

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

MEMO TO THE RECORD

ANDA — 76-752, and —

Levothyroxine Sodium Tablets, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, — , 150 mcg, 175 mcg, 200 mcg, & 300 mcg

Based on the E-mail from Cecelia Parise dated April 14, 2005, all ANDA's for Levothyroxine Sodium Tablets that are pending and all future ANDA's for Levothyroxine Sodium will need the memo to the record documenting that their formulation is not the same as Jerome Steven's formulation (NDA 21-210).

This memo is written to confirm that the formulations listed in — ANDA 76-752 for Genpharm are not the same as Jerome Steven's formulation (NDA 21-210). This chemist is the reviewer for all — ANDAs cited above.

This conclusion is made based on the composition statements for all strengths filed in Jerome Stevens NDA retrieved from COMIS.

Mujahid L. Shaikh
Office of Generic Drugs

cc: AND — 76-752, —
Division File
Field Copy

Endorsements:

HFD-630/M.Shaikh/ *Mujahid Shaikh* 5/4/05
HFD-630/Shing Liu / *S. H. Liu* 5/4/05

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