**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**PUBLIC HEALTH SERVICE**
**FOOD AND DRUG ADMINISTRATION**
**CENTER_FOR DRUG EVALUATION AND RESEARCH**

7520 Standish Place
Rockville, Maryland 20855
USA

Date: March 16, 2000 Ref. No. 00-HFD-310I-015

Ms. Debbie Young
Albany Street Pharmacy, LTD.
PO Box 6104
Dunedin
New Zealand

Dear Ms. Young:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.onlinepharmcy.co.nz. The marketing information contained on your web site includes therapeutic claims that cause the product **CODCOMOL** to be a drug under section 201 (g) of the Federal Food, Drug, and Cosmetic Act (the Act). This product may also be considered a new drug under section 201(p) of the Act. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act. Therefore, the sale and distribution of this product on your Internet web site may be illegal in this country and in violation of Title 21 of the United States Code, Sections 331(a), 331(d), and 355(a).

The information on your web site indicates that **CODCOMOL** contains 250 mgs. aspirin, 250 mgs. paracetamol, and 8 mgs. Codeine. While the combination of aspirin, paracetamol, and codeine may be legally marketed elsewhere, ie., New Zealand, this combination drug product has not been reviewed and approved in the United States. Furthermore, this combination would be considered a prescription drug in the U.S. Federal law prohibits the sale of prescription drugs to U.S. citizens without a valid prescription, 21 U.S.C. Section 353(b).

The agency is taking steps to warn our citizens that drugs promoted and sold from foreign sources via the Internet may not be approved for marketing in this country. With copies of this letter, we are advising the regulatory drug officials in the countries from which you operate of these potential violations. We are also advising the U.S. Customs Service through an Import Alert that all shipments offered for importation into the United States as a result of your activities may be detained and subject to refusal of entry.

FDA would like to take this opportunity to clarify the agency's policy concerning the importation of pharmaceutical products for personal use. For many years, FDA has permitted individuals and their physicians to bring into the United States small quantities of drugs sold abroad, but not approved in the U.S. for a patient's treatment of a serious condition. This compassionate approach has been applied to products that do not represent an unreasonable risk and for which there is no known commercialization or promotion to persons residing in the U.S. A patient seeking to import such product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. The **CODCOMOL** ordered from your web site does not meet the criteria in FDA's personal use policy.

This is not intended to be a complete listing of all objectionable statements or products found on your web site.

Please notify this office in writing what you plan to do about these potential violations. Your response may be sent electronically (E-mail) to Mr. William Nychis at the following address:

Nychis@CDER.FDA.GOV. You may also provide written response via fax at (301) 594-0165 or hard copy letter to the letterhead address. Mr. Nychis may be reached by telephone at (301) 594-0063.

Sincerely yours,

/s/

Margaret A. Tart
Acting Director
Division of Labeling and
Non-prescription Drug Compliance (HFD-310)