



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

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

June 11, 1997

Eugene I. Lambert, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, D.C. 20044-7566

Dear Mr. Lambert:

This letter responds to your letter of June 10, 1997. To help clarify why your client's product appears to be in violation of section 505 of the Federal Food, Drug, and Cosmetic Act, it is important to recognize that the agency's concerns go beyond the product labeling and the company's efforts to standardize the composition of the product. It appears that the Hong Qu in Cholestin was specifically developed to provide lovastatin, an active drug ingredient. This fact provides significant additional evidence of the intended use of the product. I hope that this information is helpful to you.

Sincerely,

Philip S. Derfler

cc: Brad Williams

97P-0441

ANS 1