

United States Food and Drug Administration

DIVISION OF WEST COAST IMPORTS

Notice of FDA Action

Entry Number: [REDACTED]
Port of Entry: 2720, Los Angeles International Airport, Los Angeles, CA Reference
No.: LAX-1803-185

Notice Number: 1
March 29, 2018

Francis Donnelly
[REDACTED]

Shipper: Unknown
P.O. Box 33893
Takapuna
Auckland, New Zealand

A mail shipment addressed to you from a foreign country is being held by the post office at the request of the U.S. Food and Drug Administration (FDA).

Summary of Current Status of Individual Lines

No.	Product Description	Quantity	Current Status
1	ASACOL Gastro-Resistant Tablets (Mesalazine) 400 mg	5 Box	Detained 03-29-2018

The shipment may also contain other items not listed above. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts, and does not preclude action should the products later be found violative.

DETAINED - Subject to Refusal

Examination of the following articles has been made and these articles are subject to refusal of admission into the United States because they do not appear to be in compliance with the requirements of the law as indicated below:

No.	Product Description	Respond By
1	ASACOL Gastro-Resistant Tablets (Mesalazine) 400 mg	5 Box April 18, 2018

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG

The article appears to be a new drug without an approved new drug application. THIS FOREIGN DRUG PRODUCT IS CONSIDERED UNAPPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION (FDA). IT IS AGAINST US LAW TO IMPORT UNAPPROVED FOREIGN DRUGS.

The FDA cannot ensure the safety of drugs PRODUCED FOR FOREIGN MARKETS, that are purchased over the Internet, and shipped from outside the U.S. to you.

Additionally, all of the conditions for personal importation exemption have not been met.