

United States Food and Drug Administration

Division of West Coast Imports

Notice of FDA Action

Entry Number: ----REDACTED

Notice Number: 2

Port of Entry: 2720, Los Angeles International Airport, Los Angeles, CA

August 1, 2019

Elizabeth [LAST NAME REDACTED]
[ADDRESS AND CITY REDACTED], CA [ZIP CODE REDACTED]

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Shipper: Unknown

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	Relpax	12 Tablets	Destroyed 08-01-2019

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.

REFUSAL OF ADMISSION AND ADMINISTRATIVE DESTRUCTION

Examination of the following articles has been made and you were given an opportunity to respond to a notice that the articles are subject to refusal of admission into the United States and subject to administrative destruction. FDA has determined that the articles are drugs that are not in compliance with the requirements of the law as indicated below. Further, FDA has determined that each article is valued at \$2500 or less. Because these drugs are not in compliance with the requirements of the law and are valued at \$2500 or less, you are hereby notified that these articles will be destroyed by FDA in accordance with the FD&CA.

No.	Product Description	Quantity
1	Relpax	12 Tablets

FD&CA Section 503(b)(4), 801(a)(3); MISBRANDING

The article has been determined to be a prescription drug but does not include the symbol "Rx only" on its label.

For the District Director of Customs:

[REDACTED], Compliance Officer U.S.
Food and Drug Administration One
World Trade Center, Suite 300 Long
Beach, CA 90831

(562) 256-9215
(562) 256-7701 (FAX)
[REDACTED]@fda.hhs.gov

Additional Information regarding FDA's administrative destruction authority can be found at:

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<http://www.fda.gov/ForIndustry/ImportProgram/Resources/ucm494173.htm>

No further action is required on your part.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: REDACTED