


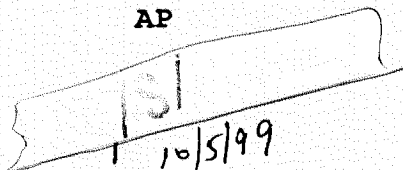
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 019676, S013

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW		1. ORGANIZATION DMEDP II, HFD-510	2. NDA NUMBER 19-676
3. NAME AND ADDRESS OF APPLICANT Genentech Inc. 1 DNA Way South San Francisco, CA 94080		4. SUPPLEMENT NUMBER; DATE SE8-013, 29-JAN-1999	
5. PROPRIETARY NAME Nutropin	6. NAME OF THE DRUG Somatropin (rdna origin) for injection	7. AMENDMENTS, REPORT, DATE 14-MAY-1999	
8. SUPPLEMENT PROVIDES FOR Labeling changes including improved bone-mineral density with Nutropin treatment in adults with growth-hormone deficiency under the Clinical Pharmacology section of the package insert.			
9. PHARMACOLOGICAL CATEGORY Growth hormone	10. HOW DISPENSED Rx	11. RELATED IND, NDA, DMF	
12. DOSAGE FORM Lyophilized powder for injection after reconstitution	13. POTENCY 5, 10 mg		
14. CHEMICAL NAME AND STRUCTURE			
15. COMMENTS The applicant proposes to add "GH therapy stimulates bone formation and results in increases in serum alkaline phosphatase" to the 'Clinical Pharmacology' section of the package insert. The application contains clinical data to support that claim. The revised labeling was provided in the amendment dated 14-MAY-1999. However, this does not reflect a new 'Indication' and therefore, no request for a waiver for the requirement to prepare an EA is necessary. The applicant also proposes to add wording to the 'Contradictions' and 'Warnings' sections of the PI. There are no CMC issues associated with these labeling changes.			
16. CONCLUSION AND RECOMMENDATION There are no CMC issues with the proposed labeling changes, and there is no requirement for an EA nor is an EA waiver request necessary. <u>The application may be Approved based on CMC review.</u>			
17. NAME WILLIAM K. BERLIN	18. REVIEWERS SIGNATURE 	19. DATE COMPLETED 8-SEP-1999	
DISTRIBUTION: ORIGINAL JACKET		CSO	REVIEWER DIVISION FILE

AP


10/5/99