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MAY 6 1975

J. P. Jewett, Area Manager  
Brookhaven Area Office

BNL PROPOSAL ENTITLED "EFFECT OF CALCIMAR<sup>R</sup> (CALCITONIN) IN PATIENTS WITH PRIMARY OSTEOPOROSIS"

The subject proposal, submitted to Headquarters by J. Desmond's April 10 letter, has been reviewed in detail by our technical and scientific staff. Their recommendations for disapproval have also been concurred in by OGC.

As we understand it, the primary objective of the study is to collect proprietary information on Calcimar<sup>R</sup> 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, we are hereby disapproving BNL's request until the above issue is resolved.

Original signed by  
W. W. Burr, Jr., M.D.

James L. Liverman, Director  
Division of Biomedical and  
Environmental Research

cc: J. Desmond, BNL  
bcc: Dr. Edington, BER  
Dr. Wood, BER  
R. Leith, BER

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PTP : PCB  
Wood/Weyzen : Leith  
Simpson/Fish  
1 175 : 515 175

MEDICINE, HEALTH & SAFETY  
MC # 4340

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