

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-522/S-013

CHEMISTRY REVIEW(S)

19-676/S-016 and 20-522/S-013

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP, HFD-510	See above
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Genentech, Inc. 1 DNA Way South San Francisco, CA 94080		24-JUN-1999
5. NAME OF DRUG	6. NONPROPRIETARY NAME	8. AMENDMENTS/REPORT, DATE
Nutropin Nutropin AQ	Somatropin for injection Somatropin injection	
7. SUPPLEMENT PROVIDES FOR:		06-APR-2000 (Rec'd 06-APR-2000)
Pubertal dosing efficacy supplement.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	10. RELATED IND, NDA, DMF
Growth hormone	Prescription	
12. DOSAGE FORM	13. POTENCY	
Lyophilized powder for inj. Injectable	5 mg/vial and 10 mg/vial 10 mg/vial	
14. CHEMICAL NAME AND STRUCTURE		
Somatropin		
15. COMMENTS		
See next page.		
16. CONCLUSION AND RECOMMENDATIONS		
Chemistry, manufacturing and controls information is satisfactory. From chemistry point of view, the supplements can be approved.		
17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Stephen Moore, Ph.D.	 Chemistry Team Leader	12-APR-2000

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R/D initialed by:

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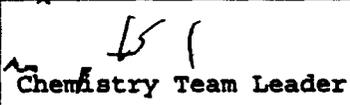
15. COMMENTS (continued from page 1):

These efficacy supplements were originally submitted on 24-JUN-1999 (see Chemistry Review dated 08-OCT-1999).

This review is for a FAX communication dated 06-APR-2000 (see attached) that provides for a categorical exclusion from the requirement to prepare an environmental assessment.

Satisfactory.

19-676/S-016 and 20-522/S-013

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP, HFD-510	See above
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Genentech, Inc. 1 DNA Way South San Francisco, CA 94080		24-JUN-1999
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Somatropin		
15. COMMENTS		
See next page.		
16. CONCLUSION AND RECOMMENDATIONS		
Chemistry, manufacturing and controls information is satisfactory. From chemistry point of view, the supplements can be approved.		
17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Stephen Moore, Ph.D.	 Chemistry Team Leader	12-APR-2000
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15. COMMENTS (continued from page 1):

These efficacy supplements were originally submitted on 24-JUN-1999 (see Chemistry Review dated 08-OCT-1999).

This review is for a FAX communication dated 06-APR-2000 (see attached) that provides for a categorical exclusion from the requirement to prepare an environmental assessment.

Satisfactory.

CHEMISTS REVIEW		1. ORGANIZATION DMEDP II, HFD-510	2. NDA NUMBER 20-522
3. NAME AND ADDRESS OF APPLICANT Genentech Inc 1 DNA Way South San Francisco, CA 94080		4. SUPPLEMENT NUMBER, DATE SE2-013, 24-JUN-1999	
5. PROPRIETARY NAME Nutropin AQ	6. NAME OF THE DRUG Somatropin (rdna origin) injection	7. AMENDMENTS, REPORT, DATE	
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. Note: This application provides for the same labeling changes as described in NDA 19-676/S-016.			
16. CONCLUSION AND RECOMMENDATION The proposed labeling changes are acceptable based on CMC review, and may be approved.			
17. NAME WILLIAM K. BERLIN	18. REVIEWERS SIGNATURE LST	19. DATE COMPLETED -1999	
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10/8/99