CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 019676, S013

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP II, HFD-510	19-676
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Genentech Inc. 1 DNA Way South San Francisco, CA 94080		SE8-013, 29-JAN-1999
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Nutropin	Somatropin (rDNA origin) for injection	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	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
Growth hormone	Rx	
12. DOSAGE FORM	13. POTENCY	
Lyophilized powder for injeciton after reconstitution	5, 10 mg	

14. CHEMICAL NAME AND STRUCTURE

[redacted]

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. The application may be Approved based on CMC review.

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN	/S/	8-SEP-1999

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