

the Fish and Wildlife Act of 1956, as amended (16 U.S.C. 742c) and reorganization plan No. 4 of 1970 (35 F.R. 15627), a mortgagor is required to obtain, among other things, hull insurance satisfactory to the Secretary of Commerce. Some of the basic requirements as respects the hull insurance coverage are that (a) the United States of America be the sole loss payee; (b) the vessel be insured for its full commercial value but in no event less than 110 percent of the outstanding balance of the note secured by the mortgage; and (c) the policy contain satisfactory Inchmaree and breach of warranty clauses. In the past, as a service to our borrowers and to potential borrowers, the interested public was notified that the Commercial Fishermen's Inter-Insurance Exchange had a master hull policy which, both in form and substance, met the requirements of our mortgage. This notice was merely informational and did not require the utilization of said master hull policy. This master hull policy expires on January 1, 1973.

The National Marine Fisheries Service in fulfilling its obligations under the Fish and Wildlife Act of 1956, as amended and reorganization plan No. 4 of 1970, desires to again notify the interested public of the existence of any master hull policies which may be available to commercial fishing vessel owners or operators whose vessels serve as collateral for fisheries loans. The name of any qualifying insurance company submitting a master hull policy, found acceptable for use in connection with the National Marine Fisheries Service lending program, will be placed in an informational release along with the applicable premium charges. While this release will be distributed to the interested public there will be no compulsion that a borrower utilize any master hull policy listed in such release.

Notice is hereby given of the intent to issue a request for such proposals. Interested persons may submit written comments, suggestions, or objections with respect to this request for proposals to the Director, National Marine Fisheries Service, Department of Commerce, Washington, D.C. 20235, by December 31, 1972.

PHILIP M. ROEDEL,
Director.

[FR Doc.72-21472 Filed 12-13-72; 8:47 am]

Judy Bryant
**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Food and Drug Administration

MANUFACTURERS AND DISTRIBUTORS

**Notice of Prescription Drugs for Human
Use Affected by Drug Efficacy Study
Implementation**

Initially all National Academy of Sciences-National Research Council re-

ports on prescription drugs for human use have been evaluated by the Food and Drug Administration and published in the FEDERAL REGISTER, and the remainder will appear shortly. This notice will inform manufacturers and distributors of prescription drugs for human use affected by the drug efficacy study about the future implementation schedule for this program.

1. On October 11, 1972, Judge William B. Bryant of the U.S. District Court for the District of Columbia entered the following order in the case of Civil No. 1847-70:

Pursuant to this court's memorandum and order entered August 23, 1972, it is hereby ordered that:

I. Defendants shall release and make available to the public immediately all reports of the National Academy of Sciences-National Research Council (NAS-NRC) relating to the effectiveness of drugs approved for marketing between 1938 and 1962, which have previously been received by the Food and Drug Administration and not heretofore released, and shall release all such reports received in the future immediately upon receipt.

II. Defendants shall proceed expeditiously, using available resources and personnel to the maximum extent feasible consistent with its other obligations under the law, to complete implementation of the drug effectiveness review with respect to human drugs as soon as possible.

III. Within 120 days from the date of this order, defendants shall evaluate all NAS-NRC reports for drugs not previously evaluated, and publish in the FEDERAL REGISTER an evaluation of each product as "effective," or "less than effective." For purposes of setting implementation priorities, each "less than effective" drug shall be further classified as "probably effective," "possibly effective," or "ineffective" for each of its multiple indications. For a drug with multiple indications, overall classification of the drug shall depend on the highest evaluation given to any one of its multiple indications. Defendants may defer such evaluation for a limited number of drugs where further clarification from the NAS-NRC is requested or where further consultation with outside experts is pursued; in these situations a report shall be filed with the court which shall be available for public inspection, and evaluation shall proceed as rapidly as is feasible.

IV. Defendants shall, beginning immediately, proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "ineffective," in accordance with the following procedures, priorities, and time limitations: A. For each drug subject to paragraph III which is classified as "ineffective," a notice of opportunity for hearing on a proposal to withdraw approval of the new drug application or form 5 for such drug shall be published in the FEDERAL REGISTER concurrently with the publication on that evaluation.

B. Within 60 days from the date of this order, a notice of opportunity for hearing shall be published for all drugs previously classified in an evaluation published in the FEDERAL REGISTER as "ineffective" but for which such a notice has not yet been published, unless a review of new data or information results in reclassification of the drug. If the drug is reclassified, an appropriate notice shall be published in the FEDERAL REGISTER and implementation with respect to the drug shall be handled as set out below.

C. With respect to each drug previously classified as "ineffective" and for which a notice of opportunity for hearing has already been published in the FEDERAL REGISTER, a final order shall be published in the FEDERAL REGISTER ruling on such notice as follows:

(1) Within 60 days from the date of this order, where no request for hearing has been filed in response to the notice of opportunity for hearing within the statutory time limit or where a request for hearing is supported by no data or information whatever; and

(2) Within 150 days from the date of this order, where a request for hearing supported by data and information has been filed in response to such proposal.

D. Within 12 months of this order, for a drug determined to be "ineffective" and for which a notice of opportunity for hearing has been published pursuant to paragraphs IV (A) and (B) of this order, a final order shall be published in the FEDERAL REGISTER ruling upon such request for hearing.

E. Work on administrative hearings and on court actions with respect to withdrawal of new drug applications and form 5's for drugs classified as "ineffective" and removal of other marketed drugs covered by such applications and form 5's shall take precedence over work on drugs classified as "possibly" or "probably effective" or as "effective."

V. Defendants shall proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "possibly effective," in accordance with the following procedures, priorities, and time limitations:

A. Within 15 months of this order a notice of opportunity for hearing shall be published in the FEDERAL REGISTER.

B. Within 30 months of this order a final order ruling on any request for hearing filed within the statutory time limit in response to a notice under subparagraph A above shall be published in the FEDERAL REGISTER.

C. Work on administrative hearings and on court actions with respect to withdrawal of new drug applications and form 5's for drugs classified as possibly effective and removal of other marketed drugs covered by such applications and form 5's shall take precedence over work on drugs classified as "probably effective" or as "effective."

VI. Defendants shall proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "probably effective" in accordance with the following procedures, priorities, and time limitations:

A. Within 33 months of this order a notice of opportunity for hearing shall be published in the FEDERAL REGISTER.

B. Within 42 months of this order a final order ruling on any request for hearing filed within the statutory time limit in response to a notice under subparagraph A above shall be published in the FEDERAL REGISTER.

C. Work on administrative hearings and on court actions with respect to withdrawal of new drug applications and form 5's for drugs classified as "probably effective" and removal of other marketed drugs covered by such applications and form 5's shall take precedence over work on drugs classified as "effective."

VII. Defendants shall proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "effective" but with one or more less than effective indications pursuant to 21 U.S.C. 355(e) in accordance with the following procedures, priorities, and time limitations:

A. Within 45 months of this order and after a refusal to delete all less than effective indications a notice of opportunity for hearing shall be published in the FEDERAL REGISTER.

B. Within 48 months of this order a final order ruling on the request for hearing filed within the statutory time limit in response to a notice under subparagraph A above shall be published in the FEDERAL REGISTER.

VIII. Defendants may implement the drug effectiveness review with respect to any specific "possibly effective" or "probably effective" or "ineffective" drug not in accordance with the priorities established in paragraphs IV-VII where public health considerations or administrative efficiency justify such action.

IX. An order to withdraw the drugs shall be issued concurrently with any denial of a request for a hearing made under paragraphs IV(C), IV(D), V(B) of this order. Defendants may grant a stay of such order in appropriate cases.

X. Defendants shall not grant any extension of time for any request for a hearing or other response to a notice of opportunity for hearing.

XI. Any notice of opportunity for hearing shall permit any person with an interest in an identical, related or similar product which is covered by the new drug application or antibiotic monograph an opportunity to submit data and information on the effectiveness of the drug and a statement why the new drug application or form 5 should not be withdrawn and/or why a hearing should be held to consider the matter.

XII. Defendants shall schedule and conduct administrative hearings, when required by 21 CFR 130.14(B), as expeditiously as practicable.

XIII. Upon withdrawal of a new drug application or form 5, defendants shall make a good faith effort to find all identical, related, or similar products which are covered by the new drug application or antibiotic monograph and shall proceed to remove them from marketing as expeditiously as possible.

XIV. A limited number of drugs may remain on the market pending completion of scientific studies to determine effectiveness where there is a compelling justification of the medical need for the drug. Such justification shall be made by defendants in writing, shall be filed with the court, and shall be available for public inspection.

XV. Over-the-counter human drugs which are the subject of NAS-NRC reports shall be reviewed and handled pursuant to the procedure established in the FEDERAL REGISTER of May 11, 1972 (37 F.R. 9464 et seq.).

XVI. This order does not affect the interim labeling and advertising requirement imposed by the Food and Drug Administration in the FEDERAL REGISTER of June 8, 1971 (36 F.R. 11022) and February 12, 1972 (37 F.R. 3175).

XVII. Six months after the date of this order, and every 6 months thereafter until completion of the implementation of the drug effectiveness review, a report on the actions implementing this order shall be submitted to this court and shall be available for public inspection.

Such reports shall include:

(1) Statistical data showing actions taken on each of the various categories of drugs during the previous 6 months and the number of drugs in the various stages of review;

(2) Statistical data on work yet to be accomplished in the drug effectiveness review according to the various categories of drugs and the various stages of review;

(3) The number and kinds of personnel who were assigned to the drug effectiveness review at the start and the conclusion of the previous 6 months and the estimated time each category of personnel spent on the review during this period;

(4) The predicted number and kinds of personnel who will be assigned to the drug

effectiveness review during the next 6 months and the estimated time each category of personnel will spend on the review during this period;

(5) Detailed information concerning any failure to comply with this order and the reasons for this failure; and

(6) Any problems anticipated for the next 6 months in complying with this order and possible methods for overcoming these problems.

XVIII. The Court expressly retains jurisdiction over this proceeding to amend or modify any provisions of this Order as may be required.

WILLIAM B. BRYANT,
Judge.

OCTOBER 10, 1972.

The Food and Drug Administration does not concur in the legality of this order. Because the court order adopts the implementation plan proposed by the Food and Drug Administration and recognizes the administrative flexibility and discretion provided by law to the agency in implementing the Drug Amendments of 1962, however, it has been concluded that no appeal will be taken from the order at this time. The Food and Drug Administration will continue to proceed expeditiously with this program and will make every effort to achieve full compliance with the provisions of the court order.

2. Pursuant to the court order, all oral or written extensions of time previously granted by the Food and Drug Administration under the DESI program, permitting further testing of drugs, are hereby revoked. Manufacturers and distributors of drugs are hereby notified that implementation of the DESI program will generally proceed according to the schedule outlined in paragraphs IV-VII of the court order, but that under paragraph VIII any drug may be the subject of a notice of opportunity for hearing or other appropriate action at any time in the future.

3. Pursuant to paragraph XIV of the court order, the Food and Drug Administration has filed with the court the following list of drugs, together with the justification of medical need, which may remain on the market pending completion of scientific studies to determine effectiveness notwithstanding the other provisions of the court order:

I. CORONARY VASODILATORS (ANTI-ANGINAL DRUGS)

Isordil (isosorbide dinitrate).
Mannitol hexanitrate.
Trolnitrate phosphate.
Pentaerythritol tetranitrate.
Persantine (dipyridamol).

II. PERIPHERAL VASODILATORS

Cyclospasmol (cycloandelate).
Roniacol (nicotinyne tartrate).
Paveril PO₄ (dioxylene phosphate).
Arlidin (nylidrin hydrochloride).

The first four coronary vasodilators, which are administered orally, and the fifth, also administered orally, were found "possibly effective" for prevention of anginal attacks, as published in the FEDERAL REGISTER on February 25, 1972, and February 17, 1971, respectively. Isosorbide dinitrate when administered sub-

lingually was found to be "probably effective" for treatment and prevention of anginal attacks.

The peripheral vasodilators were found possibly effective for symptoms associated with peripheral vascular disease, as published in the FEDERAL REGISTER on July 20, 1971, and September 18, 1970.

It is appropriate that these two classes of drugs be considered as an entity since etiologies are similar. Post mortem examinations have shown that 50 percent of American military casualties, at an average age of 22 years, had gross evidence of atherosclerosis. By age 50 the incidence rises to over 90 percent and nearly 50 percent have marked narrowing of one or more of the main coronary arteries. Heart disease and stroke are the number one cause of death in this country. Morbidity due to peripheral atherosclerosis is comparably high.

Atherosclerosis decreases arterial capacity and, when this becomes inadequate to meet the demand for blood supply, symptoms result. The outstanding symptoms are heart pain (angina pectoris) in the case of coronary artery involvement and leg pain in the case of peripheral vascular disease.

There are no drugs rated as effective for symptoms due to peripheral vascular disease. There are currently no effective drugs for long term prophylaxis of angina pectoris. Nitroglycerin, when given sublingually, is effective in the treatment of an acute attack and to abort an acute attack when given immediately prior to an activity expected to provoke an attack, but there is a definite need for drugs which can be taken orally on a chronic basis to decrease the incidence of attacks over the long term.

Because of the many variables and vagaries characteristic of the disease, complex protocols and studies of years duration are justifiable and necessary to arrive at meaningful data. There is a great need for additional ameliorating therapy of this kind. The use of these drugs will not supplant or distract from the use of effective ones since none are currently proved to be effective. The inherent hazards in the use of these drugs are negligible.

This includes the peripheral vascular drugs listed. It also includes the short acting oral forms of anti-anginal drug formulations (not "sustained release" forms designed to release the active ingredient over a prolonged period) and the sublingual form of isosorbide dinitrate.

III. TOPICAL ANTIBIOTICS

Neomycin, polymyxin and bacitracin (or gramicidin).
Neomycin, polymyxin and bacitracin (or gramicidin) with a steroid.
Chloramphenicol.
Erythromycin.

These topical antibiotics should be permitted to remain on the market pending reevaluation of the published classification or completion of scientific studies to determine effectiveness, since there are no alternatives available other than one which has been approved since 1962.

which resistant organisms have developed frequently.

Neomycin, polymyxin and bacitracin (gramicidin) topical preparations with and without steroid were considered "possibly effective" for infected dermatoses and localized infections, respectively, as published in the FEDERAL REGISTER on June 29, 1972, and June 6, 1972, respectively. Chloramphenicol topical cream was considered "probably effective" for local infections, as published in the FEDERAL REGISTER on November 28, 1970. Erythromycin topical ointment was considered "possibly effective" for the treatment of local infections, as published in the FEDERAL REGISTER on June 17, 1971.

The vast majority of cutaneous bacterial infections are due to staphylococci and streptococci. A small number are due to proteus, pseudomonas and other organisms. If infections with the gram-negative organisms are impetigo-like and not deep and spreading, they may be treated with topical antibiotics because systemically administered agents for these organisms may produce serious side effects. Bacitracin (or gramicidin) and neomycin would be used for most skin infections since they are usually due to staphylococci and streptococci.

See 1/11/73 for correction
CORRECTION from 1-11-73

in the treatment of many of the eczematous dermatoses. Superficial, relatively localized, non-spreading infections imposed on an eczematous derma may be adequately treated with topical antibiotics. Further study of available information is required to determine effectiveness for specific conditions.

IV. COMBINATION OTIC SOLUTIONS OR SUSPENSIONS

- Achromycin Ear Solution (tetracycline HCl and benzocaine).
- Aerosporin Otic Solution (polymyxin B sulfate, propylene glycol and acetic acid).
- Chloromycetin Otic Solution (chloramphenicol and benzocaine).
- Lidosporn Otic Solution (polymyxin B sulfate and lidocaine HCl).
- Vosol (acetic acid, benzethonium chloride and propylene glycol).
- Vosol HC (acetic acid, benzethonium chloride, propylene glycol and hydrocortisone).
- Cortisporin Otic Drops (neomycin, polymyxin, and hydrocortisone).
- Colymycin-S Otic (neomycin, colistin, hydrocortisone).
- Neo-Polycin Otic Suspension (neomycin sulfate-polymyxin B sulfate-dyclonine).
- Neo-Polycin HC Otic Suspension (neomycin sulfate-polymyxin B sulfate-dyclonine-hydrocortisone acetate).
- Florotic Otic Suspension (nystatin-neomycin sulfate-polymyxin B sulfate-fludrocortisone acetate).
- Cor-Otic PN (neomycin sulfate-polymyxin B sulfate-hydrocortisone).
- Bro-Parin (polymyxin B sulfate-neomycin sulfate-heparin sodium-hydrocortisone).
- Terramycin-Polymyxin Otic Powder (oxytetracycline HCl-polymyxin B sulfate-benzocaine-propylene glycol).
- Neomycin-Polymyxin (neomycin sulfate-polymyxin B sulfate).
- Reid (neomycin sulfate-polymyxin B sulfate).
- Pycocidin (polymyxin B sulfate-propylene glycol).

Ratings for these products were published at various times beginning in 1970. They were labeled as "possibly" or "probably effective" for treatment of ear infections.

Otic solutions or suspensions containing one or more anti-infective agents, with or without a steroid or local anesthetic, should be permitted to remain on the market pending reevaluation of the published classification or completion of scientific studies to determine effectiveness, since there are no alternatives available.

Because of the anatomical configuration of the external auditory canal, its dimensions become much smaller when it is infected and inflamed. The quantity of medication which can be instilled is very small. If two or more preparations were to be used separately, much of the medication would not reach the affected area. Many times, the attending physician must use a wick of very small diameter which is kept moist by the application of the medication. If extemporaneously mixed prescriptions were to be used, there would be a decrease in uniformity and sterility, as compared with the currently formulated combinations.

V. NARCOTIC ANALGESIC

Numorphan (oxymorphone hydrochloride) rectal suppository.

This drug was rated as "possibly effective" for moderate to severe pain, as published in the FEDERAL REGISTER of August 26, 1970. This is the only narcotic analgesic with this unique dosage form. This route of administration may serve as a substitute for injections and as a substitute for oral medication, for example, when the patient cannot tolerate oral drugs because of nausea and vomiting.

VI. DIAGNOSTIC AGENTS

Diagnex Blue (azuresin).

This compound was rated as "possibly effective," as published in the FEDERAL REGISTER on October 14, 1971.

Diagnex Blue is an agent for oral administration. It is used as a diagnostic screening test for determining the presence of free hydrochloric acid in the stomach. The only alternative to the Diagnex Blue method is introduction of a tube into the stomach. This involves considerably more time, expense, and patient discomfort, than the "tubeless" Diagnex Blue method. The Diagnex Blue method appears to provide useful information in a significant number of patients who are thus spared the time, expense and discomfort of the tube method.

VII. BLEPHAMIDE (SODIUM SULFACETAMIDE PREDNISOLONE ACETATE, PHENYLEPHRINE HYDROCHLORIDE, POVIDONE) AND RELATED FIXED COMBINATION OPHTHALMIC STEROID-ANTI-INFECTION DRUGS

There were a number of FEDERAL REGISTER publications concerning these combinations, e.g., on July 17, 1971. These combinations were rated as "possibly effective" for their numerous label indications.

It is recommended that this class of drugs be retained on the market pending additional clinical trials because of their apparent singular effectiveness for treatment of marginal keratitis secondary to staphylococcus blepharoconjunctivitis. Other indications in which these combinations appear to be clinically effective are phlyctenular kerato-conjunctivitis, vernal catarrh and allergic conjunctivitis with chronic bacterial conjunctivitis. In addition, such combinations are frequently used by ophthalmologists postoperatively to cut down on inflammatory reactions. It is necessary to establish by clinical trials which particular combinations and concentrations are effective for specific indications.

VIII. AMMONIA DETOXICANT

Modumate (arginine glutamate).

A FEDERAL REGISTER statement was published on June 3, 1971, stating that Modumate was "possibly effective" for use in conditions associated with elevated ammonia levels.

At the present time, there are orally administered drugs which are classified as effective for this particular indication. However, Modumate is parenterally administered and there are no other parenteral drugs specific for this indication. Uncontrolled studies utilizing Modumate indicated that all hepatic coma in acute necrosis, as well as in cirrhosis, responded to this drug. Subsequently, only those patients with hyperammonemia were found to respond. It was the opinion of the NAS/NRC that a use could be found for this drug in patients with cirrhosis who developed deep coma from exogenous ammonia intoxication, i.e., too much dietary protein or diuretic therapy. In such instances, brain damage may be lessened by use of this drug. Further testing is needed to confirm this opinion.

IX. ANTIFIBROTIC

Potaba (potassium aminobenzoate).

A FEDERAL REGISTER statement was published on August 28, 1970, stating that Potaba is possibly effective in the treatment of scleroderma, dermatomyositis, morphea, linear scleroderma, pemphigus, and Peyronie's disease.

At the present time there is no other drug classified as effective for scleroderma (systemic sclerosis), although there is a definite medical need for such. In their evaluation, the NAS/NRC commented that the long-term treatment with Potaba of patients with this disease may be accompanied by softening of the involved skin. The chief investigator in one study (3) stated: "With respect to the antifibrotic response, every patient (more than 135 with systemic sclerosis) but one has shown softening of the involved skin if treatment had been continued for 3 months or longer." Unfortunately, success of this magnitude has not been achieved by other clinicians and investigators. In another study by Lansbury (2), he stated "significant improvement is not to be expected before 3 months of treatment by which time softening of skin and improvement in general well being often occur * * *. From

personal experience we have no doubt that Potaba has a beneficial effect, sometimes striking, on the cutaneous manifestations of scleroderma in many, but not all patients." Other investigators have the impression that the acute inflammatory skin lesions are particularly responsive. A publication by Bushnell (1), based on a pilot study that attempts to apply the double-blind technique, with periodic objective clinical measurements, apparently documents gradual increase in skin mobility in patients receiving Potaba. Further testing is needed to show effectiveness.

REFERENCES

1. Bushnell, W. J., G. J. Galens, L. E. Bartholomew, G. Thompson, and I. F. Duff. The treatment of progressive systemic sclerosis: a comparison of para-amino-benzoate and placebo in a double-blind study. *Arthritis-Rheum*, 9:495-496, 1966 (Abstract).
2. Lansbury, J., and R. R. Joseph. Scleroderma calcinosis, serum sickness, erythema nodosum, Henoch-Schönlein purpura. In J. L. Hollander, Ed. *Arthritis and Allied Conditions*. (7th Ed.) Philadelphia: Lea and Febiger, 1966.
3. Zarafonitis, C. J. D. Antifibrotic therapy with Potaba. *Amer. J. Med. Sci.* 248:550-561, 1964.

X. ANABOLIC STEROIDS

Stanozolol.	Nandrolone	Phen-
Oxymetholone.	propionate.	
Methandrostenolone.	Norethandrolone.	
Nandrolone Decano-		
ate.		

A FEDERAL REGISTER statement was published on June 24, 1970, stating that these drugs are probably effective as adjunctive therapy in the treatment of senile and post-menopausal osteoporosis, and in pituitary dwarfism (until growth hormone is more available).

At the present time there are no other drugs classified as effective for these conditions, although there is definite need for such. In their evaluation the NAS/NRC commented that no single agent has been defined as being effective in treating postmenopausal and senile osteoporosis. The panel also noted that there is little evidence of unanimity of opinion regarding the therapy of osteoporosis. The use of hormones in treatment of osteoporosis is without value as a primary therapy and good general health-promoting measures. The NAS/NRC also ~~commented that there is sufficient evidence that all anabolic agents advance bone age. These agents may be used in selection cases of growth failure with extreme caution, and in pituitary dwarfism until growth hormone is more available. Further testing is needed to demonstrate effectiveness.~~

XI. PARENTERAL MULTIVITAMIN PRODUCTS

Breonex L.	Injectable.
Injectable.	Vi-Syneral
Breonex M	Injectable.
Injectable.	Manibee Injectable.
Becylsy ¹ Injectable.	Manibee-C 500
Parbexin Injectable.	Injectable.
Berocca-C	Betolake Improved
Injectable.	Injectable.
Berocca-C 500	M.V.I. Injectable.
Injectable.	Soluzyme Injectable.
Folbesyn	

These parenteral multivitamins have been declared "ineffective" as currently formulated in a FEDERAL REGISTER statement dated February 27, 1972. Because of the critical medical importance of parenteral multivitamins in preventing or treating hypovitaminosis in certain disease states or postoperative conditions, the lack of any alternative drugs for this purpose, and the fact that the only issue involved is the precise formulation that is appropriate for these products, these products should remain on the market until appropriate reformulation can be agreed upon by experts.

XII. GUANIDINE

A FEDERAL REGISTER announcement published March 27, 1970, declared this drug product ineffective for the claimed indication (myasthenia gravis). However, the NAS/NRC panel commented that this product may be valuable in the palliative treatment of the Eaton-Lambert Syndrome (Myasthenia Syndrome associated with cancer). Although this has not as yet been verified, this drug product remains on the market as an interim measure because there is no other available product for the treatment of this rare and serious syndrome.

Every manufacturer or distributor of one of these drugs, or of an identical, related, or similar product, who has not already begun the studies required to demonstrate effectiveness, or who has begun studies but has not yet discussed the protocols with the Food and Drug Administration, is required to meet with the Food and Drug Administration within 30 days from the publication date of this notice to discuss and agree to undertake the studies necessary to justify continued marketing of the product.

Any interested person may petition the Commissioner of Food and Drugs to add a drug to, or remove a drug from, this list. Any such petition shall include medical evidence and analysis relating to the uniqueness of the drug or lack thereof, the availability of safe and effective alternative drugs or lack thereof, or other compelling justification of the medical need for the drug or lack thereof. No drug product or indication will be permitted to remain on the market pursuant to paragraph XIV of the court order unless the Food and Drug Administration concludes that the manufacturer or distributor is conducting whatever studies are adequate and appropriate to show its safety and effectiveness.

4. In accordance with paragraphs XI and XIII of the court order, and 21 CFR 130.40 (37 F.R. 23185, October 31, 1972), any person with an interest in a product that is identical, related, or similar to a drug reviewed in a DESI notice or notice of opportunity for hearing shall have an opportunity to submit data and information on the effectiveness of the drug and a statement why the new drug application should not be withdrawn and/or why a hearing should be held to consider the matter. If a hearing is held, all such interested persons shall have an opportunity to participate as a party. All prior notices have been so construed and applied.

5. Any provisions in any prior notice published by the Food and Drug Administration or in any oral or written communication from the Food and Drug Administration which are not in accord with the court order and with this notice are hereby revoked.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701, 52 Stat. 1052-1053, as amended; 21 U.S.C. 355, 371), the Administrative Procedure Act (5 U.S.C. 553, 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: December 11, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-21556 Filed 12-13-72; 8:51 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. D-72-211]

ASSISTANT SECRETARY FOR ADMINISTRATION

Delegation of Authority Regarding Administrative Settlement of Ir- regularities in Accountable Officers' Accounts

SECTION A. *Authority delegated.* The Assistant Secretary for Administration is authorized to exercise the authority of the Secretary of Housing and Urban Development under the provisions of 7 GAO 28.14 with respect to resolving, by administrative action, irregularities in accountable officers' accounts. This authority does not apply to exceptions or charges raised by the General Accounting Office.

SEC. B. *Authority to redelegate.* The Assistant Secretary for Administration may redelegate the authority in section A to subordinates. This delegation supersedes the previous unpublished delegation effective April 15, 1972.

(Sec. 7(d), Department of HUD Act, 42 U.S.C. 3535(d))

Effective date. This revised delegation of authority shall be effective as of November 15, 1972.

GEORGE ROMNEY,
Secretary of Housing
and Urban Development.

[FR Doc.72-21525 Filed 12-13-72; 8:50 am]

[Docket No. D-72-210]

ASSISTANT SECRETARY FOR ADMINISTRATION

Delegation of Authority Regarding Irregularities in Accountable Offi- cers' Accounts GAO

SECTION A. *Authority delegated.* The Assistant Secretary for Administration is authorized to exercise the authority of