

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 18118**

**PHARMACOLOGY REVIEW(S)**

NDA 18-118

APR 2 1982

Lanoxicaps brand Digoxin

Burroughs-Wellcome

Review and Evaluation of Pharmacology and Toxicology Data  
Original Summary

Category: cardiac glycoside

Composition: capsules; containing 50, 100 and 200 mcg of digoxin

Indications: Digoxin is indicated for congestive heart failure, atrial fibrillation, atrial flutter, paroxysmal atrial tachycardia, and cardiogenic shock

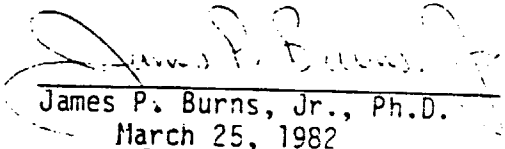
Related NDA: 9-330; Digoxin, injection (Burroughs-Wellcome)

Summary and Evaluation:

The oral form of digoxin (Lanoxin) has been marketed by Burroughs-Wellcome for over 40 years but was not the subject of an NDA since it was marketed prior to 1938. During this time, extensive clinical experience has been accumulated on the pharmacology and toxicology of digoxin. No preclinical data was submitted in the present NDA but in view of the clinical experience with this drug there would be no need for any preclinical studies.

Recommendation:

This NDA would be approvable from Pharmacology.

  
James P. Burns, Jr., Ph.D.  
March 25, 1982

cc: NDA Orig. 18-118  
HFD-110  
HFD-110/CSO  
HFD-110/JBurns/3/25/82  
th/3/26/82/9172A