

Food and Drug Administration
Rockville MD 20857

NOV 14 1997

TRANSMITTED BY FACSIMILE

George R. Hemsworth, Ph.D.
Director, Regulatory Affairs
Wallace Laboratories
Division of Carter-Wallace, Inc.
Half Acre Road, P.O. Box 1001
Cranbury, NJ 08512-0181

Re: NDA 11-792/12-365
Soma (carisoprodol) Tablets/Soma Compound (carisoprodol 200 mg and aspirin 325 mg)
MACMIS ID #5897

Dear Dr. Hemsworth:

This letter is in reference to Wallace Laboratories' (Wallace) June 11, 1997, July 2, 1997, and September 9, 1997, submissions of promotional labeling materials under cover of Form FDA 2253 for Soma (carisoprodol) Tablets and Soma Compound (carisoprodol 200 mg and aspirin 325 mg). These labeling materials included tent-fold, direct mail promotional materials and promotional brochures.¹ The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards these promotional materials to be lacking in fair balance or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

Specifically, the promotional labeling materials fail to present a fair balance between information relating to adverse events associated with the use of either Soma or Soma Compound and *information relating to the effectiveness of either drug*. Wallace fails to present any information concerning either the risk of drowsiness associated with the use of carisoprodol or the additive effects when used with agents such as alcohol, other CNS depressants, or psychotropic drugs. Moreover, in its promotion of Soma Compound, Wallace does not disclose the risk of aspirin intolerance in aspirin-sensitive patients. Therefore, DDMAC considers these promotional labeling materials to be misleading.

Wallace should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter. Wallace should

¹ These materials include, but are not limited to, items identified as SOM447E, SOM008, SOM447B, OTH367.3A, and SOM128.

George R. Hemsworth, Ph.D.
Wallace Laboratories
NDA 11-792/12-365

Page 2

submit a written response to DDMAC on or before December 1, 1997, describing the steps taken to ensure that the use of these materials, and all materials with the same or similar message, have been discontinued and date of such discontinuance.

If Wallace has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds Wallace that only written communications are considered official.

In all future correspondence regarding this matter, please refer to both the NDA number and the MACMIS ID #5897.

Sincerely,

Stephen W. Sherman, MBA
Regulatory Review Officer
Division of Drug Marketing,
Advertising & Communications