids may be safely added as nutrients to intact protein-containing foods that are considered significant dietary protein sources in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrochloride salt, hydrated, or anhydrous form:

L-Alanine.
L-Arginine.
L-Aspartic acid.
L-Cysteine.
L-Cystine.
L-Glutamic acid.
Glycine.
L-Histidine.
L-Isoleucine.
L-Leucine.
L-Lysine.
DL-Methionine.
L-Methionine.
L-Phenylalanine.
L-Proline.
L-Serine.
L-Threonine.
L-Tryptophan.
L-Tyrosine.
L-Valine.

(b) The food additive meets the following specifications:

(1) As found in "Food Chemicals Codex," National Academy of Sciences-National Research Council (NAS-NRC) Publication No. 1406, First Edition (1966), and supplements thereto for the following:

L-Cystine.
L-Glutamic acid.
Glycine.
L-Leucine.
L-Lysine.
DL-Methionine.
L-Methionine.
L-Tyrosine.

(2) As found in "Specifications and Criteria for Biochemical Compounds," NAS-NRC Publication No. 1344, Second Edition (1967), for the following:

L-Alanine.
L-Arginine.
L-Aspartic acid.
L-Cysteine.
L-Histidine.
L-Isoleucine.
L-Phenylalanine.
L-Proline.
L-Serine.
L-Threonine.
L-Tryptophan.
L-Valine.

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the original protein in intact protein-containing foods that are considered significant dietary protein sources, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of intact protein (based upon 10 percent of the daily allowance for the "reference" adult male recommended by the Food and Nutrition Board of the NAS-NRC ("Recommended Dietary Allowances," NAS-NRC Publication No. 1694, Seventh Edition (1968)).

(2) The original protein has a protein efficiency ratio (PER) of less than 2.50 (as determined by the method specified in paragraph (d) of this section).

(3) The additive(s) results in a PER of 2.50 or more for the finished food (as determined by the method specified in paragraph (d) of this section), unless an exception to this limitation has been authorized based on adequate data submitted in a petition. The Food and Drug Administration will consider petitions submitted by any interested person requesting such exceptions. Petitions must include scientific data establishing the specific nutritional value (relative to human requirements) of protein in finished foods with PER values of less than 2.50 in which the biological quality of the original protein has been improved by the addition of an amino acid(s) in accord with all of the other provisions of this section. When exceptions are granted, this section will be amended to indicate the approved exemptions from this limitation.

(4) Each additive results individually in an increase of 0.25 or more in the PER (as determined by the method described in paragraph (d) of this section). This increase must be substantiated by a statistically significant difference of at least a probability (P) value of less than 0.05.

(5) The amount of the additive added plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine	6.1
L-Arginine	6.6
L-Aspartic acid	7.0
L-Cystine (including L-cysteine)	2.3
L-Glutamic acid	12.4
Glycine	3.5
L-Histidine	2.4
L-Isoleucine	6.6
L-Leucine	8.8
L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 39.166–39.170, "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Edition, 1970, if applicable, or if not applicable, then by appropriate animal feeding tests. If more than one amino acid is added, it will be necessary that the tests be designed to demonstrate that each added amino acid is required to significantly improve the biological quality of the protein as described in paragraph (c) of this section. Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain, throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health, Education, or Welfare and shall permit such officer or employee to inspect and copy such records and to make such inventories of stock as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The name of the amino acid(s) contained therein, including the specific optical and chemical forms.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: March 28, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

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[21 CFR Part 130]

METHADONE

Proposed Special Requirements for Use

Methadone has been under investigation for use in the maintenance treatment of narcotic addicts for approximately 9 years. For the past 2 years, interest in this use has grown steadily and intensely. In the FEDERAL REGISTER of April 2, 1971 (36 F.R. 6075), the Food and Drug Administration published § 130.44 (21 CFR 130.44) which established guidelines for investigating the use of methadone in maintenance treatment, for assuring the availability of valid data on such use, and for protecting the community from the hazards of diversion and abuse of methadone. These guidelines were developed in cooperation with the National Institute of Mental Health (NIMH) and the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Justice. To date the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs have approved a substantial number of individual treatment units for use of methadone in treating addiction.

In addition to being used for investigational purposes, methadone has been prescribed by individual physicians and has been dispensed in medical institutions both for heroin detoxification and for maintenance therapy. It is not possible to determine how widespread the use of methadone for maintenance therapy has been outside investigational new drug plans, but there is evidence that this use is substantial.

The Food and Drug Administration, in cooperation with the National Institute of Mental Health and the Special Action Office for Drug Abuse Prevention, is undertaking an intensive inspection program to ascertain that existing programs operating under investigational new drug status (IND) meet the requirements of § 130.44. Within the immediate future, each program will be visited by an inspection team. Programs will be allowed to continue to operate if they meet the existing requirements of § 130.44. However, in addition, the proposed special requirements contained in this notice are being encompassed by the inspection in anticipation of improved requirements to be in effect in the future. To reduce the potential for diversion and misuses methadone is also being withdrawn systematically from pharmacies that are not dispensing it solely as part of approved treatment programs using methadone.

The use of methadone presents difficult and unique questions of medical judgment, law enforcement, and public policy that have not previously been encountered with other new drugs. Methadone presently represents the only drug for which there is substantial evidence of effectiveness in the treatment of heroin addiction. Although the short-term use of the drug has been shown to be relatively safe from a toxicity standpoint, more information is necessary on the toxicity of long-term use. Balancing the benefits against the risks, the Food and Drug Administration and numerous professional groups, advisory committees, and experts with whom it has consulted have concluded that the drug should be made available for all addicts who consent to use it in approved treatment programs. Retention of the drug solely on an investigational status appears to be no longer warranted.

At the same time, concern has been expressed that the usual form of NDA (new drug application) approval could lead to greater diversion or misuse of the drug, since it permits unrestricted distribution and allows physicians to use wide discretion in prescribing the drug. It has been suggested that the investigational status of the drug should be retained both to obtain additional toxicity data and as a control mechanism, at least until greater experience is obtained in reducing the potential dangers of diversion and medical misuse. The FDA recognizes these dangers and agrees that strong control must be maintained over the distribution and use of the drug. Since it is an opiod the potential for abuse is greater than for other drugs permitted for widespread medical use. The Food and Drug Administration could not conclude that it is safe if it cannot be properly controlled and would be required to disapprove its use. Some diversion and misuse will inevitably result from the availability of any drug, but it is particularly important that strong controls be available for methadone because of its known addicting potential. Finally, some have pointed out that it is premature to move completely from IND to NDA status because more information has yet to be obtained. The Commissioner concurs that unlimited approval of an NDA for methadone would not be appropriate at this time.

To provide the strongest possible control over the distribution and use of methadone, the Commissioner has concluded that both the IND and NDA control mechanisms should be utilized together with the authority granted under the Comprehensive Drug Abuse Control Act of 1970. Like an NDA, the drug will be available for treatment in all cases where there is medical justification. Like an IND controlled drug, there will be a permanent record showing the pattern of distribution of the drug because the institutions using the drug and the physicians and pharmacists operating in cooperation with the institution will be required to register all use of the drug. It will permit the Food and Drug Administration to withdraw methadone from its present unqualified approval status in pharmacies for detoxification, analgesic, and antitussive purposes. Thus, a new closed system of distribution will be established, under which any diversion or misuse can immediately be stopped at the source of supply. At the same time the drug will be available for use without all the IND restrictions for all addicts for whom it is medically justified.

The Commissioner recognizes that this is a novel form of control designed to reflect the unique problems posed by this drug. It has not previously been necessary to utilize IND and the NDA procedures concurrently in order to assure the safe and effective use of a new drug. Because of the seriousness of the medical and social problems associated with heroin addiction and because methadone is the only drug available for the treatment of heroin addiction, the Commissioner has concluded that it is no longer feasible to retain methadone solely for investigational use. It is therefore appropriate to add the special requirements set forth in this proposal in order to permit the drug to be available wherever medical opinion concludes that it should be used in the treatment of heroin addiction.

The Commissioner feels that the mandate in section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 can be appropriately applied to determining the conditions under which methadone may be safely used in treating narcotic addicts. This section requires the Secretary of Health, Education, and Welfare * * * after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, to determine the appropriate methods of professional practice in the medical treatment of narcotic addiction. * * * The Secretary has delegated the authority to make this determination to the Commissioner of Food and Drugs.

In carrying out the requirements of the Comprehensive Drug Abuse Prevention and Control Act, the Commissioner has widely consulted and maintained close communications with the medical profession regarding use of methadone. Among those associations or groups consulted are the American Medical Association's Council on Mental Health, the National Research Council's Committee on Problems of Drug Dependence, the American Psychiatric Association's Commission on Drug Abuse, a task force of the American Society of Pharmacology and Experimental Therapeutics, the Joint Food and Drug Administration/National Institutes of Mental Health Psychotomimetic Advisory Committee, the FDA Drug Abuse Advisory Committee, the Special Action Office of the White House, and the National Institute of Mental Health. The consensus is strong among medical experts and the Food and Drug Administration that currently available evidence on the safety and effectiveness of methadone is sufficient to permit its use for the maintenance treatment of narcotic addiction as proposed in this notice.

On the basis of the above considerations, the Commissioner of Food and Drugs, after consultation with the associations and groups listed above and the Bureau of Narcotics and Dangerous Drugs, and with the endorsement of the Special Action Office of the White House, proposes that the special requirements set out in this notice be imposed upon the use of methadone. These new controls should not interfere with the availability of methadone in the treatment of severe pain or for detoxification of hospitalized addicts. Methadone for the treatment of severe pain on either an inpatient or outpatient basis will be available from hospital pharmacies.

It is proposed that patients under 18 not be admitted to a treatment program using methadone until additional study is completed to determine whether methadone may be safely and effectively used in their treatment. Such additional study must be conducted pursuant to all the requirements of the usual investigational new drug plan. This will mean that juveniles will be excluded from virtually all ongoing treatment programs using methadone except investigational programs with an IND approval. Comment is solicited as to whether the benefits of completing additional studies outweigh the risks of excluding these patients from treatment programs at this time with the likely result that they will continue to use injected heroin.

Under this proposal, the distribution of the drug is limited to treatment programs using methadone and to hospital pharmacies approved by the Food and Drug Administration. Requests for approval of programs received by FDA will be sent to BNDD for any comment it may have prior to FDA approval. BNDD may inspect any such program or may furnish FDA any relevant information from its files. FDA will give great weight to any information, comments, or recommendation received from BNDD in determining whether approval should be granted or, once granted, should be revoked. Methadone will no longer be permitted for antitussive use as the benefits of methadone for this use do not outweigh the risk involved from unsafe and ineffective use.

The Food and Drug Administration believes that State health or mental health authorities are essential to adequately controlling methadone, to assuring that the need for a methadone program exists, and to establishing criteria and guidance for rehabilitation efforts. Approval of a program by the State health or mental health authority designated under the provisions of section 314(d) of the Public Health Service Act or by his designee will be a part of approval of the treatment programs using methadone by FDA. The Food and Drug Administration will contact each State to establish the necessary channels of communication and to establish procedure for the implementation of the program, and will provide information upon request.

Section 130.44 *Conditions for investigational use of methadone for maintenance programs for narcotic addicts* (21 CFR 130.44) will continue in effect until a final order is issued after consideration of the comments submitted on this proposal. To increase control over methadone and to improve patient care prior to the finalization of this proposal, however, the guidelines in § 130.44 will be enforced as a requirement for a methadone maintenance investigational program. Any IND that varies in any material respect from the protocol in § 130.44 will require justification.

The following additional provisions will be required of all methadone maintenance investigational programs during the time between the publication of this proposal and its final promulgation:

1. Only oral dosage forms of methadone formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion will be provided patients for unsupervised use under approved programs.

2. The selection of patients is to be carried out in accordance with the requirements of item V, B, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed § 130.48(b)(2)(i).

3. Dosage for detoxification and maintenance is to be in accordance with the requirements of item VIII, A, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed § 130.48(b)(2)(i).

4. The recordkeeping requirements are to be in accordance with the information requested in the form "Annual Report for Treatment Program Using Methadone" which appears in proposed § 130.48(b)(2)(iii).

5. All patients in the methadone investigational program are to be given careful consideration for discontinuance of methadone in accordance with item VIII, D, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed § 130.48(b)(2)(i).

6. Distribution of methadone will be restricted to direct shipments to approved investigational programs and hospital pharmacies, unless an alternative method of distribution is approved by FDA after consultation with BNDD.

The above stated provisions will be required of all new and ongoing methadone investigational programs within 30 days of the date of publication of this notice. An amended "Notice of Claimed Investigational Exemption for Methadone for Use in the Maintenance Treatment of Narcotic Addicts" shall be submitted by all ongoing programs and by new programs. These amended forms may be obtained from the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052–53 as amended, 1055; 21 U.S.C. 355, 371(a)) and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 U.S.C. 257a) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes that § 130.48 be amended by adding a new paragraph (b), as follows:

§ 130.48 Drugs that are subjects of approved new drug applications and that require special studies, records, and reports.

* * * * *

(b) *Methadone.* Methadone is an approved drug for marketing as an analgesic and for the detoxification and treatment of narcotic addicts. Methadone has been under investigation for a number of years for use as an oral substitute for heroin in the maintenance treatment of narcotic addicts. The nature of the use of methadone in maintenance treatment is such that the drug may be used for long periods of time. Further chronic toxicity studies are needed to establish the safety of long-term use. In view of the usefulness of methadone and the tremendous social problems associated with the narcotics problem, the Commissioner of Food and Drugs finds that it is not in the public interest to withhold the drug from the market until further long-term studies have been completed. In view of problems of abuse and misuse associated with the widespread availability of methadone, adequate controls are essential for the safe use of the drug. The drug should nevertheless continue to be available for treatment of severe pain in patients where no substitute therapy is suitable. In view of these considerations, the Commissioner of Food and Drugs has concluded that it is essential to the public interest to prescribe detailed conditions for safe and effective use of methadone. Methadone maintenance treatment will be permitted under both the IND and NDA control mechanisms established in the statute and regulations. These conditions of use are intended to assure that the required studies for assessing the safety of the long-term administration are performed, to monitor records and determine that required reports are maintained, to maintain close control over distribution and availability of the drug, and to detail responsibilities for such control:

(1) The following conditions must be met in order for methadone to be used for maintenance and detoxification in connection with a treatment program using methadone:

(i) The drug is limited to oral dosage forms formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion.

(ii) The manufacturers of methadone will develop additional data from chronic animal toxicity studies in which the drug is administered orally at high doses to dogs or monkeys for 1 year and rats for 18 months or mice for 2 years. Observations will include effects on behavior, growth, food and water consumption, blood and urine chemistry, hematological systems, cardiovascular and respiratory systems. Postmortem examinations will include complete gross and histopathological examinations. Reproduction studies following the FDA 1966 guidelines will be performed.

(iii) Further chronic clinical studies with particular attention to the toxicity of methadone in the hematopoietic, cardiovascular, endocrine, hepatic, and immunological systems will be performed under federally sponsored programs.

(iv) Reports of studies will be submitted pursuant to § 130.13.

(v) At the end of each year after the date of approval, representatives of the Food and Drug Administration, the applicant, appropriate experts, and, if necessary, the investigator(s) will meet to determine whether or not clinical studies should be continued.

(vi) Shipments of the drug are restricted to direct shipments by the holders of approved or investigational new drug applications for methadone to approved treatment programs using methadone. Alternative methods of distribution may be used if they are approved by FDA after consultation with the Bureau of Narcotics and Dangerous Drugs. These treatment programs using methadone must have been reviewed by the appropriate State health or mental health authority designated pursuant to section 314(d) of the Public Health Service Act, or his designee, and notification of the program's approval must have been received from the Food and Drug Administration. Prior to such notification, applications for treatment programs using methadone shall be reviewed by FDA and shall be sent by FDA to BNDD for any information, comments, or recommendations it may have.

(2) A treatment program using methadone shall be approved by FDA if all of the following conditions are met:

(i) The person assuming responsibility for the program must complete, sign, and file in triplicate with the Food and Drug Administration a Form FD ______, "Application for Approval of Treatment Program Using Methadone" as follows:

Form FD ______ —Application for Approval of Treatment Program Using Methadone

Name of other identification of program ____
Address ________________________________

COMMISSIONER,
Food and Drug Administration,
Bureau of Drugs (BD–22),
Rockville, Md. 20852.

DEAR SIR: As the person (program director) responsible for this program, I submit this request for approval of a treatment program using methadone to provide maintenance treatment and detoxification for narcotic addicts. I understand that failure to abide by the requirements described below are a violation of the law and may result in revocation of approval of my application, seizure of my drug supply, an injunction, and criminal prosecution.

I. Attached is evidence to indicate approval of the program by the State authority designated pursuant to section 314(d) of the Public Health Service Act (or his designee).

II. Attached is the name, complete address, and a summary of the scientific training and experience of each physician and all other professional personnel having major responsibilities for the program and rehabilitative efforts and a signed Form FD ______, "Medical Responsibility Statement for Treatment Program Using Methadone" for every licensed practitioner authorized to prescribe, dispense, or administer methadone under the program. (Copies of the required form are obtainable from this agency at the same address to which this application is mailed.)

III. Attached is the name, address, and description of each hospital, institution, clinical laboratory facility, or other facility available to provide the necessary services. The program must have ready access to a comprehensive range of medical and rehabilitative services. These shall be describd and shall comply with any guidelines established by Federal or State authorities.

IV. Attached is a statement of the approximate number of addicts to be included in the program.

V. The following minimal treatment standards will be used:

A. Attached is a statement which will be given to the addicts to inform them about the program. Participation in the program should be voluntary.

B. Care will be exercised in the selection of patients to prevent the possibility of admitting a person who has not been dependent upon heroin or other morphine-like drugs and thereby creating de novo a state of dependence upon methadone. The mere use of an opiate, even if periodic or intermittent, cannot be equated with drug dependence. Admission to the program will be dependent upon a history of physiological dependence on one or more opiate drugs (which will be recorded in the applicant's medical record) and evidence of current physiological dependence on opiates as demonstrated by the results of urinalysis and signs of opiate withdrawal. It is highly unlikely that an individual would be currently dependent on opiates without a positive urinalysis for opiates and/or without demonstrating at least the early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilatation, and piloerection) during the initial period of abstinence. Other positive evidence of use can be obtained by noting the presence of needle tracks and by obtaining additional history from relatives and friends. The withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection requires inpatient observations.

C. An exception to the requirement for evidence of current physiological dependence on opiates will be allowed under exceptional circumstances. For example, methadone treatment may be initiated for an individual with a history of opiate addiction a short time prior to or upon release from a stay of 1 month or longer in a penal or chronic care institution. In these circumstances, the reasons for this exception, appropriate descriptions of the facilities, procedures, and qualifications of the personnel of the institution or other appropriate justification will be sent to the Food and Drug Administration at the time of filing this application or with the Annual Report.

D. Additional study is necessary to determine whether methadone may be safely and effectively used in the treatment of patients under 18. No such patients will be admitted to a treatment program using methadone unless prior approval of a Form FD 1571, "Notice of Claimed Investigational Exemption for a New Drug," has been obtained. Such approval will be granted only for a controlled clinical study and not for an ongoing treatment program.

VI. I agree that an admission evaluation and record will be made and maintained for each patient upon admission to the program and will consist of the following:

A. Personal, history including age, sex, educational level, employment history, criminal history, and past history of drug abuse of all types;

B. Medical history and history of psychiatric illness and current legal problems, if any; and

C. Physical examination results.

VII. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone maintenance program in order to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. To prevent such multiple enrollments, I will participate in whatever local, regional, or national patient identification system exists or is developed. Except in an emergency situation, methadone shall not be provided to a patient who is known to be currently receiving the drug from any other treatment program using methadone. Except as provided in item XV of this form, information that would identify the patient will be kept confidential pursuant to section 303 of the Public Health Service Act and will not be divulged in any civil, criminal, administrative, legislative, or other proceedings conducted by Federal, State, or local authorities.

VIII. The following minimal procedures will be used for ongoing care:

A. Dosage and administration for detoxification and maintenance:

1. The methadone will be administered in oral form.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedule indicated below is recommended but should be varied depending upon clinical judgment. Initially, a single oral dose of 15-20 milligrams of methadone will often be sufficient. Additional methadone can be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. With the exception of such patients, 40 milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone can be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or, at most, in 2-day intervals. However, the amount of intake must always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and causes little discomfort. When the total dosage has decreased to 20 milligrams per day, the dose can be reduced by 50 percent per day without producing significant discomfort. If a patient complains of undue distress, phenothiazine may be used in lieu of increasing the methadone dose. In ambulatory patients, a somewhat slower schedule may be needed.

In any event, if methadone is administered for more than 3 weeks, the procedure will be considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to that of methadone maintenance even though the goal and intent may be eventual total withdrawal:

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of heroin but should not be so great as to cause marked sedation or respiratory depression. It is important that the initial dosage be adjusted to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage can be one half these quantities. When there is any doubt, a smaller dose can be used initially. Then the patient should be kept under observation, and, if symptoms of abstinence are distressing, 10-milligram doses may be repeated as needed. Subsequently the dosage can be adjusted individually as tolerated and required with a maintenance level of approximately 40 to 100 milligrams daily. Occasionally, higher dosage levels may be required but must be justified in the medical record.

4. The methadone will be dispensed by a practitioner licensed by law to administer drugs and administered by him or under close supervision. For maintenance, initially (the first several weeks), the subject will receive the medication under observation daily, or at least 6 days a week. For detoxification, the drug will be administered daily under close observation. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a clinic may be incompatible with gainful employment, education, and responsible homemaking. Therefore, in maintenance treatment, after demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in his rehabilitation, the patient may be permitted to reduce to twice weekly the times when he must receive the drug under observation. The rest of the time he may administer the drug himself, but no more than a 3-day supply will routinely be allowed in his possession. However, the requirement that the drug always be administered under supervision will be relaxed only in the following instances: (a) If the patient is responsibly employed on a regular and full-time basis, or (b) if the patient is a full-time student in a recognized institution of learning and is regularly in attendance and performing satisfactorily, or (c) if the patient is a part-time employee and part-time student and otherwise meets the criteria set forth in (a) and (b) above, or (d) if the patient is directly responsible, as a parent or as one in *loco parentis*, for the day-to-day welfare of one or more children under the age of 10 and customary observed medication intake would cause such a child or children to be without adequate supervision. Additional medication may also be provided in exceptional circumstances such as illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for such specific period as may be in question. In such circumstances the reasons for providing additional medication will be recorded.

B. In maintenance treatment, a urinalysis will be performed at least once a week for morphine and any other drug clinically indicated. Patients with take-home privileges for methadone should also be tested weekly for methadone. Urine specimens will be collected under direct observation. It is recommended but not required that patients be followed for other drug and alcohol abuse.

C. An adequate clinical record will be maintained for each patient. This record will contain the date of each visit, the results of each urinalysis, a detailed account of any adverse reactions, any significant physical or psychological disability, and other relevant aspects of the treatment programs. If a patient misses appointments for 2 weeks or more without notifying the program, the episode of care will be considered terminated, and this will be noted on his clinical record. If he returns for care, he will be readmitted and his record will be reopened.

D. All patients in the maintenance program will be given careful consideration for discontinuance of methadone after social rehabilitation has been maintained for a reasonable period of time. The patient will be given sufficient information regarding the methadone maintenance technique, so that he can elect to pursue the goal of eventually withdrawing from methadone and becoming drug-free.

IX. A report on Form FD ______, "Annual Report for Treatment Program Using Methadone" will be submitted to the Food and Drug Administration by January 30 of each year. (Copies of the form are available from this agency at the same address to which this application is mailed.)

X. To prevent diversion into illicit channels, adequate security will be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Bureau of Narcotics and Dangerous Drugs.

XI. Accurate records traceable to patients will be maintained showing dates, quantity, and batch or code marks of the drug used. These records should be retained for a period of 3 years.

XII. In a maintenance program, the program director may establish satellite operations for treatment and dispensing of medication but will obtain and submit to FDA a signed FD ______, "Medical Responsibility Statement for Treatment Program Using Methadone," for every such operation. Only after patients have been stabilized at their optimal dosage level may they be referred to the satellite operations for obtaining medication and other treatment including any appropriate rehabilitative services. Subsequent to such referral, the program director will retain continuing responsibility for the patient's care, and the patient must be periodically checked at the primary facility of the program. No satellite operation will provide care for more than 10 patients at any one time, unless the program director has justified an increase and obtained approval from the State authority.

XIII. All representations in this application are currently accurate, and no changes will be made in the program until they have been approved by the Food and Drug Administration.

XIV. If the program or any individual under the program is disapproved, the program director will recall the methadone from the disapproved sources and return the drug to the manufacturer.

XV. Inspections of this program may be undertaken by the State authority and the Food and Drug Administration. The identity of the patient will be kept confidential except when the patient or his legal representative consents to the release of such information, when it is necessary to make followup investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records pursuant to proceedings to revoke approval of the program.

Signature: ________________________
(Program Director)

(ii) The following completed and signed form referred to in items II and XII of Form FD ______ is submitted in duplicate to the Food and Drug Administration:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD ______—Medical Responsibility Statement for Treatment Program Using Methadone

(To be completed by the individual responsible for the dispensing of medication in each facility and every physician working in an approved program, whether ultimately responsible for dispensing medication or not.)

Name of practitioner licensed by law to administer drugs ______________________

Name of program or program director ______

Program address ________________________

Date ___________________________________

The undersigned ___________ agrees to assume responsibility for the prescribing and administering of methadone under the above identified program and to abide by the standards for maintenance treatment and detoxification.

The name of each patient treated at a satellite facility and the frequency of visits will be registered with the program director. An annual report (Form FD ______), "Annual Report for Methadone Maintenance Programs" will be submitted to the program director for submission to FDA. The patient must always report to the same satellite operation unless prior approval is obtained from the program director for treatment at another satellite operation.

I. The following minimal treatment standards will be used:

A. A program statement will be given to the addicts to inform them about the program. Participation in the program should be voluntary.

B. Care will be exercised in the selection of patients to prevent the possibility of admitting a person who has not been dependent upon heroin or other morphine-like drugs and thereby creating de novo a state of dependence upon methadone. The mere use of an opiate, even if it is periodic or intermittent, cannot be equated with drug dependence. Admission to the program will depend upon a history of physiological dependence on one or more opiate drugs (which will be recorded in the applicant's medical record) and evidence of current physiological dependence on opiates as demonstrated by the results of urinalysis and signs of opiate withdrawal. It is highly unlikely that an individual would be currently dependent on opiates without a positive urinalysis for opiates and/or without demonstrating at least the early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilatation, and piloerection) during the initial period of abstinence. Other positive evidence of use can be obtained by noting the presence of needle tracks and by obtaining additional history from relatives and friends. The withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection requires inpatient observation.

C. An exception to the requirement for evidence of current physiological dependence on opiates will be allowed under exceptional circumstances. For example, methadone treatment may be initiated for an individual with a history of opiate addiction a short time prior to or upon release from a stay of 1 month or longer in a penal or chronic care institution. In these circumstances, the reasons for this exception, appropriate descriptions of the facilities, procedures, and qualifications of the personnel of the institution or other appropriate justification will be sent to the Food and Drug Administration at the time of filing this form or with the annual report.

D. Additional study is necessary to determine whether methadone may be safely and effectively used in the treatment of patients under 18. No such patients will be admitted to a treatment program using methadone unless prior approval of Form FD 1571, "Notice of Claimed Investigational Exemption for a New Drug," has been obtained. Such approval will be granted only for a controlled clinical study and not for an ongoing treatment program.

II. I agree that an admission evaluation and record will be made and maintained for each patient upon admission to the program and will consist of the following:

A. Personal history including age, sex, educational level, employment history, criminal history, and past history of drug abuse of all types;

B. Medical history and history of psychiatric illness and current legal problems, if any; and

C. Physical examination results.

III. The following minimal procedures will be used for on-going care;

A. Dosage and administration for detoxification and maintenance:

1. The methadone will be administered in oral form.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedule indicated below is recommended but should be varied depending upon clinical judgment. Initially, a single oral dose of 15–20 milligrams of methadone will often be sufficient. Additional methadone can be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone it may be necessary to exceed these levels. With the exception of such patients, 40 milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone can be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or, at most, in 2-day intervals. However, the amount of intake must always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and causes little discomfort. When the total dosage has decreased to 20 milligrams per day, the dose can be reduced by 50 percent per day without producing significant discomfort. If a patient complains of undue distress, phenothiazine may be used in lieu of increasing the methadone dose. In ambulatory patients, a somewhat slower schedule may be needed.

In any event, if methadone is administered for more than 3 weeks, the procedure will be considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to that of methadone maintenance even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment, the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of heroin but should not be so great as to cause marked sedation or respiratory depression. It is important that the initial dosage be adjusted to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later or 40 milligrams in a single oral does, If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage can be one half these quantities. When there is any doubt, a smaller dose can be used initially. Then the patient should be kept under observation, and, if symptoms of abstinence are distressing, the administration of 10-milligram doses may be repeated as needed. Subsequently the dosage can be adjusted individually as tolerated and required with a maintenance level of approximately 40 to 100 milligrams daily. Occasionally, higher dosage levels may be required but must be justified in the medical record.

4. The methadone will be dispensed by a practitioner licensed by law to administer drugs and administered by him or under close supervision. For maintenance, initially (the first several weeks) the subject will receive the medication under observation daily, or at least 6 days a week. For detoxification, the drug will be administered daily under close observation. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a clinic may be incompatible with gainful employment, education, and responsible homemaking. Therefore, in maintenance treatment, after demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in his rehabilitation, the patient may be permitted to reduce to twice weekly the times when he must receive the drug under observation. The rest of the time he may administer the drug himself, but no more than a 3-day supply will routinely be allowed in his possession. However, the requirement that the drug always be administered under supervision will be relaxed only in the following instances: (a) If the patient is responsibly employed on a regular and full-time basis, or (b) if the patient is a full-time student in a recognized institution of learning and is regularly in attendance and performing satisfactorily, or (c) if the patient is a part-time employee and/or part-time student and otherwise meets the criteria set forth in (a) and (b) above, or (d) if the patient is directly responsible, as a parent or as one in *loco parentis*, for the day-to-day welfare of one or more children under the age of 10 and customary observed medication intake would cause such a child or children to be without adequate supervision. Additional medication may also be provided in exceptional circumstances such as illness, family crisis, or necessary travel when hardship would result from requiring the customary observed medication intake for such specific period as may be in question. In such circumstances the reasons for providing additional medication will be recorded.

B. In maintenance treatment, a urinalysis will be performed at least once a week for morphine and any other drug clinically indicated. Patients with take-home privileges for methadone should also be tested weekly for methadone. Urine specimens will be collected under direct observation. It is recommended but not required that patients be followed for other drug and alcohol abuse.

C. An adequate clinical record will be maintained for each patient. This record will contain the date of each visit, the results of each urinalysis, a detailed account of any adverse reactions, any significant physical or psychological disability, and other relevant aspects of the treatment program. If a patient misses appointments for 2 weeks or more without notifying the program, the episode of care will be considered terminated, and this will be noted on his clinical record. If he returns for care, he will be readmitted and his record will be reopened.

D. All patients in the maintenance program will be given careful consideration for discontinuance of methadone maintenance after social rehabilitation has been maintained for a reasonable period of time. The patient will be given sufficient information regarding the methadone maintenance technique, so that he can elect to pursue the goal of eventually withdrawing from methadone and becoming drug-free.

IV. To prevent diversion into illicit channels, adequate security will be maintained over stocks of methadone under my control, and over the manner in which it is distributed, as required by the Bureau of Narcotics and Dangerous Drugs.

V. All representations in this application are currently accurate, and no changes will be made in the program until they have been approved by the program director and the Food and Drug Administration.

VI. If I am disqualified, I agree to return any remaining stock of methadone to the parent program.

VII. Inspections of this program may be undertaken by the State authority and the Food and Drug Administration. The identity of the patient will be kept confidential except when the patient or his legal representative consents to the release of such information, when it is necessary to make followup investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records pursuant to proceedings to revoke approval of the program.

Signature: ______________________
(Participating physician)

(iii) The following completed and signed form refered to in item IX of Form FD ______, "Application for Approval of Methadone Program," is submitted in duplicate in accordance with the instructions in item IX.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD ______—Annual Report for Treatment Program Using Methadone

This form is to be completed in duplicate for each calendar year. One copy is to be sent to the Food and Drug Administration and one copy to the State authority on or before January 30.

1. Name of other identification of program ______________________

Address ______________________

Number of satellite units ______ (Attach a list showing address and person responsible for each unit).

2. Total Treatment Capacity ____________

3. Drug Forms Dispensed:

Amount of each formulation dispensed (in grams) during the year:

Formulation	*Amount*
a. ______________	______________
b. ______________	______________
c. ______________	______________

4. Number of individuals who applied to the program but were not admitted or given admission evaluation ______________

5. Census of Patients Maintained on Methadone:

a. Number under care at the beginning of the year being reported ______________

Of those in treatment at the beginning of the year:

(1) Number continuously under care through the year being reported (still under care) ______________

(2) Number discharged or transferred to other types of programs and not readmitted ______________

(3) Number discharged or transferred to other types of programs and readmitted (still under care) ______________

(4) Number discharged and readmitted (no longer under care) ______________

b. Number admitted to care during year—not previously treated in this program:

(1) Number still under care at the end of the year ______________

(2) Number discharged or transferred to other types of programs and not readmitted ______________

(3) Number discharged or transferred to other types of programs and readmitted (still under care) ______________

(4) Number discharged and readmitted (no longer under care) ______________

c. Number admitted to care during the year—previously treated in this program prior to the past year:

(1) Number still under care at the end of the year ______________

(2) Number discharged or transferred to other types of programs and not readmitted ______________

(3) Number discharged and transferred to other types of programs and readmitted (still under care) ______________

(4) Number discharged and readmitted (no longer under care) ______________

6. Demographic and treatment characteristics of patients under care at the end of the year being reported:

a. Give the number of males and females in each age category:

Age	*Sex* *Male*	*Female*
Under 18______________	______	______
18–20 ______________	______	______
21–25 ______________	______	______
26–35 ______________	______	______
36–45 ______________	______	______
46+ ______________	______	______

b. For the year being reported, give the number of patients who have been under continuous care for the following periods of time:

Under three months_____	______________
3 months to one year_____	______________
One to two years_______	______________
Two to five years_______	______________
Over five years_________	______________

c. Total number of individuals treated to date ______________

d. For the year being reported, give the number of patients stabilized at each dosage level:

Daily dosage, mgm.	*No. of patients*
Under 40__________	______________
40–59 __________	______________
60–79 __________	______________
80–99 __________	______________
100–119 __________	______________
120–160 __________	______________
Over 160__________	______________

e. For the year being reported, give the number of patients in the past 8 weeks who have fallen in the following categories:

	No. of Patients
No positive urinalysis for opiates for 2 months or more ______________	____________
Occasional positive urinalysis for opiates (monthly or less) ______________	____________
Frequent positive urinalysis for opiates (more than once per month; still dependent) ____________	____________
In program for less than 2 months ______________	____________

7. Give the number of patients having significant adverse reactions, particularly reactions related to hematopoietic, cardiovascular, endocrine, and immunological functions (attach a completed copy of Form FD–1639 "Drug Experience Report" for each incident; forms obtainable from the Food and Drug Administration):

Type of reaction	*No. of patients*
______________	______________
______________	______________
______________	______________

8. Give the number of patients who have died while under methadone care (attach a completed copy of Form FD–1639 "Drug Experience Report" for each incident; forms obtainable from the Food and Drug Administration):

	No. of patients
a. Definitely methadone-related ______________	____________
b. Not methadone-related___	____________

Signature: ______________________
Program Director

3. Within 60 days after receipt of an application for a treatment program using methadone, the applicant will receive notification of approval or refusal.

4. Refusal or revocation of a program approval.

(i) Refusal or revocation of approval of a program may be proposed to the Commissioner of Food and Drugs by the Director of the FDA Bureau of Drugs, on his own initiative or at the request of representatives of the Bureau of Narcotics and Dangerous Drugs or the designated State authority.

(ii) Before presenting such a proposal to the Commissioner, the Director of the Bureau of Drugs or his representative will notify the program applicant of the proposed action and the reasons therefor and will offer him an opportunity to explain the matters in question in an informal conference and/or in writing. If an explanation is offered by the applicant but not accepted by the Bureau of Drugs and if the hearing is requested within 10 days after receipt of notification that the explanation is unacceptable, the Commissioner will provide the program applicant an opportunity for an informal hearing on the question of whether the applicant should be entitled to receive methadone for use in a treatment program. Representatives of the State authority and/or BNDD may participate in the conference with the Bureau official or with the Commissioner.

(iii) The Commissioner will evaluate all available information, including any explanation or assurance presented by the program applicant. If he finds that the program applicant has failed to submit adequate assurance that the conditions for receiving methadone for use in a program will be met or that the program applicant has repeatedly or deliberately failed to comply with the conditions for receiving methadone for treatment of addicts or that the applicant has deliberately submitted false information to the Food and Drug Administration, the Commissioner will notify the program applicant, the appropriate State officials, BNDD, and all other appropriate persons that the program applicant is not entitled to receive methadone for treatment of narcotic addicts.

(iv) If a program applicant has had a program application refused or revoked, such refusal or revocation may be reversed when the Commissioner determines that the applicant has presented adequate assurance that he will employ such drugs solely in compliance with the requirements for a methadone program.

5. Program directors will be allowed 3 months from the final promulgation of this paragraph in order to obtain the necessary approvals and establish procedures for adhering to these conditions. During this interim period the State authority may permit one or more hospitals in areas of the State without approved programs to dispense methadone for the detoxification and maintenance treatment of narcotic addicts. The holders of approved new drug applications will be notified by the Food and Drug

Administration that methadone can be distributed to these hospital pharmacies after the State authority has so informed FDA.

6. Conditions for approving the use of methadone in analgesia and in hospitalized patients in detoxification.

(i) The drug is in oral or parenteral form.

(ii) Transportation is restricted to direct shipments to hospitals which have submitted a notification (FD ______ "Application for approval of Methadone Program,") to the Food and Drug Administration that they wish to receive the drug. The Food and Drug Administration will provide methadone manufacturers with the names of the hospitals that have submitted signed Forms FD ______, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification".

(iii) For a hospital to receive shipments of methadone for use as an analgesic and for detoxification, a responsible hospital official must complete, sign, and file in triplicate with the Food and Drug Administration a Form FD ______, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification," as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD ______

Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification

Name of Hospital________________________
Address ________________________________

COMMISSIONER,
Food and Drug Administration,
Bureau of Drugs (BD-22),
Rockville, Md. 20852.

DEAR SIR: I submit this notice of intent to receive supplies of methadone to be used for analgesia and detoxification. I understand that the failure to abide by the requirements described below may result in discontinuance of shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

1. The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone is ________________.

2. There are ______ beds in the hospital. (Give the number.)

3. A general description of the hospital and nature of patient care undertaken is attached.

4. The anticipated quantity of supply needed per year is ______________________.

5. Adequate security will be maintained over stocks of methadone to prevent diversion into illicit channels. All stocks will be secured in a locked cabinet or safe.

6. Methadone will be dispensed for detoxification of hospitalized patients only and for analgesia in severe pain for hospitalized and outpatients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to methadone maintenance. Such treatment can be undertaken only by approved methadone maintenance programs. This does not preclude the maintenance of an addict who is hospitalized for treatment for medical conditions other than addiction and whose enrollment in a specific maintenance program has been verified by the hospital.

7. Prior to filling a physician's prescription for methadone for outpatients, I will obtain from the physician a statement indicating that all such prescriptions will be limited to use for analgesia in severe pain and his agreement to maintain records to substantiate such use. These records will be available in the hospital or made available at the request of the hospital administrator. On January 30 of each year, the hospital will report to the Food and Drug Administration the names of all physicians who prescribed methadone for analgesia on an outpatient basis during the previous year.

8. Prescriptions will not be filled if they are written by a physician who has not submitted the required commitment to the hospital.

9. Accurate records are maintained showing dates, quantity, and batch or code marks of the drug used. The records are to be retained for a period of 3 years.

10. The Food and Drug Administration may inspect the supplies or use of the drug. The identity of the patient will be kept confidential except when the patient or his legal representative consents to the release of such information, when it is necessary to make followup investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records pursuant to proceedings to revoke approval of the hospital.

Signature: ________________________
(Hospital Official)

Interested persons may, within 90 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: April 3, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-5297 Filed 4-5-72;8:48 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[33 CFR Part 82]

[CGD 72-67P]

CALCASIEU CHANNEL, LA., SABINE PASS, TEX. AND VENTURA MARINA, CALIF.

Boundary Lines of Inland Waters

The Coast Guard is considering amending the lines of demarcation for inland waters at Calcasieu Channel, La., Sabine Pass, Tex., and Ventura Marina, Calif. This amendment is being proposed to bring the line of demarcation descriptions into conformance with recent changes to aids to navigation in the affected locations.

Calcasieu Channel Lighted Whistle Buoy 1 has been discontinued in connection with the deepening and extension of the channel. Therefore, it is proposed to use Calcasieu Channel Lighted Whistle Buoy 20 in the boundary description. This proposed change moves the line of demarcation at Calcasieu Channel 500 yards to seaward.

Sabine Pass Lighted Whistle Buoy 1 has been discontinued in connection with the deepening and extension of the channel. Therefore, it is proposed to use Sabine Bank Channel Lighted Bell Buoy 18 in the boundary description. This proposed change moves the line of demarcation 900 yards seaward.

Because of a detached, offshore breakwater, Ventura Marina presents an unusual harbor entrance not clearly described by the general rules for boundary lines for inland waters (33 CFR 82.2). The proposed regulation provides a specific line of demarcation at the entrance to Ventura Marina.

Interested persons may participate in this proposed rule making by submitting written data, views, or arguments to the Executive Secretary, Marine Safety Council, U.S. Coast Guard Headquarters, Room 8234, 400 Seventh Street SW., Washington, DC 20590. Each person submitting comments should include his name and address and give reasons for any recommended change in the proposal. Copies of all written communications received will be available for examination by interested persons at the office of the Executive Secretary, Marine Safety Council.

All comments received before May 8, 1972, will be considered before final action is taken on this proposal. The proposed regulations may be changed in the light of comments received.

In consideration of the foregoing, it is proposed that Part 82 be amended by revising §§ 82.103, and 82.106 and adding § 82.144 to read as follows:

§ 82.103 Mississippi Passes, La., to Sabine Pass, Tex.

A line drawn from a point 5.1 miles, 107° true, from Pass a Loutre Abandoned Lighthouse to South Pass Lighted Whistle Buoy 2; thence to southwest Pass Entrance Midchannel Lighted Whistle Buoy; thence to Ship Shoal Daybeacon; thence to Calcasieu Channel Lighted Whistle Buoy 20; thence to Sabine Bank Channel Lighted Bell Buoy 18.

§ 82.106 Sabine Pass, Tex., to Galveston, Tex.

A line drawn from Sabine Bank Channel Lighted Bell Buoy 18 to Galveston Bay Entrance Channel Lighted Whistle Buoy 1.

§ 82.144 Ventura Marina.

(a) A line drawn from the south end of the detached breakwater to Ventura Marina Light 4.

(b) A line drawn 080° true from the north end of the detached breakwater to shore.

(Sec. 2, 28 Stat. 672, as amended, sec. 6(b)(1), 80 Stat. 938; 33 U.S.C. 151, 49 U.S.C. 1655(b); 49 CFR 1.46(b))

Dated: March 31, 1972.

G. H. READ,
Captain, U.S. Coast Guard, Acting Chief, Office of Merchant Marine Safety.

[FR Doc.72-5288 Filed 4-5-72;8:47 am]