CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

19-676/S-016

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		SE2-016, 11-JUN-1999
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Nutropin	Somatropin (rDNA origin) injection	
8. SUPPLEMENT PROVIDES FOR		
Changes to the "Clinical Pharmacology" and "Dose and Administration" sections of the package insert.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
12. DOSAGE FORM	13. POTENCY	
14. CHEMICAL NAME AND STRUCTURE		
See Chemistry Review #1		
15. COMMENTS		
The clinical pharmacology section has been updated to include information concerning trials performed with pubertal patients, and to specify length of therapy. Additionally, the applicant proposes to update the dose and administration section with the following: "In pubertal patients, a weekly dosage of up to 0.70 mg/kg divided daily may be used.] Neither of these changes are CMC issues. As there are no changes to the "Indications and Usage" section (the application was previously approved for Pubertal dosing), there is no requirement for an environmental assessment in support of this application.		
16. CONCLUSION AND RECOMMENDATION		
The proposed labeling changes are acceptable based on CMC review, and may be approved.		
17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN	/S/	8-OCT-1999
DISTRIBUTION: ORIGINAL JACKET	CSO REVIEWER	DIVISION FILE

AP

/S/

10/8/99

EER

NOT NEEDED

ENVIRONMENTAL ASSESSMENT
NDA 19-676-016

The categorical exclusion from preparing an environmental assessment was granted (see Chemistry Review #2).