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APPLICATION NUMBER:
20-522/S-013

PHARMACOLOGY REVIEW

NDA 20-522/S-013

7 Sep 1999

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

Submission: 24 June 1999

PHARMACOLOGY REVIEW OF NDA SUPPLEMENT
Supplement to NDA 20-522 #013

DRUG: Nutropin AQ (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-013 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

cc: NDA 20-522 Orig
HFD-510 Division File
HFD-510 RSteigerwalt
HFD-510 DHertig
HFD-510 CKing

LS
David H. Hertig
Pharmacologist

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9/8/99