

NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL

Division of Medical Sciences

DRUG EFFICACY STUDY

Form A

(To be submitted in duplicate by applicant)

Reg. No. 146c.231 40.02 EC2
 1. NDA Number _____ 2. Date Originally Approved 4/21/58 3. Rx ☒ OTC ☐
 4. Brand Name Signemycin Capsules 125 mg. and 250 mg., Signemycin 375 Capsules
 5. Applicant's Name Chas. Pfizer & Co., Inc.
 and Address 235 East 42nd Street, New York, New York 10017

6. Quantitative Formula

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

Amount (per tablet, per ml., etc.)

Signemycin Capsules 125 mg.

Signemycin 125 mg. (83 mg. of tetracycline hydrochloride, 42 mg. of oleandomycin as triacetyloleandomycin)

Signemycin Capsules 250 mg.

Signemycin 250 mg. (167 mg. of tetracycline hydrochloride, 83 mg. of oleandomycin as triacetyloleandomycin)

Signemycin 375 Capsules

Signemycin 375 mg. (250 mg. of tetracycline hydrochloride, 125 mg. of oleandomycin as triacetyloleandomycin)

7. Dosage Form (tablets, etc.) Capsules8. Route of Adm. (Oral, etc. Where a new drug application covers different routes of administration, separate forms should be used.) Oral

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 The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council.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

12. In this space, please list and describe briefly the supplementary material that is submitted with Form A (white).

PANEL ON ANTI-INFECTIVE DRUGS (III)

INDICATIONS

I. Signemycin is indicated in the therapy of acute severe infections caused by susceptible organisms and primarily by bacteria more sensitive to the combination than to either component alone.

Evaluation: Ineffective as a fixed combination.

Comments: Although either tetracycline or oleandomycin is effective in the treatment of some infections, there are serious objections to the use of the combination as formulated. Oleandomycin is present in insufficient amounts for effective treatment. If sufficient oleandomycin is administered for effective treatment, tetracycline overdosage results.

The Panel is not aware of infections caused by bacteria more sensitive to this combination than to either of its components.