CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20236/S017

MEDICAL REVIEW(S)

DEC 1 4 1998

MEDICAL OFFICER REVIEW

DIVISION OF PULMONARY DRUG PRODUCTS (HFD-570)

APPLICATION #:	20-236	**APPLICATION TYPE:**	Labeling Supplement
SPONSOR:	Glaxo-Wellcome	**PROPRIETARY NAME:**	Serevent Inhalation Aerosol
CATEGORY OF DRUG:	Long Acting Beta Agonist	**USAN / Established Name:**	Salmeterol xinafoate
		ROUTE:	Inhaled
MEDICAL REVIEWER:	Robert J. Meyer, MD	**REVIEW DATE:**	12-1-98

SUBMISSIONS REVIEWED IN THIS DOCUMENT

Document Date:	CDER Stamp Date:	Submission Type:	Comments:
7-6-98	7-7-98	Labeling Supplement	SLR-017 to unify Diskus-MDI label

RELATED APPLICATIONS (if applicable)

Document Date:	APPLICATION Type:	Comments:

Overview of Application/Review: This labeling supplement for the Serevent MDI is to provide for enhanced unity between the approved Diskus labeling and that of the MDI (in part occurring secondary to labeling negotiations during the approval process for the Diskus).

Outstanding Issues: The Project Manager needs to complete her review to assure that only the highlighted changes in the mark-up labeling were made. If this is the case, the labeling supplement is approvable from the clinical standpoint as the mark-up changes are acceptable and consistent with the Diskus labeling. For both products, however, at the next printing, the efficacy tables in the Clinical Trials subsection should be modified to specify which Serevent product was the source of the data (i.e., the Serevent MDI labeling table should replace "Serevent" with "Serevent Inhalation Aerosol").

Recommended Regulatory Action:

New Clinical Studies: _____ **Clinical Hold** _____ **Study May Proceed**

NDAs:

Efficacy / Label Supp.: X **Approvable** _____ **Not Approvable**

Signed: **Medical Reviewer:** /S/ **Date:** 12/14/98

Medical Team Leader: **Date:** 12/14/98

cc: HFD-570/Jani/Project Manager