United States Food and Drug Administration

Division of Northeast Imports

Notice of FDA Action

Entry Number: ----0509484-0
Port of Entry: 4701, JFK Airport, Jamaica, NY

Notice Number: 1
January 27, 2022

[redacted] WA [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	AZITHROMYCIN TABLETS IP 250 MG; AZEETOP - 250	180 Tablets	Detained 01-26-2022
2	HYDROXYCHLOROQUINE TABLETS IP 200 MG; HETQUENIL - 200	200 Tablets	Detained 01-26-2022
3	IVERMECTIN TABLETS USP 12 MG; IVEROTAJ 12 MG	300 Tablets	Detained 01-26-2022

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	AZITHROMYCIN TABLETS IP 250 MG; AZEETOP - 250	180 Tablets	February 15, 2022

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article has been determined to lack adequate directions for use. Article lacks any directions of use.

The product also does not meet criteria to be considered for exemption under FDA's Personal Importation Policy. Refer to: <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>

While no response is required, if you decide to respond, please submit evidence to overcome the appearance of the violation to my email address (below) and include your name and entry number in the subject heading.

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. The product is a prescription drug and the label/labeling does not bear the "Rx only" legend.

The product also does not meet criteria to be considered for exemption under FDA's Personal Importation Policy. Refer to: <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>

While no response is required, if you decide to respond, please submit evidence to overcome the appearance of the violation to my email address (below) and include your name and entry number in the subject heading.

2	HYDROXYCHLOROQUINE TABLETS IP 200 MG; HETQUENIL -200	200 Tablets	February 15, 2022

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article has been determined to lack adequate directions for use. Article lacks any directions of use.

The product also does not meet criteria to be considered for exemption under FDA's Personal Importation Policy. Refer to: <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>

While no response is required, if you decide to respond, please submit evidence to overcome the appearance of the violation to my email address (below) and include your name and entry number in the subject heading.

FD&CA Section 503(b)(4), 801(a)(3); MISBRANDING
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The product also does not meet criteria to be considered for exemption under FDA's Personal Importation Policy. Refer to: <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>

While no response is required, if you decide to respond, please submit evidence to overcome the appearance of the violation to my email address (below) and include your name and entry number in the subject heading.

3	IVERMECTIN TABLETS USP 12 MG; IVEROTAJ 12 MG	300 Tablets	February 15, 2022

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article has been determined to lack adequate directions for use. Article lacks any directions of use.

The product also does not meet criteria to be considered for exemption under FDA's Personal Importation Policy. Refer to: <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>

While no response is required, if you decide to respond, please submit evidence to overcome the appearance of

the violation to my email address (below) and include your name and entry number in the subject heading.

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.
The product is a prescription drug and the label/labeling does not bear the "Rx only" legend.

The product also does not meet criteria to be considered for exemption under FDA's Personal Importation Policy.
Refer to: <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>

While no response is required, if you decide to respond, please submit evidence to overcome the appearance of the violation to my email address (below) and include your name and entry number in the subject heading.

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:

Gabriel Feng, Compliance Officer
U.S. Food and Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

(718) 662-5550

Gabriel.Feng@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: SJ