CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-522/S-013

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

CLINICAL PHARMACOLOGY & BIOPHARMACEUTICS REVIEW

NDA 20-522 / SE2-013	**SUBMISSION DATE:**	**24-JUN-99**
BRAND NAME:	**Nutropin AQ**	
GENERIC NAME:	**Somatropin (rDNA origin) for injection**	
REVIEWER:	**Robert M. Shore, Pharm.D.**	
SPONSOR:	**Genentech, Inc., South San Francisco, CA**	
TYPE OF SUBMISSION:	**Labeling for Pubertal dosing**	

SUBMISSION:

A supplement providing clinical data to support new dosing of Nutropin pubertal patients was submitted under NDA 19-676/SE2-016 on 11-JUN-99. Since Nutropin and Nutropin AQ have been found to be bioequivalent, this Nutropin AQ submission seeks to change labeling based on the Nutropin submission. The proposed labeling changes are in the 'Efficacy Studies' and 'Dosage' sections only. The data collected in the Nutropin study were clinical endpoints, including final height, growth rate, and IGF-1 levels; no pharmacokinetic data for growth hormone had been collected in the study.

As with the Nutropin NDA, a formal review of this Nutropin AQ submission by The Office of Clinical Pharmacology and Biopharmaceutics is not necessary.

Robert M. Shore, Pharm.D. 6/24 9-00
Division of Pharmaceutical Evaluation II
Office of Clinical Pharmacology and Biopharmaceutics

Hae-Young Ahn, Ph.D., Team Leader 6/24

CC: NDA 20-522/SE2-013 (orig., 1 copy), HFD-510(King), HFD-870(HuangS, Ahn), ~~HFD-880(Lazor)~~, CDR

code: NR