

VI. *General provisions.* 1. As fiscal agents of the United States, Federal Reserve Banks are authorized and requested to receive subscriptions, to make such allotments as may be prescribed by the Secretary of the Treasury, to issue such notices as may be necessary, to receive payment for and make delivery of notes on full-paid subscriptions allotted, and they may issue interim receipts pending delivery of the definitive notes.

2. The Secretary of the Treasury may at any time, or from time to time, prescribe supplemental or amendatory rules and regulations governing the offering, which will be communicated promptly to the Federal Reserve Banks.

[SEAL] DAVID M. KENNEDY,
Secretary of the Treasury.

[F.R. Doc. 70-10108; Filed, July 31, 1970;
8:51 a.m.]

DEPARTMENT OF JUSTICE
VOTING RIGHTS ACT OF 1965
Determination Regarding Literacy
Tests

JULY 24, 1970.

Determination of the Attorney General pursuant to section 4(b) of the Voting Rights Act of 1965 as amended.

1. Section 4 of the Voting Rights Act of 1965, 79 Stat. 438, 42 U.S.C. 1973b (Supp. IV, 1965-68), suspended the use of literacy tests and similar tests in States and counties which fell within a formula based upon the percentage of the voting-age population which was registered for or voted in the November 1964 election. Now subject to such coverage are the States of Alabama, Georgia, Louisiana, Mississippi, South Carolina, and Virginia; 39 counties in North Carolina; one county in Hawaii; and one county in Arizona.

The Voting Rights Act Amendments of 1970, Public Law 91-285, 84 Stat. 315, amend section 4 of the 1965 Act by adding a coverage formula based upon registration for or participation in the 1968 presidential election in States and counties (not already subject to suspension under section 4(a) of the 1965 Act) which the Attorney General determines maintained a "test or device" on November 1, 1968.

2a. The following States are not, except to the extent specifically indicated, presently subject to suspension of tests and devices pursuant to section 4(a) of the Voting Rights Act of 1965, 42 U.S.C. 1973b(a) (Supp. IV, 1965-68), 79 Stat. 438. In accordance with section 4(b) of the Voting Rights Act of 1965 as amended by the Voting Rights Act Amendments of 1970, Public Law 91-285, 84 Stat. 315, I have determined that each of the following States maintained on November 1, 1968, a test or device as defined in section 4(c) of the Voting Rights Act of 1965, 42 U.S.C. 1973b(c) (Supp. IV, 1965-68), 79 Stat. 438:

Alaska.	Idaho.
Arizona (except Yuma County).	Maine.
California.	Massachusetts.
Connecticut.	New Hampshire.
Delaware.	New York.
Hawaii (except Honolulu County).	Oregon.
	Washington.
	Wyoming.

b. The following counties are not presently subject to suspension of tests and devices pursuant to section 4(a) of the Voting Rights Act of 1965. I have determined that each of the following counties of North Carolina maintained on November 1, 1968, a test or device as defined in section 4(c) of the Voting Rights Act of 1965:

Alamance.	Lincoln.
Alexander.	Macon.
Alleghany.	Madison.
Ashe.	McDowell.
Avery.	Mecklenburg.
Brunswick.	Mitchell.
Buncombe.	Montgomery.
Burke.	Moore.
Cabarrus.	New Hanover.
Caldwell.	Orange.
Carteret.	Pamlico.
Catawba.	Pender.
Chatham.	Polk.
Cherokee.	Randolph.
Clay.	Richmond.
Columbus.	Rowan.
Currituck.	Rutherford.
Dare.	Sampson.
Davidson.	Stanly.
Davie.	Stokes.
Duplin.	Surry.
Durham.	Swain.
Forsyth.	Transylvania.
Graham.	Tyrrell.
Haywood.	Wake.
Henderson.	Warren.
Hyde.	Watauga.
Iredell.	Wilkes.
Jackson.	Yadkin.
Johnston.	Yancey.
Jones.	

JOHN N. MITCHELL,
Attorney General.

JULY, 1970.

[F.R. Doc. 70-9956; Filed; July 31, 1970;
8:46 a.m.]

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation
BYLAWS OF CORPORATION

The bylaws of the Commodity Credit Corporation, amended July 2, 1970, are as follows:

OFFICES

1. The principal office of the Corporation shall be in the city of Washington, District of Columbia, and the Corporation shall also have offices at such other places as it may deem necessary or desirable in the conduct of its business.

SEAL

2. There is impressed below the official seal which is hereby adopted for the Corporation. Said seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced.



MEETINGS OF THE BOARD

3. Regular meetings of the Board shall be held without notice in the Board meeting room in the U.S. Department of Agriculture in the city of Washington, D.C., on Wednesday of each week, or if that day be a legal holiday, on the next succeeding business day, at 9:30 a.m., unless notice of another hour is given.

4. Special meetings of the Board may be called at any time by the Chairman or by the President or the Executive Vice President and shall be called by the Chairman, the President, or the Executive Vice President at the written request of any four directors. Notice of special meetings shall be given either personally or by mail (including the intradepartmental mail channels of the Department of Agriculture or interdepartmental mail channels of the Federal Government) or by telegram, and notice by telephone shall be personal notice. Any Director may waive in writing such notice as to himself, whether before or after the time of the meeting, and the presence of a Director at any meeting shall constitute a waiver of notice of such meeting. No notice of an adjourned meeting need be given. Any and all business may be transacted at any special meeting unless otherwise indicated in the notice thereof.

5. The Secretary of Agriculture shall serve as Chairman of the Board. In the absence or unavailability of the Chairman, the President of the Corporation shall preside at meetings of the Board. In the absence or unavailability of the Chairman and the President, the Directors present at the meeting shall designate a Presiding Officer.

6. At any meeting of the Board a quorum shall consist of four Directors. The act of a majority of the Directors present at any meeting at which there is a quorum shall be the act of the Board.

7. The General Counsel of the Department of Agriculture, whose office shall perform all legal work of the Corporation, and the Deputy Counsel of the Department of Agriculture shall, as General Counsel of the Department of Agriculture shall, as General Counsel and Deputy General Counsel of the Corporation, respectively, attend meetings of the Board.

8. The Executive Vice President, the Vice President who is the Associate Administrator of the Agriculture Stabilization and Conservation Service, the Vice President who is the General Sales Manager of the Export Marketing Service,

the Secretary and the Controller shall attend meetings of the Board. Each of the other Vice Presidents and Deputy Vice Presidents shall attend meetings of the Board during such times as the meetings are devoted to consideration of matters as to which they have responsibility.

9. Other persons may attend meetings of the Board upon specific authorization by the Chairman or the President.

COMPENSATION OF BOARD DIRECTORS

10. The compensation of each Director shall be prescribed by the Secretary of Agriculture. Any director who holds another office or position under the Federal Government, the compensation for which exceeds that prescribed by the Secretary of Agriculture for such Director, may elect to receive compensation at the rate provided for such other office or position in lieu of compensation as a Director.

OFFICERS

11. The officers of the Corporation shall be a President, Vice Presidents, and Deputy Vice Presidents as hereinafter provided for, a Secretary, a Controller, a Treasurer, a Chief Accountant, and such additional officers as the Secretary of Agriculture may appoint.

12. The Assistant Secretary of Agriculture for International Affairs and Commodity Programs shall be ex officio President of the Corporation.

13. The following officials of the Agricultural Stabilization and Conservation Service (referred to as ASCS), Export Marketing Service (referred to as EMS), Foreign Agricultural Service (referred to as FAS), Food and Nutrition Service (referred to as FNS), and Consumer and Marketing Service (referred to as C&MS) shall be ex officio officers of the Corporation:

Administrator, ASCS; Executive Vice President.
 General Sales Manager, EMS; Vice President.
 Administrator, FAS; Vice President.
 Administrator, C&MS; Vice President.
 Administrator, FNS; Vice President.
 Associate Administrator, ASCS; Vice President.
 Deputy Administrator, Commodity Operations, ASCS; Deputy Vice President.
 Deputy Administrator, State and County Operations, ASCS; Deputy Vice President.
 Deputy Administrator, Management, ASCS; Deputy Vice President.
 Executive Assistant to the Administrator, ASCS; Secretary.
 Director, Fiscal Division, ASCS; Controller.
 Deputy Director, Fiscal Division, ASCS; Treasurer.
 Chief, Accounting Systems Branch, Fiscal Division, ASCS; Chief Accountant.

The person occupying, in an acting capacity, the office of any person designated ex officio by this paragraph 13 as an officer of the Corporation, shall, during his occupancy of such office, act as such officer.

14. Officers who do not hold office ex officio shall be appointed by the Secretary of Agriculture and shall hold office until their respective appointments shall have been terminated.

THE PRESIDENT

15. The President shall be Vice Chairman of the Board and shall have general supervision and direction of the Corporation, its officers and employees.

THE VICE PRESIDENTS

16. (a) The Executive Vice President shall be the chief executive officer of the Corporation and shall be responsible for submission of all Corporation policies and programs to the Board. Except as provided in paragraphs (b), (c), (d), and (e) below, the Executive Vice President shall have general supervision and direction of the preparation of policies and programs for submission to the Board, of the administration of the policies and programs approved by the Board, and of the day-to-day conduct of the business of the Corporation and of its officers and employees.

(b) The Vice President who is the Administrator, Foreign Agricultural Service, shall be responsible for preparation for submission by the Executive Vice President to the Board of those policies and programs of the Corporation which are for performance through the facilities and personnel of the Foreign Agricultural Service. He shall also have responsibility for the administration of those operations of the Corporation, under policies and programs approved by the Board, which are carried out through facilities and personnel of the Foreign Agricultural Service. He shall also perform such special duties and exercise such powers as may be prescribed, from time to time, by the Secretary of Agriculture, the Board, or the President of the Corporation.

(c) The Vice President who is Administrator, Consumer and Marketing Service, shall be responsible for the administration of those operations of the Corporation, under policies and programs approved by the Board, which are carried out through facilities and personnel of the Consumer and Marketing Service. He shall also perform such special duties and exercise such powers as may be prescribed, from time to time, by the Secretary of Agriculture, the Board, or the President of the Corporation.

(d) The Vice President who is the General Sales Manager of the Export Marketing Service shall be responsible for preparation for submission by the Executive Vice President to the Board of policies and programs of the Corporation which are for performance through the facilities and personnel of the Export Marketing Service. He shall also have responsibility for the administration of those operations of the Corporation, under policies and programs approved by the Board, which are carried out through facilities and personnel of the Export Marketing Service. He shall also perform such special duties and exercise such powers as may be prescribed, from time to time, by the Secretary of Agriculture, the Board, or the President of the Corporation.

(e) The Vice President who is the Administrator, Food and Nutrition Service, shall be responsible for the administration of those operations of the Corporation, under policies and programs approved by the Board, which are carried out through facilities and personnel of the Food and Nutrition Service. He shall also perform such special duties and exercise such powers as may be prescribed, from time to time, by the Secretary of Agriculture, the Board, or the President of the Corporation.

17. The Vice President who is the Associate Administrator, Agricultural Stabilization and Conservation Service, and the Deputy Vice Presidents shall assist the Executive Vice President in the performance of his duties and the exercise of his powers to such extent as the President or the Executive Vice President shall prescribe, and shall perform such special duties and exercise such powers as may be prescribed from time to time by the Secretary of Agriculture, the Board, the President of the Corporation, or the Executive Vice President of the Corporation.

THE SECRETARY

18. The Secretary shall attend and keep the minutes of all meetings of the Board; shall attend to the giving and serving of all required notices of meetings of the Board; shall sign all papers and instruments to which his signature shall be necessary or appropriate; shall attest the authenticity of and affix the seal of the Corporation upon any instrument requiring such action; and shall perform such other duties and exercise such other powers as are commonly incidental to the office of Secretary as well as such other duties as may be prescribed from time to time by the President or the Executive Vice President.

THE CONTROLLER

19. The Controller shall have charge of all fiscal and accounting affairs of the Corporation, including all borrowings and related financial arrangements, claims activities, and formulation of prices in accordance with established policies; and shall perform such other duties as may be prescribed from time to time by the President or the Executive Vice President.

THE TREASURER

20. The Treasurer, under the general supervision and direction of the Controller, shall have charge of the custody, safekeeping and disbursement of all funds of the Corporation; shall designate qualified persons to authorize disbursement of corporate funds; shall direct the disbursement of funds by disbursing officers of the Corporation or by the Treasurer of the United States, Federal Reserve Banks and other fiscal agents of the Corporation; and shall issue instructions incidental thereto; shall be responsible for documents relating to the general financing operations of the Corporation, including borrowings from the U.S. Treasury, commercial banks and

others; shall arrange for the payment of interest on and the repayment of such borrowings; shall arrange for the payment of interest on the capital stock of the Corporation; shall coordinate and give general supervision to the claims activities of the Corporation and shall have authority to collect all monies due the Corporation, to receipt therefor and to deposit same for the account of the Corporation; and shall perform such other duties relating to the fiscal and accounting affairs of the Corporation as may be prescribed from time to time by the Controller.

THE CHIEF ACCOUNTANT

21. The Chief Accountant, under the general supervision and direction of the Controller, shall have charge of the general books and accounts of the Corporation and the preparation of financial statements and reports. He shall be responsible for the initiation, preparation and issuance of policies and practices related to accounting matters and procedures, including official inventories, records, accounting and related office procedures where standardized, and adequate subsidiary records of revenues, expenses, assets and liabilities; and shall perform such other duties relating to the fiscal and accounting affairs of the Corporation as may be prescribed from time to time by the Controller.

OTHER OFFICIALS

22. Except as otherwise authorized by the Secretary of Agriculture or the Board, the operations of the Corporation shall be carried out through the facilities and personnel of the Agricultural Stabilization and Conservation Service, the Foreign Agricultural Service, the Export Marketing Service, the Food and Nutrition Service and the Consumer and Marketing Service, in accordance with any assignment of functions and responsibilities made by the Secretary of Agriculture and, within his respective agency, by the Administrators of the Agricultural Stabilization and Conservation Service, Foreign Agricultural Service, Food and Nutrition Service, Consumer and Marketing Service, or the General Sales Manager of the Export Marketing Service.

23. The Directors of the divisions and commodity offices of the Agricultural Stabilization and Conservation Service shall be contracting officers and executives of the Corporation in general charge of the activities of the Corporation carried out through their respective divisions or offices. The responsibilities of such Directors in carrying out activities of the Corporation, which shall include the authority to settle and adjust claims by and against the Corporation arising out of activities under their jurisdiction, shall be discharged in conformity with these bylaws and applicable programs, policies, and procedures.

BONDS

24. Such officers and employees of the Corporation, including officers and employees of the Department of Agriculture who perform duties for the Corporation,

as may be specified by the Secretary of Agriculture, shall be bonded in such manner, upon such conditions, and in such amounts as the Secretary of Agriculture may determine. The Corporation shall pay the premium of any bond or bonds.

CONTRACTS OF THE CORPORATION

25. Contracts of the Corporation relating to any of its activities may be executed in its name by the Secretary of Agriculture or the President. The Vice Presidents, the Deputy Vice Presidents, the Comptroller, the Treasurer, and the Directors of the divisions and commodity offices of the Agricultural Stabilization and Conservation Service may execute contracts relating to the activities of the Corporation for which they are respectively responsible.

26. The Executive Vice President who is the Administrator of ASCS and, subject to the written approval by such Executive Vice President of each appointment, the Vice Presidents, the Deputy Vice Presidents, the Comptroller, and the Directors of the divisions and commodity offices of the Agricultural Stabilization and Conservation Service may appoint, by written instrument or instruments such Contracting Officers as they deem necessary, who may, to the extent authorized by such instrument or instruments, execute contracts in the name of the Corporation. A copy of each such instrument shall be filed with the Secretary.

27. Appointments of Contracting Officers may be revoked by written instrument or instruments by the Executive Vice President or by the official who made the appointment. A copy of each such instrument shall be filed with the Secretary.

28. In executing a contract in the name of the Corporation, an official shall indicate his title.

ANNUAL REPORT

29. The Executive Vice President shall be responsible for the preparation of an annual report of the activities of the Corporation, which shall be filed with the Secretary of Agriculture and with the Board.

AMENDMENTS

30. These bylaws may be altered or amended or repealed by the Secretary of Agriculture, or subject to his approval by action of the Board at any regular meeting of the Board or at any special meeting of the Board, if notice of the proposed alteration, amendment, or repeal be contained in the notice of such special meeting.

APPROVAL OF BOARD ACTION

31. The actions of the Board shall be subject to the approval of the Secretary of Agriculture and the Assistant Secretary for International Affairs and Commodity Programs.

I, Seeley G. Lodwick, Acting Secretary, Commodity Credit Corporation, do hereby certify that the above is a full, true, and correct copy of the bylaws of

Commodity Credit Corporation, adopted by the Board of Directors, Commodity Credit Corporation, at a meeting held June 30, 1970, and approved by the Secretary of Agriculture, effective close of business July 2, 1970.

In witness whereof I have officially subscribed my name and have caused the corporate seal of the said Corporation to be affixed this second day of July 1970.

[SEAL] SEELEY G. LODWICK,
Acting Secretary,
Commodity Credit Corporation.

[F.R. Doc. 70-9852; Filed, July 31, 1970;
8:45 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 3158]

[Docket No. FDC-D-183; NDA No. 3-158
et al.]

CERTAIN ANDROGEN PREPARATIONS

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs:

1. Perandren Propionate, for Intramuscular Injection, Vials, containing 25 milligrams, 50 milligrams, or 100 milligrams testosterone propionate per milliliter; Ciba Pharmaceutical Co., 556 Morris Avenue, Summit, N.J. 07901 (NDA 7029).

2. Perandren Phenylacetate Intramuscular Repository, Vials, containing 50 milligrams testosterone phenylacetate per milliliter and 1 percent procaine hydrochloride; Ciba Pharmaceutical Company (NDA 9349).

3. Oreton Pellets for Subcutaneous Implantation, containing 75 milligrams testosterone per pellet; Schering Corp., 60 Orange Street, Bloomfield, N.J. 07003 (NDA 4652).

4. Halotestin Tablets, contain 10 milligrams, 5 milligrams; or 2 milligrams fluoxymesterone per tablet; The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002 (NDA 10-611).

5. Ultandren Tablets containing 2 milligrams or 5 milligrams fluoxymesterone per tablet, Ciba Pharmaceutical Co. (NDA 11-424).

6. Ora-Testryl Tablets, containing 2 milligrams or 5 milligrams fluoxymesterone per tablet; E. R. Squibb and Sons Inc., Georges Road, New Brunswick, N.J. 08903 (NDA 11-359).

7. Delatestryl, Sterile Solution, for Intramuscular Injection, containing 200 milligrams testosterone enanthate per milliliter, and in disposable syringes containing 200 mg. testosterone enanthate per syringe; E. R. Squibb and Sons Inc. (NDA 9165).

8. Neo-Hombreol (M), Tablets, containing 10 milligrams or 25 milligrams methyltestosterone per tablet; Organon Inc., 375 Mount Pleasant Avenue, West Orange, N.J. 07052 (NDA 3234).

9. Metandren Linguets and Tablets, containing 5 milligrams or 10 milligrams methyltestosterone per linguet, and 10 milligrams or 25 milligrams methyltestosterone per tablet; Ciba Pharmaceutical Co. (NDA 3240).

10. Oreton Methyl Tablets, containing 10 milligrams or 25 milligrams methyltestosterone per tablet; Schering Corp. (NDA 3158).

The drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drugs without approval.

The Food and Drug Administration is prepared to approve new-drug applications and supplements to previously approved new-drug applications under conditions described in this announcement.

I. Testosterone for subcutaneous implantation—A. Effectiveness classification. The Food and Drug Administration has considered the Academy report, as well as other available evidence, and concludes that:

1. This drug is effective for eunuchism, eunuchoidism, and male climacteric.

2. It lacks substantial evidence of effectiveness for advanced breast carcinoma.

B. Form of drug. This preparation is in pellet form suitable for subcutaneous implantation.

C. Labeling conditions. 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guideline for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "Indications" section of the labeling is as follows:

INDICATIONS

1. Eunuchoidism and eunuchism.

2. Male climacteric symptoms when these are secondary to testosterone deficiency.

D. Marketing status. Marketing of the drug may continue under the conditions described in items VIII and IX of this announcement.

II. Testosterone enanthate solution for intramuscular injection—A. Effectiveness classification. The Food and Drug Administration has considered the Academy report, as well as other available evidence, and concludes that:

1. This drug is effective in the therapy of eunuchism, eunuchoidism, deficiency after castration, male climacteric symptoms, and oligospermia.

2. This drug is probably effective for postmenopausal or senile osteoporosis.

3. This drug is possibly effective for use in senile pruritis; tissue atrophy in geriatric patients; cryptorchidism with evidence of hypogonadism; and for an anabolic effect in protein depletion and chronic debility, depletion of protein osseous tissue during corticoid therapy, spinal paraplegia, and delayed fracture union.

4. Testosterone enanthate lacks substantial evidence of effectiveness for involuntional melancholia, dysfunctional uterine bleeding, prevention of postpartum breast engorgement and inhibition of lactation, menopausal syndrome, frigidity, and mammary cancer in premenopausal women.

B. Form of drug. Testosterone enanthate preparations are solutions suitable for intramuscular administration.

C. Labeling conditions. 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "indications" section of the labeling is as follows:

INDICATIONS

In the male:

1. Eunuchism, eunuchoidism, deficiency after castration.

2. Male climacteric symptoms when these are secondary to androgen deficiency.

3. Oligospermia.

In the female or male:

1. Postmenopausal or senile osteoporosis. Androgens are without value as a primary therapy, but may be of value as adjunctive therapy. Equal or greater consideration should be given to diet, calcium balance, physiotherapy, and good general health-promoting measures.

D. Marketing status. Marketing of the drug may continue under the conditions described in items VIII and IX of this announcement except those claims referenced in item VII below may continue to be included in the labeling for the periods stated.

III. Methyltestosterone for oral or buccal administration—A. Effectiveness classification. The Food and Drug Administration has considered the Academy reports, as well as other available evidence, and concludes that:

1. This drug is effective for eunuchism and eunuchoidism, male climacteric symptoms when these are secondary to androgen deficiency, impotence due to androgenic deficiency, androgen-responsive breast cancer, prevention of postpartum breast manifestations of pain and engorgement, and postpuberal cryptorchidism with evidence of hypogonadism.

2. This drug is probably effective for postmenopausal osteoporosis.

3. This drug is possibly effective for suppression of lactation, prepuberal cryptorchidism with evidence of hypogonadism, convalescent and cachectic states for anabolic effect.

4. Methyltestosterone lacks substantial evidence of effectiveness for the menopausal syndrome, dysmenorrhea and premenstrual tension, and functional uterine bleeding.

B. Form of drug. Methyltestosterone preparations are in tablet form suitable for oral or buccal administration.

C. Labeling conditions. 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "Indications" section of the labeling is as follows:

INDICATIONS

In the male:

1. Eunuchoidism and eunuchism.

2. Male climacteric symptoms when these are secondary to androgen deficiency.

3. Impotence due to androgenic deficiency.

4. Postpuberal cryptorchidism with evidence of hypogonadism.

In the female:

1. Prevention of postpartum breast manifestations of pain and engorgement. There is no satisfactory evidence that this drug prevents or suppresses lactation per se.

2. Postmenopausal osteoporosis. Androgens are without value as a primary therapy, but may be of value as adjunctive therapy. Equal or greater consideration should be given to diet, calcium balance, physiotherapy, and good general health-promoting measures.

3. Palliation of androgen-responsive, advancing, inoperable breast cancer, in women who are more than 1, but less than 5 years postmenopausal or who have been proven to have a hormone-dependent tumor, as shown by previous beneficial response to castration.

D. Marketing status. Marketing of the drug may continue under the conditions described in items VIII and IX of this announcement except those claims referenced in item VII below may continue to be included in the labeling for the periods stated.

IV. Testosterone propionate solution for intramuscular injection—A. Effectiveness classification. The Food and Drug Administration has considered the Academy report, as well as other available evidence, and concludes that:

1. This drug is effective for postpuberal cryptorchidism with evidence of hypogonadism, eunuchism, and eunuchoidism, male climacteric symptoms due to testosterone deficiency; palliation of mammary cancer, impotence due to inadequate androgen production, and for prevention of post-partum pain and engorgement.

2. The drug is probably effective for postmenopausal osteoporosis.

3. The drug is possibly effective for prepuberal cryptorchidism with evidence of hypogonadism, suppression of lactation, convalescence and cachectic states for anabolic effect.

4. Testosterone propionate lacks substantial evidence of effectiveness for

menopause, dysmenorrhea, and premenstrual tension, functional uterine bleeding, menorrhagia, metrorrhagia, endometriosis, and chronic cystic mastitis.

B. *Form of drug.* Testosterone propionate preparations are solutions suitable for intramuscular administration.

C. *Labeling conditions.* 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "indications" section of the labeling is as follows:

INDICATIONS

In the male:

1. Postpubertal cryptorchidism with evidence of hypogonadism.
2. Eunuchism and eunuchoidism. Treatment is not usually begun until puberty.
3. Impotence (due to inadequate androgen production).
4. Male climacteric symptoms, if these are due to testosterone deficiency.

In the female:

1. Prevention of postpartum breast manifestations of pain and engorgement. There is no satisfactory evidence that this preparation prevents or suppresses lactation itself.
2. Postmenopausal osteoporosis. Androgens are without value as a primary therapy, but may be of value as adjunctive therapy. Equal or greater consideration should be given to diet, calcium balance, physiotherapy, and good general health-promoting measures.
3. Palliation of androgen-responsive, advanced, inoperable mammary cancer in women who are more than 1, but less than 5 years postmenopausal or who have been proven to have hormone-dependent tumor, as shown by previous beneficial response to castration.

D. *Marketing status.* Marketing of the drug may continue under the conditions described in items VIII and IX of this announcement except those claims referenced in item VII below may continue to be included in the labeling for the periods stated.

V. *Testosterone phenylacetate suspension for intramuscular repository—A. Effectiveness classification.* The Food and Drug Administration has considered the Academy report, as well as other available evidence, and concludes that:

1. This drug is effective for eunuchoidism, male climacteric symptoms when these are secondary to testosterone deficiency, and palliation of mammary cancer.
2. This drug is probably effective for osteoporosis (postmenopausal).
3. This drug is possibly effective for anabolic effect in fracture after surgery and injury in convalescence to oppose catabolic action of cortisone.
4. Testosterone phenylacetate lacks substantial evidence of effectiveness for prepubertal hypogonadism, menorrhagia and metrorrhagia.

B. *Form of drug.* Testosterone phenylacetate preparations are suspensions suitable for intramuscular repository administration.

C. *Labeling conditions.* 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "Indications" section of the labeling is as follows:

INDICATIONS

In the male:

1. Eunuchoidism and eunuchism.
2. Climacteric symptoms when these are secondary to testosterone deficiency.

In the female:

1. Postmenopausal osteoporosis. Androgens are without value as a primary therapy, but may be of value as adjunctive therapy. Equal or greater consideration should be given to diet, calcium balance, physiotherapy, and other good general health-promoting measures.
2. Palliation of androgen-responsive, advanced, inoperable mammary cancer in women who are more than 1 year, or less than 5 years postmenopausal who have been proven to have a hormone-dependent cancer. With the use of this long-acting preparation, it would be impossible to properly nullify the untoward effects of tumor progression, hypercalcemia, or salt and water retention.

D. *Marketing status.* Marketing of the drug may continue under the conditions described in items VIII and IX of this announcement except those claims referenced in item VII below may continue to be included in the labeling for the periods stated.

VI. *Fluoxymesterone for oral administration—A. Effectiveness classification.* The Food and Drug Administration has considered the Academy reports, as well as other available evidence, and concludes that:

1. This drug is effective for panhypopituitarism, eunuchism and eunuchoidism, delayed puberty, male climacteric symptoms when these are secondary to androgen deficiency, palliation of advanced inoperable mammary cancer, prevention of postpartum breast manifestations and impotence due to androgen deficiency.
2. This drug is probably effective for osteoporosis (postmenopausal).
3. This drug is possibly effective for control of lactation; in the treatment of protein depletion states which occur in geriatric patients, in debilitation disorders, in chronic corticoid therapy; resistant fractures; cryptorchidism; creating a positive nitrogen balance, tissue repair and other anabolic effects.
4. Fluoxymesterone lacks substantial evidence of effectiveness for menorrhagia and metrorrhagia, and treatment of frigidity.

B. *Form of drug.* Fluoxymesterone preparations are in tablet form suitable for oral administration.

C. *Labeling conditions.* 1. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

2. The drug is labeled to comply with all requirements of the Act and regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the FEDERAL REGISTER of February 6, 1970. The "Indications" section of the labeling is as follows:

INDICATIONS

In the male:

The primary indication in the male is replacement therapy in conditions associated with a deficiency or absence of endogenous testicular hormone. Androgen therapy prevents the development of atrophic changes in the accessory male sex organs following castration; as long as replacement therapy is continued, these organs can be maintained in a relatively normal state.

1. Primary eunuchoidism and eunuchism.
2. Male climacteric symptoms when these are secondary to androgen deficiency.
3. Those symptoms of panhypopituitarism related to hypogonadism. Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance.
4. Impotence due to androgen deficiency.
5. Delayed puberty, provided it has been definitely established as such, and it is not just a familial trait.

In the female:

1. Prevention of postpartum breast manifestations of pain and engorgement. There is no satisfactory evidence that this drug prevents or suppresses lactation per se.
2. Postmenopausal osteoporosis. Androgens are without value as a primary therapy, but may be of value as adjunctive therapy. Equal or greater consideration should be given to diet, calcium balance, physiotherapy, and good general health-promoting measures.
3. Palliation of androgen-responsive, advanced, inoperable female breast cancer, in women who are more than 1, but less than 5 years postmenopausal or who have been proven to have a hormone-dependent tumor, as shown by previous beneficial response to castration.

D. *Marketing status.* Marketing of the drug may continue under the conditions described in items VII and IX of this announcement except those claims referenced in item VII below may continue to be included in the labeling for the periods stated.

VII. *Indications permitted during the extended period for obtaining substantial evidence.* A. Those indications for which the drugs are described in paragraphs II.A, III.A, IV.A, V.A, and VI.A above as probably effective are included in the labeling conditions and may continue to be used for 12 months following the date of this publication to allow additional time within which holders of previously approved applications or persons marketing the drugs without approval may obtain and submit to the Food and Drug Administration data to provide substantial evidence of effectiveness.

B. Those indications for which the drugs are described in paragraphs II.A, III.A, IV.A, V.A, and VI.A above as possibly effective (not included in the labeling conditions) may continue to be used for 6 months following the date of this publication to allow additional time within which such persons may obtain

and submit to the Food and Drug Administration data to provide substantial evidence of effectiveness. To be acceptable for consideration in support of the effectiveness of a drug, any such data must be previously unsubmitted, well-organized, and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published as a final order in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under controlled or partially controlled situations are not acceptable as a sole basis for the approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

VIII. Previously approved applications. 1. Each holder of a "deemed approved" new-drug application (i.e., an application which became effective on the basis of safety prior to Oct. 10, 1962) for such drug is requested to seek approval of the claims of effectiveness and bring the application into conformance by submitting supplements containing:

a. Revised labeling as needed to conform to the labeling conditions described here for the drug, and complete current container labeling, unless recently submitted.

b. Adequate data to assure the biologic availability of the drug in the formulation which is marketed. For preparations claiming sustained action, timed release, or other delayed or prolonged effect, these data should show that the drug is available at a rate of release which is safe and effective. If such data are already included in the application, specific reference thereto may be made.

c. Updating information as needed to make the application current in regard to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls), of the new-drug application form 356H to the extent described for abbreviated new-drug applications, § 130.4(f), published in the FEDERAL REGISTER of April 24, 1970 (35 F.R. 6574). (One supplement may contain all the information described in this paragraph.)

2. Such supplements should be submitted within the following periods after the date of publication of this notice in the FEDERAL REGISTER:

a. 60 days for revised labeling—the supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new drug regulations (21 CFR 130.9) which permit certain changes to be put into effect at the earliest possible time.

b. 180 days for biologic availability data.

c. 60 days for updating information.

3. Marketing of the drug may continue until the supplemental applications submitted in accord with the preceding subparagraphs 1 and 2 are acted upon, provided that within 60 days after the date of this publication, the labeling of the preparation shipped within the jurisdiction of the Act is in accord with the labeling conditions described in this announcement. (It may continue to include

the indications referenced in section VII for the periods stated.)

IX. New applications. 1. Any other person who distributes or intends to distribute such drug which is intended for the conditions of use for which it has been shown to be effective, as described under A above, should submit an abbreviated new drug application meeting the conditions specified in § 130.4(f) (1), (2), and (3), published in the FEDERAL REGISTER of April 24, 1970 (35 F.R. 6574). Such applications should include proposed labeling which is in accord with the labeling conditions described herein and adequate data to assure the biologic availability of the drug in the formulation which is marketed or proposed for marketing. For preparations claiming sustained action, timed release, or other delayed or prolonged effect, these data should show that the drug is available at a rate of release which will be safe and effective.

2. Distribution of any such preparation currently on the market without an approved new drug application may be continued provided that:

a. Within 60 days from the date of publication of this announcement in the FEDERAL REGISTER, the labeling of such preparation shipped within the jurisdiction of the Act is in accord with the labeling conditions described herein. (It may continue to include the indications referenced in item VII for the periods stated.)

b. The manufacturer, packer, or distributor of such drug submits, within 180 days from the date of this publication, a new drug application to the Food and Drug Administration.

c. The applicant submits within a reasonable time, additional information that may be required for the approval of the application as specified in a written communication from the Food and Drug Administration.

d. The application has not been ruled incomplete or unapprovable.

X. Exemption from periodic reporting. The periodic reporting requirements of §§ 130.35 (e) and 130.13(b) (4) are waived in regard to applications approved for these drugs solely for the conditions of use for which the drugs are regarded as effective as described herein. The reporting requirements of §§ 130.35(f) and 130.13(b) (1), (2), and (3) are not waived by this exemption and are a continuing obligation of the applicant.

XI. Opportunity for a hearing. A. The Commissioner of Food and Drugs proposes to issue an order under the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of all new-drug applications and all amendments and supplements thereto providing for the indications for which substantial evidence of effectiveness is lacking as described in paragraphs I.A, II.A, III.A, IV.A, V.A, and VI.A of this announcement. An order withdrawing approval of the applications will not issue if such applications are supplemented, in accord with this notice, to delete such indications. Promulgation of the proposed order would cause any drug

for human use containing the same components and offered for the indications for which substantial evidence of effectiveness is lacking, to be a new drug for which an approved new-drug application is not in effect. Any such drug then on the market would be subject to regulatory proceedings.

B. In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the holders of any such applications, and any interested person who would be adversely affected by such an order, an opportunity for a hearing to show why such indications should not be deleted from labeling. A request for a hearing must be filed within 30 days after the date of publication of this notice in the FEDERAL REGISTER. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing, together with a well-organized and full-factual analysis of the clinical and other investigational data the objector is prepared to prove in a hearing. Any data submitted in response to this notice must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in section 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety. If a hearing is requested and is justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue a written notice of the time and place at which the hearing will commence.

XII. Unapproved use or form of drug.

1. If the article is labeled or advertised for use in any condition other than those provided for in this announcement, it may be regarded as an unapproved new drug subject to regulatory proceedings until such recommended use is approved in a new drug application, or is otherwise in accord with this announcement.

2. If the article is proposed for marketing in another form or for use other than the use provided for in this announcement, appropriate additional information as described in § 130.4 or § 130.9 of the regulations (21 CFR 130.4, 130.9) may be required, including results of animal and clinical tests intended to show whether the drug is safe and effective.

A copy of the NAS-NRC report has been furnished to each firm referred to above. Any other interested person may obtain a copy by request to the appropriate office named below.

Communications forwarded in response to this announcement should be identified with the reference number

DESI 3158 and be directed to the attention of the following appropriate office and unless otherwise specified be addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Requests for Hearing (Identify with docket number): Hearing Clerk, Office of General Counsel (GC-1) Room 6-62, Parklawn.
Supplements (Identify with NDA number): Office of Marketed Drugs (BD-200), Bureau of Drugs.

Original abbreviated new-drug applications (Identify as such): Office of Marketed Drugs (BD-200) Bureau of Drugs.

All other communications regarding this announcement:

Special Assistant for Drug Efficacy Study Implementation (BD-201), Bureau of Drugs.

Requests for NAS-NRC reports: Press Relations Office (CE-200), Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: July 6, 1970.

SAM D. FINE,
Associate Commissioner
for Compliance.

[F.R. Doc. 70-9969; Filed, July 31, 1970;
8:47 a.m.]

GEIGY CHEMICAL CORP.

Notice of Filing of Petition for Food Additives

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409 (b) (5), 72 Stat. 1786; 21 U.S.C. 348(b) (5)), notice is given that a petition (FAP 0B2566) has been filed by Geigy Industrial Chemicals, Division of Geigy Chemical Corp., Ardsley, N.Y. 10502, proposing that § 121.2566 *Antioxidants and/or stabilizers for polymers* (21 CFR 121.2566) be amended to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer at levels not to exceed 0.25 by weight of polystyrene and rubber-modified polystyrene, complying with § 121.2510, intended for food-contact use.

Dated: July 23, 1970.

R. E. DUGGAN,
Acting Associate Commissioner
for Compliance.

[F.R. Doc. 70-9966; Filed, July 31, 1970;
8:46 a.m.]

o-ISOPROPOXYPHENYL METHYLCARBAMATE

Notice of Extension of Temporary Tolerance

Chemagro Corp., Post Office Box 4913, Kansas City, Mo. 64120, was granted a temporary tolerance for residues of the

insecticide o-isopropoxyphenyl methylcarbamate in or on the raw agricultural commodities straws of barley, oats, and wheat at 1 part per million and grains of barley, oats, and wheat at 0.5 part per million on April 23, 1969 (notice was published in the FEDERAL REGISTER of May 1, 1969; 34 F.R. 7180) which expired April 23, 1970.

The firm has amended its petition by reducing the tolerance levels to 0.2 part per million for the straws and 0.1 part per million for the grains of barley, oats, and wheat and has requested a 1-year extension to permit additional tests in accordance with temporary permits issued by the U.S. Department of Agriculture.

The Commissioner of Food and Drugs has determined that such extension would protect the public health. Therefore, an extension has been granted and will expire July 24, 1971.

This section is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(j), 68 Stat. 512; 21 U.S.C. 346a(j)) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: July 24, 1970.

SAM D. FINE,
Acting Associate Commissioner
for Compliance.

[F.R. Doc. 70-9955; Filed, July 31, 1970;
8:46 a.m.]

DEPARTMENT OF COMMERCE

Office of the Secretary

[Department Organization Order 10-1;
Amdt. 1]

ASSISTANT SECRETARY FOR SCIENCE AND TECHNOLOGY

Delegation of Authority

The following amendment to the order was issued by the Secretary of Commerce on July 1, 1970. This material supersedes the material appearing at 30 F.R. 15042 of December 4, 1965; and amends the material appearing at 34 F.R. 12840 of August 7, 1969.

The Office of State Technical Services (OSTS) is hereby abolished, and Department Organization Order 10-1 of July 25, 1969, is hereby amended as follows:

1. Sec. 3. *Scope of authority.* Paragraph .01 is amended to delete the reference to the Office of State Technical Services, and a new paragraph .021 is added to read:

"1. To exercise the functions, powers, duties, and authorities of the Secretary of Commerce pursuant to the provisions of the State Technical Services Act of 1965 (Public Law 89-182, 15 U.S.C. 1351-1368), as may be required, including reduction of the Department's activities under the Act in the absence of authorized funds."

2. SEC. 6. *Saving provision.* References in any document or order to OSTs or the Director, OSTs, shall be deemed to re-

late to or refer to the Assistant Secretary for Science and Technology.

Effective date: July 1, 1970.

LARRY A. JOBE,
Assistant Secretary
for Administration.

[F.R. Doc. 70-9964; Filed, July 31, 1970;
8:46 a.m.]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

ACTING FEDERAL INSURANCE ADMINISTRATOR

Designation

The following persons are hereby designated to serve as Acting Federal Insurance Administrator during the absence of the Federal Insurance Administrator, with all the powers, functions, and duties delegated or assigned to the Administrator: *Provided*, That no official is authorized to act in the Administrator's capacity, unless all of the officials whose position titles precede his in this designation are unable to act by reason of absence or a vacancy:

1. Charles W. Wiecking, Assistant Administrator for Program Development.
2. Richard W. Krimm, Assistant Administrator for Flood Insurance.

This designation amends the designation effective March 26, 1970 (35 F.R. 5570, Apr. 3, 1970).

(Secretary's delegations of authority effective Feb. 27, 1969 (34 F.R. 2680, Feb. 27, 1969)).

Effective date. This designation shall be effective as of Monday, July 22, 1970.

GEORGE K. BERNSTEIN,
Federal Insurance Administrator.

[F.R. Doc. 70-9970; Filed, July 31, 1970;
8:47 a.m.]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGFR 70-104]

BOSTON HARBOR

Security Zone

By virtue of the authority vested in the Commandant, U.S. Coast Guard, by Executive Order 10173, as amended (33 CFR Part 6), sec. 6(b)(1), 80 Stat. 937, 49 U.S.C. 1655(b)(1), 49 CFR 1.46(b) and the redelegation of authority to Chief, Office of Operations, U.S. Coast Guard, as contained in the FEDERAL REGISTER of May 27, 1970 (35 F.R. 8279), I hereby affirm for publication in the FEDERAL REGISTER the order of W. B. Ellis, Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District, who has exercised authority as District Commander, such order reading as follows:

BOSTON HARBOR SECURITY ZONE

"Under the present authority of section 1 of title II of the Espionage Act of June 15, 1917, 40 Stat. 220, as amended, 50 U.S.C. 191, and Executive Order 10173, as amended, I declare that from 0900 Eastern Daylight Time on Monday, August 3, 1970, until 1200 Eastern Daylight Time on Monday, August 3, 1970, and from 0900 Eastern Daylight Time on Wednesday, 5 August, 1970 until 1200 Eastern Daylight Time on Wednesday, 5 August 1970, the following area is a security zone and I order it to be closed to any person or vessel due to the transiting of this area by the U.S.S. JOHN F. KENNEDY and the restrictive size of the channels which will not allow any other traffic during the times indicated above:

"The waters of Boston Harbor including the East and West Parts of the Boston North Channel as far north as Finns Ledge (42-22-12N & 70-55-12W), that part of President Roads west of 70-56W and north of 42-19-52N (excluding anchorage 2) and the Boston Main Channel east of 71-02W."

No person or vessel shall remain in or enter this security zone without permission of the Captain of the Port.

The Captain of the Port, Boston, Mass., shall enforce this order. In the enforcement of this order, the Captain of the Port may utilize, by appropriate agreement, personnel and facilities of any other Federal agency, or of any state or political subdivision thereof.

For violation of this order, section 2 of title II of the Espionage Act of June 15, 1917 (40 Stat. 220 as amended, 50 U.S.C. 192), provides:

"If any owner, agent, master, officer, or person in charge, or any member of the crew of any such vessel fails to comply with any regulation or rule issued or order given under the provisions of this chapter, or obstructs or interferes with the exercise of any power conferred by this chapter, the vessel, together with her tackle, apparel, furniture, and equipment, shall be subject to seizure and forfeiture to the United States in the same manner as merchandise is forfeited for violation of the customs revenue laws; and the person guilty of such failure, obstruction, or interference shall be punished by imprisonment for not more than 10 years, and may, in the discretion of the court, be fined not more than \$10,000.

"(a) If any other person knowingly fails to comply with any regulation or rule issued or order given under the provisions of this chapter, or knowingly obstructs or interferes with the exercise of any power conferred by this chapter, he shall be punished by imprisonment for not more than 10 years and may, at the discretion of the court, be fined not more than \$10,000."

Dated: July 30, 1970.

R. E. HAMMOND,
Rear Admiral, U.S. Coast Guard,
Chief, Office of Operations.

[F.R. Doc. 70-10074; Filed, July 31, 1970;
8:51 a.m.]

National Transportation Safety Board
[Docket No. SS-H-10]

**INVESTIGATION OF CHARTERED BUS
CRASH NEAR NEW SMITHVILLE,
PA.**

Notice of Hearing

In the matter of investigation of the Chartered Bus Crash on U.S. Route 22, (I-78), near New Smithville, Pa., on July 15, 1970.

Notice is hereby given that a Highway Accident Investigation Hearing on the above matter will be held commencing at 9 a.m. e.d.t., on Tuesday, September 22, 1970, in the South Room of the Holiday Inn-West, located on U.S. Route 22 at U.S. Route 309, Allentown, Pa.

Dated this 27th day of July 1970.

For the Board.

[SEAL] FRANCIS H. McADAMS,
Chairman, Board of Inquiry.

[F.R. Doc. 70-9959; Filed, July 31, 1970;
8:46 a.m.]

**FEDERAL COMMUNICATIONS
COMMISSION**

[Dockets Nos. 18737, 18738; FCC 70R-258]

**MEYER BROADCASTING CO. AND
HARRISCOPE BROADCASTING CORP.
Memorandum Opinion and Order**

**Memorandum Opinion and Order
Enlarging Issues**

In regard applications of Meyer Broadcasting Co., Glendive, Mont., Docket No. 18737, File No. BPTTV-3723; Harriscope Broadcasting Corp., Glendive, Mont., Docket No. 18738, File No. BPTTV-3758; for construction permit for new television broadcast translator station.

1. This proceeding involves the mutually exclusive applications of Meyer Broadcasting Co. (Meyer) and Harriscope Broadcasting Corp. (Harriscope) for permits to construct a new 100-watt VHF television broadcast translator station on Channel 9 at Glendive, Mont. Meyer proposes to rebroadcast the signals of its Station KUMV-TV, Channel 8, Williston, N. Dak.; and Harriscope proposes to rebroadcast the signals of its Station KULR-TV, Channel 8, Billings, Mont. By memorandum opinion and order, FCC 69-1226, 20 FCC 2d-532, released November 14, 1969, the Commission designated the applications for hearing on three comparative issues.¹ Presently before the Review Board is a petition to enlarge issues, filed April 21, 1970, by Meyer,² requesting the addition

¹ The designated issues are:

1. To determine, on a comparative basis, which of the proposals would better meet the programming tastes, needs, and interests of the community.

2. To determine which of the applicants offers the better prospect for eventual construction and operation of a regular television broadcast station on the channel in Glendive.

3. To determine which of the proposals would better serve the public interest, convenience, and necessity.

4. To determine, in the light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

² Also before the Review Board are: (a) opposition, filed May 25, 1970, by Harriscope; (b) Broadcast Bureau's comments, filed May 25, 1970; (c) reply, filed June 1, 1970, by Meyer; and (d) supplemental information to petition to enlarge issues, filed July 6, 1970, by Meyer.

of a comparative issue to determine which of the proposals would provide the most reliable signal from the originating station to the proposed TV translator stations.

2. Meyer concedes that its petition is not timely under § 1.229 of the Commission's rules and requests that the rule be waived. In support of a waiver, Meyer submits the following: In the designation order, the Commission directed that "the issues and conduct of the hearing are to be governed by the principles * * * set out in the Montana Network, 9 FCC 2d 705, 10 RR 2d 1104 [(1967)] and WLUC, Inc., 13 FCC 2d 406, 13 RR 2d 508 [(1968)]." Beyer states that the issues in this proceeding are identical with those specified by the Commission in The Montana Network case. Petitioner further contends that in The Montana Network case evidence was adduced at the hearing and findings of fact and conclusions of law were made by the Hearing Examiner with respect to the technical engineering factors affecting the reception of the signal by the TV translators from the originating stations and to reception conditions over the areas in question.³ Meyer states that at the March 31, 1970, hearing session in this proceeding, it submitted evidence purporting to show the nature and quality of the signals which would be provided by each of the applicants to the city of Glendive. The Hearing Examiner ruled that such evidence was not within the scope of the existing issues, and that Meyer could request an enlargement of the issues in order to determine which applicant would provide the most reliable service to Glendive. Relying upon its interpretation of the principles in The Montana Network, supra, and the engineering evidence accepted therein, Meyer explains that it did not timely petition the Commission for enlargement of issues as prescribed by § 1.229. As to the merits of its request, Meyer submits that its translator station will receive KUMV-TV's signal on a one-hop basis over a distance of 75.5 miles, while the Harriscope proposal requires transmission over a path distance of more than 209 miles, necessitating relays of four separate hops. The hearing exhibits originally offered by Meyer and a sworn engineering statement are attached to the petition to support Meyer's contentions. Petitioner contends, with regard to Harriscope's proposal, that the terrain over which these signals are directed is extremely rugged and mountainous and that line-of-sight transmission does not exist on any hop with the exception of a marginal situation for the path between Miles City and Terry (third leg). Meyer asserts that considering the nature of the terrain, the large distances between transmitters and receivers, and the comparatively low power of the translators for the four-hop system, very low signal strengths can be expected at the relay

³ The initial decision (FCC 68D-14, released Feb. 21, 1968, 12 FCC 2d 396, 12 RR 2d 1265) became effective Apr. 11, 1968, pursuant to § 1.276.