In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR 310, 314), the applicant(s) and all other persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above (21 CFR 310.6), are hereby given an opportunity for a hearing to show why approval of the new drug application(s) providing for the claim(s) involved should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and all identical, related, or similar drug products.

If an applicant or any person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before August 15, 1974, a written notice of appearance and request for hearing, and (2) on or before September 16, 1974, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 130.14 as published and discussed in detail in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), recodified as 21 CFR 314.200 on March 29, 1974 (39 FR 11680).

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of such drug product. Any such drug product labeled for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A.2 of this notice may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action any time.

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. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk (address given below) during regular business hours, Monday through Friday.

Communications forwarded in response to this announcement should be identified with the reference number DESI 6566, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (HFD-100), Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Generic Drug Staff (HFD-107), Office of Scientific Evaluation, Bureau of Drugs.

Submissions pursuant to the notice of opportunity for hearing (identify with docket number): Hearing Clerk, Food and Drug Administration (HFC-20), Room 6-86, Parklawn Building.

Requests for the Academy's report: Drug Efficacy Information Activity (HFD-8), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Manager (HFD-101), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Director of the Bureau of Drugs (21 CFR 2.121).

Dated: June 8, 1974.

CARL M. LEVENTHAL,
Acting Director,
Bureau of Drugs.

[FR Doc.74-16182 Filed 7-15-74;8:45 am]

[DESI 8922; Docket No. FDC-D-701; NDA 10-573, etc.]

DISODIUM EDETATE INJECTION

Followup Notice and Notice of Opportunity for Hearing

In a notice (DESI 8922) published in the FEDERAL REGISTER of January 13, 1970 (35 FR 437), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs:

1. NDA 10-573; Sodium Versenate Concentrated Solution for preparing intravenous infusion only, containing 1 Gm. of disodium edetate per 5 ml.; Riker Laboratories, 19901 Nordhoff Street, Northridge, Calif. 91324.

2. NDA 11-355; Endrate Disodium, Sterile Solution containing 150 mg. disodium edetate per ml.; Abbott Laboratories, 14th and Sheridan Road, North Chicago, IL 60064.

Disodium Edetate Injection was regarded as effective and less-than-effective (probably effective and possibly effective) for the labeled indications. No new data have been received pursuant to the announcement, therefore the less-than-effective claims are reclassified as lacking substantial evidence of effectiveness. Abbott Laboratories has supplemented their new drug application to delete the less-than-effective claims from their labeling.

Accordingly the previous notice is revised to read as follows, insofar as it pertains to the drug Disodium Edetate Injection.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that:

1. Disodium edetate injection is effective in selected patients, for the emergency treatment of hypercalcemia and for the control of ventricular arrhythmias associated with digitalis toxicity.

2. Disodium edetate injection lacks substantial evidence of effectiveness for all its other labeled indications.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Disodium edetate preparations are in injectable form suitable for intravenous administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indications are:

In selected patients, for the emergency treatment of hypercalcemia and for the control of ventricular arrhythmias associated with digitalis toxicity.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled *Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study,*

published in the FEDERAL REGISTER July 14, 1970 (35 FR 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and an abbreviated supplement for updating information as described in paragraphs (a)(1) (i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold approved or effective new drug application, the submission of an abbreviated new drug application as described in paragraph (a)(3)(i) of that notice.

C. *Notice of opportunity for hearing.* On the basis of all the data and information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111 (a)(5), demonstrating the effectiveness of the drug(s) for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A.2 of this notice.

Notice is given to the holder(s) of the new drug application(s), and to all other interested persons, that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application(s) (or, if indicated above, those parts of the application(s) providing for the drug product(s) listed above) and all amendments and supplements thereto providing for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A.2 of this notice on the ground that new information before him with respect to the drug product(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug product(s) will have all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application(s) supplemented, in accord with this notice, to delete the claim(s) lacking substantial evidence of effectiveness.

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201 (p) of the act, or pursuant to section 107 (c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR 310, 314), the applicant(s) and all other persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above (21 CFR 310.6), are hereby given an opportunity for a hearing to show why approval of the new drug application(s) providing for the claim(s) involved should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and all identical, related, or similar drug products.

If an applicant or any person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before August 15, 1974, a written notice of appearance and request for hearing, and (2) on or before September 16, 1974, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 130.14 as published and discussed in detail in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), recodified as 21 CFR 314.200 on March 29, 1974 (39 FR 11680).

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of such drug product. Any such drug product labeled for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A.2 of this notice may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action any time.

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. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk (address given below) during regular business hours, Monday through Friday.

Communications forwarded in response to this announcement should be identified with the reference number DESI 8922, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (HFD-100), Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Generic Drug Staff (HFD-107), Office of Scientific Evaluation, Bureau of Drugs.

Submissions pursuant to the notice of opportunity for hearing (identify with docket number): Hearing Clerk, Food and Drug Administration (HFC-20), Room 6-86, Parklawn Building.

Requests for the Academy's report: Drug Efficacy Information Activity (HFD-8), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Manager (HFD-101), Bureau of Drugs.

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 the authority delegated to the Director, Bureau of Drugs (21 CFR 2.121).

Dated: July 5, 1974.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.74-16183 Filed 7-15-74;8:45 am]

Office of the Secretary

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

Notice of Meeting

The ninth meeting of the National Professional Standards Review Council, which was established to advise the Secretary of Health, Education, and Welfare on the administration of Professional Standards Review (Title XI, Part B, Social Security Act), will be held Monday, July 22, 1974, 1 p.m. to 5 p.m., and Tuesday, July 23, 1974, 9 a.m. to 1 p.m., in Room 5051, HEW North Building, 330 Independence Avenue SW., Washington, D.C. Professional standards review is the procedure to assure that the services for which payment may be made under the