

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**19-676/S-016**

**Pharmacology Review(s)**

NDA 19-676/S-016

7 Sep 1999

Genentech Inc.  
460 Point San Bruno Blvd.  
South San Francisco, CA 94080-4990

Submission: 11 Jun 1999

**PHARMACOLOGY REVIEW OF NDA SUPPLEMENT**  
**Supplement to NDA 19-676 #016**

**DRUG:** Nutropin [somatropin (rDNA origin) for injection]

**CATEGORY:** Growth hormone.

**INDICATION:** This submission provides a clinical data supplement to support the addition of a higher pubertal dose for pubertal patients to the dosing section of the product insert.

**PHARMACOLOGY COMMENTS:** There were no preclinical data submitted under supplement S-016 and none is deemed to be needed. Thus, no pharmacology review is necessary for this supplement. There were no labeling changes made to the previously approved preclinical sections of the label.

**RECOMMENDATION:** AP

*St*  
~~David H. Hertig~~  
Pharmacologist

cc: NDA 19-676 Orig  
HFD-510 Division File  
HFD-510 RSteigerwalt  
HFD-510 DHertig  
HFD-510 Cking

*Team Leader Consensus*

*9/8/99 St*