

Food and Drug Administration
Rockville MD 20857

9517 '00 MAR 31 P3:28

MAR 30 2000

March 30, 2000

Connie McNabb
Regulatory Affairs Associate
Mallinckrodt Inc.
675 McDonnell Blvd.
P.O. Box 5840
St. Louis, MO 63134

Re: Docket No. 99P-4209/CP1

Dear Ms. McNabb:

This responds to your citizen petition, dated September 27, 1999, requesting that the Food and Drug Administration (FDA) determine whether hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, were withdrawn from sale for reasons of safety or effectiveness and, if not, to keep the drug in the *Orange Book*.

The FDA has reviewed its records and has determined that hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain the listing of hydrocodone bitartrate and acetaminophen tablets USP, 5 mg/325 mg, in the "Discontinued Drug Product List" of *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the *Orange Book*.

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you require any further information, please do not hesitate to call me at 301-594-2041.

Sincerely yours,

Dave Read
Supervisory Regulatory Counsel
Regulatory Policy Staff (HFD-7)
Center for Drug Evaluation and Research

Enclosure

99P-4209

ANSI