



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

MEMORANDUM

Date: June 23, 2004
To: Docket Number 2004P-0061
From: Office of Chief Counsel
Food and Drug Administration
Subject: Meeting with Daniel Troy, Chief Counsel

On April 14, 2004, Daniel Troy, Chief Counsel, Kim Dettelbach and Kevin Fain (by phone), Office of Chief Counsel, met with Marc Scheineson, counsel for Jerome Stevens Pharmaceuticals, Inc. (JSP) to discuss JSP's citizen petition, Docket No. 2004-0061. Mr. Scheineson presented the arguments raised in JSP's citizen petition concerning approval standards for abbreviated new drug applications for levothyroxine sodium products. Mr. Scheineson also indicated that JSP intended to file a written scientific statement in support of its citizen petition.