NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL
Division of Medical Sciences

DRUG EFFICACY STUDY

Form A
(To be submitted in duplicate by applicant)
CD027 E01

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1. NDA Number 146c.231 2. Date Originally Approved October 4, 1956 3. Rx ☒ OTC ☐

4. Brand Name Signemycin (Sigmamycin) Capsules 50,100 and 250 mg.

5. Applicant's Name Chas. Pfizer & Co., Inc.(INTERNATIONAL)

and Address 235 East 42nd Street, New York, New York 10017

6. Quantitative Formula

Established (Non-Proprietary) Name of Active Ingredients (in order shown on label)	Amount (per tablet, per ml., etc.)
50 mg.	
Tetracycline (HCl)	33.3 mg.
Oleandomycin (Phosphate)	16.7 mg.
100 mg.	
Tetracycline (HCl)	66.7 mg.
Oleandomycin (Phosphate)	33.3 mg.
250 mg.	
Tetracycline (HCl)	167 mg.
Oleandomycin (Phosphate)	83 mg.

7. Dosage Form (tablets, etc.) Capsules

8. 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 The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council.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. Sigmamycin 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.