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

Notice Number: 1
June 24, 2019

Elizabeth [LAST NAME REDACTED]
[ADDRESS REDACTED
[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	Detained 06-24-2019

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.

DETAINED - Subject to Refusal and Administrative Destruction

Examination of the following articles has been made and FDA has determined that these articles are drugs that are not in compliance with the requirements of the law, as indicated below. Additionally, 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, they are subject to refusal of admission into the United States and are subject to administrative destruction.

No.	Product Description	Respond By
1	Relpax 12 Tablets	July 15, 2019

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.

All products of this kind must meet the requirements of the Federal Food Drug and Cosmetic Act or other laws enforced by the U.S. Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles.

This Notice does not in any manner accuse you of violating any law.

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony

must be provided to FDA on or before the dates shown above.

Please direct your response to:

FDA AGENT NAME REDACTED
U.S. Food and Drug Administration One World Trade Center, Suite 300 Long Beach, CA 90831

(562) 256-9215
(562) 256-7701 (FAX)
FDA ANGENT NAME REDACTED@fda.hhs.gov

If you do not wish to claim this shipment, you may disregard this notice and the shipment will be destroyed.

If the shipment is destroyed, you may be held liable for the costs of storage and destruction. However, if you are a consumer who imported these articles for your personal use, FDA will not seek to collect the costs of storage and destruction from you.

Additional Information regarding FDA's administrative destruction authority can be found at:
http://www.fda.gov/ForIndustry/ImportProgram/Resources/ucm494173.htm

The shipment may contain items not included in this notice.

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