

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

DATE: May 31, 2002

FROM: Eric P. Duffy, Ph.D.
Director, DNDCII, ONDC

SUBJECT: Approval of NDA 21-292
Novothyrox™ (levothyroxine sodium tablets, USP)
Genpharm, Inc.

TO: Docket # 02P-0135/PSA1
NDA 21-292

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Jerome Stevens Pharmaceuticals, Inc. (Jerome) submitted a Petition for a Stay of Action, No. 02P-0135/PSA1, dated March 26, 2002, and filed by the Agency on March 28, 2002. The petition requests that FDA immediately and indefinitely stay (1) all grants of drug pre-market authority that were based on New Drug Applications (NDAs) or Abbreviated New Drug Applications (ANDAs) that used, relied on, or were based on Jerome's confidential and trade secret manufacturing information for orally-administered levothyroxine sodium (LS) and (2) all pending and prospective NDAs and ANDAs that use, rely on, or are based on Jerome's confidential and trade secret manufacturing information for orally administered LS. Jerome claimed in a Notice of Claims Pursuant to the Federal Tort Claims Act dated March 26, 2002 (Notice) that certain information that had been posted on FDA's Website (<http://www.fda.gov/cder/>) on August 22, 2000, regarding Jerome's NDA 21-210 for LS was confidential and trade secret information.

The Office of New Drug Chemistry has reviewed Genpharm Inc. (Genpharm's) NDA 21-292, submitted on June 27th, 2000, and has determined that the Genpharm NDA did not use or rely on, and was not based on Jerome's allegedly confidential information. This determination is based on the fact that the batches Genpharm used to support its NDA were manufactured prior to the posting on the agency's website of the approval materials from Jerome's NDA for LS.¹

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¹ The filing of this memorandum solely represents a determination that the Genpharm NDA did not use or rely on, and was not based on Jerome's allegedly confidential information. It does not represent a determination with regard to any other issue, nor does it constitute an admission of any issue raised by Jerome's Petition or Notice.

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/s/

Eric Duffy
5/31/02 04:07:13 PM
CHEMIST