

If you have further questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Lisa Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control 355 East Paces Ferry Road, NE., Mailstop E-14, Atlanta, GA 30305, (404) 842-6796. Programmatic technical assistance will be provided by Ted Jones, Project Officer, Division of Injury Control, National Center for Environmental Health and Injury Control, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F-36, Atlanta, Georgia 30333, (404) 488-4285.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone (202) 783-3238).

Copies of Position Papers from The Third National Injury Control Conference "Setting the National Agenda for Injury Control in the 1990's"; Injury in America: Injury Prevention: Meeting the Challenge; and Cost of Injury may be obtained by calling (404) 488-4662.

Dated: April 23, 1992.

Robert L. Foster,

Acting Director, Office of Program Support,
Centers for Disease Control.

[FR Doc. 92-3945 Filed 4-28-92; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 76N-0110; DESI 11802]

Certain Oral Drug Products for Human Use Containing Potassium Chloride, Alone or in Combination With Other Drugs; Withdrawal of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug application (NDA) for an oral drug product containing potassium chloride held by Eli Lilly and Co. (Lilly), and the NDA's for oral drug products containing potassium chloride in fixed combination with other drugs (diuretics and/or antihypertensives) held by E. R. Squibb and Sons (Squibb). The basis for the withdrawal is that these potassium chloride drug products are not shown to

be safe and, in addition, the combination drug products lack substantial evidence of effectiveness. Both Lilly and Squibb have withdrawn their requests for a hearing on their products.

EFFECTIVE DATE: May 29, 1992.

ADDRESSES: Requests for an opinion of the applicability of this notice to a specific product should be identified with DESI No. 11802 and directed to the Division of Drug Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Megan L. Foster, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-3041.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of April 8, 1978 (41 FR 14568), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research) offered an opportunity for a hearing on a proposal to withdraw approval of the following NDA's for solid oral dosage forms of potassium salt, alone or in fixed combination with other active ingredients, that supply 100 milligrams (mg) or more of potassium per dosage unit:

NDA 11-302 for Rautrax Tablets containing flumethiazide, potassium chloride, and rauwolfia serpentina; E. R. Squibb and Sons, P. O. Box 4000, Princeton, NJ 08540.

NDA 12-183 for Naturetin W/K Tablets containing bendroflumethiazide and potassium chloride; Squibb.

NDA 12-243 for Di-Ademil-K 25-625 Tablets and Di-Ademil-K 50-625 Tablets containing hydroflumethiazide and potassium chloride; Squibb.

NDA 12-244 for Rautrax Improved Tablets and Rautrax Improved 25 Tablets containing hydroflumethiazide, potassium chloride, and rauwolfia serpentina; Squibb.

Those parts of NDA 12-320 that provide for Rautrax-N Modified Tablets and Rautrax-N Tablets containing bendroflumethiazide, potassium chloride, and rauwolfia serpentina; Squibb.

NDA 16-286 for Potassium Chloride Enseais; Eli Lilly and Co., P.O. Box 613, Indianapolis, IN 46206.

The Director evaluated these products as unacceptable based on a benefit/risk assessment. The Director found that new reports of small-bowel lesions

associated with the use of concentrated solid oral dosage forms of potassium salt coupled with the availability of alternative methods for prophylaxis or treatment of potassium depletion rendered these products no longer shown to be safe. In addition, the Director concluded that the potassium salt combination drug products lack substantial evidence of effectiveness because they do not satisfy the requirements for fixed-combination prescription drugs as described in 21 CFR 200.50. The Director noted that, because potassium loss is variable in patients, the dose of potassium must be individualized, and this is not possible with the fixed-combination drug products.

In response to the 1978 notice, Squibb and Lilly requested hearings. Recently, both Squibb and Lilly discontinued the manufacture and distribution of the drug products listed above, requested withdrawal of approval of the NDA's, and withdrew their hearing requests. Accordingly, the Director of the Center for Drug Evaluation and Research is withdrawing approval of the NDA's for these products.

Any drug product that is identical, related, or similar to the drug products named above and is not the subject of an approved NDA is covered by the NDA's reviewed and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance (address above).

The Director of the Center for Drug Evaluation and Research, under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to him (21 CFR 5.82), finds that, on the basis of: (1) New evidence of clinical experience, not contained in the applications or not available to him until after the applications were approved, evaluated together with the evidence available to him when the applications were approved, shows that the drugs listed above are not shown to be safe for use under the conditions of use on the basis of which the applications were approved; and as to the potassium salt combination drug products only (2) new information before him with respect to the drugs, evaluated together with the evidence available to him when the applications were approved, there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, pursuant to the foregoing findings, approval of NDA 11-302, NDA 12-183, NDA 12-243, NDA 12-244, those parts of NDA 12-320 described above, and NDA 18-288 is hereby withdrawn, effective May 29, 1992.

Shipment in interstate commerce of the products listed above or any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: April 13, 1992.
[FR Doc. 92-3894 Filed 4-28-92; 8:45 am]
BILLING CODE 4160-01-M

Health Resources and Services Administration

National Organ Transplant Act; Grants to Increase Organ Donation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of grant funds.

SUMMARY: The Health Resources and Services Administration (HRSA), announces that fiscal year (FY) 1992 funds are available for grants for assistance to Organ Procurement Organizations (OPs) and other nonprofit private entities to increase organ donation. The grants are authorized by sections 371 and 374 of the Public Health Service (PHS) Act, as amended. Funds are appropriated under Public Law 102-170.

DATES: To receive consideration, grant applications must be received by the close of business on or before June 29, 1992.

Applications will meet the deadline if they are either: (1) Received on or before the deadline date; or (2) postmarked on or before the deadline date and received in time for submission to the review committee. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be acceptable as proof of timely mailing. Hand delivered applications must be received by 5 p.m. on or before June 29, 1992. Applications received after the deadline will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Additional information relating to technical or program issues may be obtained from Mr. Remy Aronoff, Chief, Operations and Analysis Branch, Division of Organ Transplantation, Parklawn Building, room 11A-22, 5600 Fishers Lane, Rockville, Maryland 20857, 301-443-7577. Grant applications and additional information regarding business, administrative or fiscal issues

related to the awarding of grants under this Notice may be requested from the Grants Management Officer (GMO), Ms. Gienna Wilcom, Parklawn Building, room 13A-38, 5600 Fishers Lane, Rockville, Maryland 20857, 301-443-2290. Applicants for grants will use Form PHS 5161-1, approved under OMB Control Number 0937-0189. Completed applications should be sent to the GMO.

SUPPLEMENTARY INFORMATION:

Background and Objective

Section 371 of the Public Health Service (PHS) Act authorizes a program of grants and special projects for the purpose of increasing the number of organ donors. Organ procurement organizations and nonprofit private entities are eligible to receive grant awards to increase organ donation.

The Public Health Service urges applicants to submit work plans that address specific objectives of Healthy People 2000. Potential applicants may obtain a copy of Healthy people 2000 (Full Report; Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, 202-783-3238.

Types of Grants and Program Priorities

The principal purpose of this grant program is to increase the availability of organ donors in this country by improving both public education regarding organ donation and the overall organ procurement system. To accomplish the objective of increasing organ donors, grants will be awarded to OPOs and nonprofit private entities consistent with the statute as specified in this Notice. There will be two categories of grants: (A) Those that are national in their immediate application or scope and (B) those that focus on and will be applied or tested in a local area. National grants may be funded for as much as \$150,000; local grants may be funded for up to \$50,000.

Examples of category A grants are:

1. Education programs to recruit into the transplantation field minority nurses, social workers, physician assistants, and members of other professional groups from which transplant and procurement coordinators and educators are recruited. The objective would be to increase the number of minorities who are familiar with organ procurement as a specialty and who would be qualified candidates for organ procurement and community education positions. Activities that should be considered for such projects are (1) development of

training programs in conjunction with professional associations' annual conferences or (2) internships for trainees with organ procurement organizations.

2. Development of initial activities of a national campaign to increase organ donation. These activities must be coordinated with organizations currently involved in donor awareness efforts including such organizations as the Association of Organ Procurement Organizations and the United Network for Organ Sharing.

3. Conducting seminars with pre-medical, medical, nursing and hospital administration students in Historically Black Colleges and Universities to provide them with appropriate information about organ donation and transplantation.

4. Development of a monograph on minority organ donation specifically directed to black clergy, followed by a series of church workshops for black clergy interested in promoting organ donation.

5. A study of the variety of reasons that transplant centers choose to recruit or not recruit living related kidney donors. The study would include information from transplant centers with both high and low proportions of living donors.

6. A study of the question of whether, and to what extent, donor families or insurers are being charged for hospital and/or funeral expenses incurred because of the donation process.

Examples of category B grants are:

1. Consolidation of organ and tissue recovery programs in order to increase efficiency in procurement efforts and services to donor hospitals. In some areas there is dysfunctional competition among recovery organizations.

2. Demonstration programs designed to test new approaches to the organ donation process. Such programs might include the application of more effective managerial techniques for the administration of organ procurement organizations, or expanded educational efforts designed to increase the number of organ donors.

3. Demonstration programs to increase black and/or Hispanic donation. Minority donation rates are lower than the minority representation in the total population.

4. Development, implementation and evaluation of a campus-wide campaign to increase awareness and information about organ donation and transplantation among students and alumni of Historically Black Colleges and Universities. The contact points in such a project could include classrooms.

product will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

Therefore, pursuant to the foregoing finding, approval of that part of new drug application 10-528 providing for the drug product described above, and all amendments and supplements applying thereto, is withdrawn effective August 10, 1977.

Shipment in interstate commerce of the above listed product or of any identical, related, or similar product, not the subject of an approved new drug application, will then be unlawful.

Dated: July 20, 1977.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 77-21914 Filed 7-28-77; 8:45 am.]

[Docket No. 76N-0403; DESI 11250]

ARGININE GLUTAMATE

Withdrawal of Approval of New Drug Application

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice withdraws approval of the new drug application described below for arginine glutamate on the basis of lack of substantial evidence of effectiveness for its labeled indications. The drug has been used in conditions associated with elevated blood ammonia levels.

DATE: August 10, 1977.

ADDRESSES: Requests for opinion of the applicability of this notice to a specific product should be identified with the reference number DESI 11250 and directed to: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of January 25, 1977 (42 FR 4536), the Director of the Bureau of Drugs offered an opportunity for hearing on the proposal to issue an order withdrawing approval of the following product:

NDA 11-640: Modumate Solution for Injection containing arginine glutamate; Abbott Laboratories, 14th and Sheridan Rd., North Chicago, IL 60064.

All drug products that are identical, related, or similar to the drug product

named above, not the subject of an approved new drug application, are covered by the new drug application reviewed and are subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific drug product is covered by this notice should write to the Division of Drug Labeling Compliance (address given above).

Neither the holder of the application nor any other person filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to him (21 CFR 3.82), finds that on the basis of new information before him with respect to the drug product, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, pursuant to the foregoing finding, approval of new drug application 11-640 providing for the drug product named above, and all amendments and supplements applying thereto is withdrawn, effective August 10, 1977.

Shipment in interstate commerce of the above product or of any identical, related, or similar product, not the subject of an approved new drug application, will then be unlawful.

Dated: July 20, 1977.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 77-21914 Filed 7-28-77; 8:45 am.]

[Docket No. 76N-0110; DESI 11802]

CERTAIN SOLID DOSAGE FORMS OF ORAL POTASSIUM SALT DRUG PRODUCTS

Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice withdraws approval of the new drug applications described below for oral potassium salt drug products containing 100 milligrams or more of potassium per dosage unit on the basis of an unfavorable benefit-to-risk ratio.

DATES: Effective August 8, 1977.

ADDRESSES: Requests for opinion of the applicability of this notice to a specific product should be identified with the reference number DESI 11802 and directed to: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

FURTHER INFORMATION CONTACT:

Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION:

In a notice published in the FEDERAL REGISTER of April 6, 1976 (41 FR 14568), the Director of the Bureau of Drugs offered an opportunity for hearing on the proposal to issue an order withdrawing approval of the drug products described below. The basis of the proposed action was that the benefit-to-risk ratio associated with the use of solid oral dosage forms of potassium salt drug products that supply 100 milligrams or more of potassium per dosage unit is unacceptable in consideration of both the high incidents of nonspecific small-bowel lesions and the availability of acceptable alternative therapy. In addition for those combination drug products containing a thiazide and potassium chloride or a thiazide, potassium chloride, and rauwolfia serpentina the basis of the proposed action is also a lack of substantial evidence that these combination drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling. Since a hearing was not requested concerning the following products, approval of the new drug applications for them is now being withdrawn.

1. NDA 16-281; Potassium Chloride Enteric Coated Tablets; previously marketed by Cooper Laboratories, 300 Fairfield Rd., Wayne, N.J. 07470.

2. NDA 16-285; Potassium Chloride Enteric Coated Tablets; previously marketed by Stanley Drug Products, Inc., Division: Sperry Drug Products, Inc., P.O. Box 3108, Portland, OR 97208.

3. NDA 16-289; Potassium Chloride Emplet; previously marketed by Parke, Davis & Co., Joseph Campau Ave. at the River, Detroit, MI 48232.

4. NDA 16-292; Potassium Chloride Enteric Coated Tablets; Richlyn Laboratories, 3725 Castor Ave., Philadelphia, PA 19124.

5. NDA 16-302; Potaklor Plus Enteric Coated Tablets containing potassium chloride; Kirkman Laboratories, Inc., 924 Northeast 25th Ave., Portland, OR 97232.

6. NDA 16-313; Potassium Chloride Enteric Coated Tablets; Strong Cobb Arner, Inc., subsidiary of ION Pharmaceuticals, 11700 Shaker Blvd., Cleveland, OH 44120.

7. NDA 16-314; Potassium Chloride Enteric Coated Tablets; American Pharmaceutical Co., Inc., P.O. Box 448, Passaic, N.J. 07055.

In response to the April 6, 1976 notice, requests for a hearing were submitted for the following drug products:

1. NDA 18-802; Rautrax Tablets containing flumethazide, potassium chloride, and rauwolfia serpentina;

2. NDA 12-163; Naturetin with K Tablets containing bendroflumethazide and potassium chloride;

3. NDA 12-243; Di-Ademil-K Tablets containing hydronumethazide and potassium chloride;

NDA 12-244; Baurtrax Improved Tablets
Baurtrax Improved 25 Tablets containing
hydroflumethiazide, potassium chloride, and
rauwolfia serpentina; and

• 5. NDA 12-320; Baurtrax-N Modified Tablets
and Baurtrax-N Tablets containing bendro-
flumethiazide, potassium chloride, and rau-
wolfia serpentina; all marketed by E. R.
Squibb & Sons.

• 6. NDA 16-286; Potassium Chloride En-
seals; Eli Lilly & Co.

• 7. NDA 16-287; Kaon Coated Tablets con-
taining potassium gluconate; Warren-Teed
Pharmaceuticals.

In addition, Dr. W. Gordon Walker of
The Johns Hopkins University submit-
ted data in support of Warren-Teed's
Kaon Coated Tablets. These drug prod-
ucts will be the subject of a subsequent
FEDERAL REGISTER notice and are not
affected by this notice.

All drug products that are identical,
related, or similar to a product named
above, not the subject of an approved
new drug application, are covered by the
new drug applications reviewed and are
subject to this notice (21 CFR 310.6),
except controlled release dosage forms
and those products formulated and
labeled for preparation of solution prior
to ingestion. Any person who wishes to
determine whether a specific drug
product is covered by this notice should
write to the Division of Drug Labeling
Compliance (address given above).

No other persons filed a written ap-
pearance of election as provided by said
notice. The failure to file such an ap-
pearance constitutes election by such
persons not to avail themselves of the
opportunity for a hearing.

The Director of the Bureau of Drugs,
under the Federal Food, Drug, and Cos-
metic Act (sec. 505, 52 Stat. 1052-1053,
as amended (21 U.S.C. 355)), and un-
der authority delegated to him (21
CFR 5.82) finds that, on the basis of
new information before him with re-
spect to these drug products, evaluated
together with the evidence available to
him when the applications were ap-
proved, such drugs are not shown to be
safe for use under the conditions of use
on the basis of which the applications
were approved. In addition, for those
combination drug products containing a
thiazide and potassium chloride or a
thiazide, potassium chloride, and rau-
wolfia serpentina, such combination
drugs lack substantial evidence that
they will have the effect they purport or
are represented to have under the con-
ditions of use prescribed, recommended,
or suggested in their labeling.

Therefore, pursuant to the foregoing
findings, approval of new drug applica-
tions 16-281, 16-285, 16-289, 16-292, 16-
302, 16-313 and 16-314 providing for the
drug products named above (except for
new drug applications 11-802, 12-163,
12-243, 12-244, 12-320, 16-286 and 16-
287 that are the subject of hearing re-
quests), and all amendments and sup-
plements applying thereto, is withdrawn
effective August 8, 1977.

Shipment in interstate commerce of
the above listed products or of any iden-
tical, related, or similar products, not

the subject of an approved new drug
application, will then be unlawful.

Dated: July 20, 1977.

J. RICHARD GROUT,
Director, Bureau of Drugs

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