

NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL

Division of Medical Sciences

DRUG EFFICACY STUDY

1205

1163

Form A

(To be submitted in duplicate by applicant)

1. NDA Number 11355 2. Date Originally Approved April 9, 1959 3. Rx OTC 4. Brand Name ENDRATE (R) DISODIUM5. Applicant's Name Abbott Laboratoriesand Address North Chicago, Illinois

6. Quantitative Formula

Established (Non-Proprietary) Name of Active Ingredients (in order shown on label)

Amount (per tablet, per ~~tablets~~)

List No.

6940 Disodium Edetate 150 mg./ml.

7. Dosage Form (tablets, etc.) Sterile Solution8. Route of Adm. (Oral, etc. Where a new drug application covers different routes of administration, separate forms should be used) I.V.

9. Therapeutic Claims—Attach 10 labels and 10 package inserts (if used) to original Form A (blue) and 1 copy to duplicate Form A (white).

10. List of literature references most pertinent to an evaluation of the effectiveness of the drug for the purposes for which it is offered in the label, the package insert, or brochure. Approximately 5 to 10 key references are requested, if available. (Attach 10 copies to original Form A (blue) and 1 copy to duplicate Form A (white).)

11. The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug to the National Research Council. This supplementary material should be packaged with Form A (white). A single copy of this material is requested.

Please attach to the next page a sufficient and relevant bibliography for evaluation of the drug.

Keech, M.K. et al, Effect of EDEA and Tetrahydroxyquinone on Scleroderatous Skin, Histologic and Chemical Studies, J. Invest. Dermatol., to be published.

A copy of this report is attached to Form A (white).

One copy is original.

The back of this form may be

1163
JUL 1975
100 1200

1163

This drug was evaluated by the following Panels:

1. Panel on Drugs Used in Metabolic Disorders
2. Panel on Drugs Used in Correction of Fluid and Electrolyte Balance
3. Panel on Cardiovascular Drugs (I)
4. Panel on Drugs Used in Rheumatic Diseases

Evaluations follow: