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

DRUG EFFICACY STUDY

Form A
(To be submitted in duplicate by applicant)

1. NDA Number 6D315 (90142) 2. Date Originally Approved September 20, 1963 3. Rx ☒ OTC ☐

4. Brand Name Chloromycetin Sodium Succinate - Infant, 250 mg.

5. Applicant's Name Parke, Davis & Company

and Address Joseph Campau at the River; Detroit, Michigan

6. Quantitative Formula

Established (Non-Proprietary) Name of Active Ingredients (in order shown on label)	Amount (per tablet, per ml., etc.)
Chloramphenicol Sodium Succinate	250 mg. base/vial

7. Dosage Form (tablets, etc.) sterile-vial

8. Route of Adm. (Oral, etc. Where a new drug application covers different routes of administration, separate forms should be used.) parenteral

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 The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council.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