

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: April 4, 2000

FROM: Lilia Talarico, M.D.; Director, Division of Gastrointestinal and Coagulation  
Drug Products *Lilia Talarico M.D. 4-4-00*

and  
*Thomas Permutt*  
Thomas Permutt, Ph.D.; Team Leader, Division of Biometrics II

SUBJECT: Background Package for the May 2, 2000 Cardiovascular and Renal Drugs  
Advisory Committee Meeting Regarding NDA 20-807/S-004, Recludan®  
[lepirudin (rDNA) for injection]

TO: Chairperson and Members, Cardiovascular and Renal Drugs Advisory  
Committee

Enclosed is the Division's background package for the May 2 meeting of the Committee in which the application for Recludan® [lepirudin (rDNA) for injection] for anticoagulation in adult patients with acute coronary syndromes (unstable angina and acute MI without ST segment elevations on EKG) submitted by Aventis Pharmaceuticals Incorporated will be discussed. The package consists of the Medical Team Leader's Review dated April 3, 2000 and the Statistical Review and Evaluation dated March 31, 2000. Both are preliminary, subject to supervisory review and comments by the Committee.

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