



UNITED STATES
ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION
WASHINGTON, D.C. 20545

Weyzer

4/29/75

J. S. Kirby-Smith, ADILI

PROPOSAL TO STUDY THE EFFECT OF CALCITONIN IN OSTEOPOROTIC PATIENTS

The subject proposal is in essence a Phase III Investigational Drug Study on the efficacy of Calcimar^R--an Armour Pharmaceutical Company product--in osteoporotic females. As I understand it, the primary objective of the study is to collect proprietary information on Calcimar^R in a government supported facility to be used in support of a New Drug Application by Armour to the Food and Drug Administration. There is no indication in the proposal or protocol that the information obtained is intended primarily for public dissemination. In effect, use of a government owned facility would provide one-sided and unfair advantage in drug development to Armour. In view of this, I must recommend against approving BNL's request until the above issue is resolved.

CWE

C. W. Edington
Associate Director for Research
and Development Programs

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