

MEMORANDUM

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

DATE: June 5, 2002

FROM: Gary Buehler *Gary Buehler 6/5/02*
Director
Office of Generic Drugs
Center for Drug Evaluation and ResearchSUBJECT: Approval of ANDA 76-187
Levothyroxine Sodium Tablets
Mylan Pharmaceuticals, Inc.TO: Docket # 02P-0135/PSA1
ANDA 76-187 File

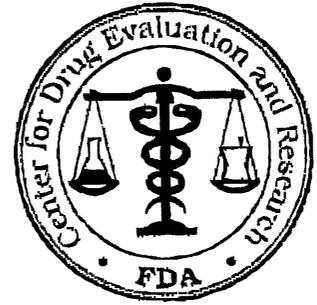
Jerome Stevens Pharmaceuticals Inc. (Jerome) submitted a Petition for a Stay of Action, No. 02P-0135/PSA1, dated March 26, 2002, and filed by the Agency on March 28, 2002. The petition requests that FDA immediately and indefinitely stay (1) all grants of drug pre-market authority that were based on New 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 the 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 Generic Drugs has reviewed Mylan Pharmaceuticals, Inc. (Mylan)'s ANDA 76-187, submitted on June 5, 2001, and has determined that the Mylan ANDA 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 Mylan used to support its ANDA were manufactured prior to the posting on the agency's website of the approval materials from Jerome's NDA for LS.¹

¹ The filing of this memorandum solely represents a determination that the Mylan ANDA 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.

02P-0135

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FAX COVER SHEET

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Public Health Service

Food and Drug Administration

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Office of Generic Drugs

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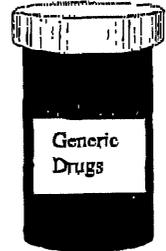
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02P-01357/ASA1

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