

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020280/S008

CHEMISTRY REVIEW(S)

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CHEMISTS REVIEW		1. ORGANIZATION	2. NDA NUMBER
		DMEDP II, HFD-510	"M 30 1997 20-280
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE	
Pharmacia & Upjohn 700 Portage Rd. Kalamazoo, MI 49001-0199		SEI-008 1-11-97 11-1-96	
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE	
Genotropin	somatropin (rdNA) for injection		
8. SUPPLEMENT PROVIDES FOR			
A new indication for the drug for "long-term replacement therapy in adults with growth-hormone deficiency."			
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF	
growth hormone	RX		
12. DOSAGE FORM	13. POTENCY		
small volume parenteral	1.3, 5.0, and 12, mg/mL (equivalent to 4, 15, and 36 IU/mL)		
14. CHEMICAL NAME AND STRUCTURE			
See Chemistry Review #1			
15. COMMENTS			
This supplemental application seeks approval for a new indication for Genotropin to be used to treat adult growth-hormone deficiency. The sponsor has, in addition to the clinical results, provided updated labeling to include the new indication, clinical pharmacology, reviews of the clinical results, a dose and administration section for adult users, and changes to conform to the "pediatric patients" rules. The annotated labeling provided with the application is acceptable. Additionally, the sponsor has provided an abbreviated EA to support the application. The EA has been reviewed and found to be adequate			
16. CONCLUSION AND RECOMMENDATION			
The sponsor has provided appropriate labeling to support the proposed indication. No CMC changes were instituted. Updated EA information was provided and is acceptable. The application is approvable from a chemistry standpoint.			
17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED	
WILLIAM K. BERLIN	/S/	6-17-97	
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/S/

6/30/97