

King Pharmaceuticals, Inc.
501 Fifth St.
Bristol, TN 37620



800-336-7783
(423) 989-8125
Fax (423) 274-8677

James E. Green, Esq.
Executive Vice President,
Corporate Affairs

INTRODUCTION

Slide Showing King Logo and James Green's name and title

Good morning. My name is James Green, Executive Vice President of Corporate Affairs at King Pharmaceuticals. King manufactures and markets prescription pharmaceutical products that cover a diverse range of therapeutic categories. We appreciate the opportunity to provide you today with King's perspective on the importation of prescription drugs.

Foremost, we share your concern about the safety of imported drugs. Over the last two years, our customers – *our patients* – have increasingly begun to fill their prescriptions through Internet sites with products of unknown quality and integrity, from unknown origins.

Many of King's products are "maintenance" drugs – that is, drugs that are intended to maintain patients with chronic conditions – such as hypertension or hypothyroidism – within a healthy, normal range. These conditions are often asymptomatic, and a patient who receives a substandard drug may be at serious risk of harm and may not even know it. Such a situation is of grave concern to us.

In a moment, I will show you some examples of the types of products that are being imported into the United States, in place of King's FDA-approved products. Before I do that, I must emphasize this point. The measure of the safety of imported drugs should not be whether we can point to examples of sudden adverse events or acute toxic reactions. When U.S. patients look outside the U.S. for their medications – particularly for maintenance drugs – the risk of harm may escape immediate detection; it may not even be recognized until the effect is irreversible.

That said, we want to share with you our own investigation into the purchase of imported drug products. In particular, we attempted to purchase two of our leading maintenance drugs, Altace® and Levoxyl®, from various non-U.S. Internet pharmacies. We attempted twenty-two such purchases, finding significant problems with every drug we received. The slides that follow will illustrate some of these problems:

Slide of Spinning Synthroid bottle

King's product, Levoxyl®, is one of several branded levothyroxine products for the treatment of hypothyroidism approved by the FDA. When we attempted to purchase "Levoxyl®" from Cross Border Pharmacy.com, we received this bottle of "Synthroid®" instead, filled by Total Care Pharmacy in Canada. The manufacturer's label on this bottle clearly states that Synthroid® is "Not Interchangeable with Other Brands." On the other side, Total Care Pharmacy's label falsely states that Synthroid® is the "Canadian Equivalent for Levoxyl."

Synthroid® and Levoxyl® are narrow therapeutic range drugs. That means they must be precisely dosed and the same dose must be delivered to the patient each time. Synthroid® and Levoxyl® are “BX-rated” in FDA’s *Orange Book*, indicating that patients who switch brands cannot expect to receive the same therapeutic effect. Here, Cross Border Pharmacy.com and Total Care Pharmacy have overridden FDA’s judgment and deemed these two brands “equivalent.”

It is noteworthy that this bottle of Synthroid®, although purchased from Crossborderpharmay.com, was filled by Total Care Pharmacy, one of three pharmacies that appears on the Wisconsin Internet pharmacy referral site (at http://drugsavings.wi.gov/section_detail.asp?linkcatid=59&linkid=25&sname=Ordering%20Information also one of two Canadian pharmacies listed on the Minnesota Internet pharmacy referral site at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?id=536885147&agency=Rx>) as a safe and reliable Canadian pharmacy. We do not agree, however, that substituting narrow therapeutic range drugs, such as Synthroid® for Levoxyl®, and falsely labeling either as the equivalent of the other, contrary to both manufacturers’ labeling and FDA’s *Orange Book* rating, represents safe pharmacy practice – yet this is what Total Care Pharmacy did in this case (according to CrossBorderPharmacy.com’s Internet site, all prescriptions ordered through CrossBorderPharmacy.com are filled by Total Care Pharmacy).

Slide showing four different Levothyroxine Products in Quadrants

This slide shows some of the products sent to us when we ordered Levoxyl®.

Again, none of these products is interchangeable with Levoxyl®. The patient may think he is receiving Levoxyl®, or a drug that is clinically equivalent. Instead, he is putting his carefully structured dosing regimen at risk.

Slide From MedCenterStore.com Levoxyl known as Synthroid

Some websites provide blatantly false information about Levoxyl®. For example, MedCenter Store.com falsely claims on its website that “Levoxyl is known as Synthroid in Canada.” We discovered that often, as the patient proceeds through the screens of many Internet pharmacies, it is not until the very last screen that the patient is told he or she will be getting a product other than Levoxyl®. Clearly, this is a dangerous “bait and switch” scam.

Slide of Generic Ramipril for Altace (w/ capsule comparison)

We also attempted to order King’s product, Altace®, an ACE inhibitor indicated for the chronic treatment of hypertension and to reduce the risk of stroke, heart attack, and death from cardiovascular disease. As you can see, the product we received is not an FDA-approved drug and it certainly is not King’s Altace®. Importantly, because hypertension is asymptomatic, a patient taking the product we received will not know whether he is getting the intended therapeutic effect.

Also note that the letter that accompanied this order stated, “Your medication may appear different in shape, color, or packaging from those you have received previously. Please be assured that the products are the same and have been manufactured by the same company at FDA approved plants.”

Slide of Altace-Ramipril Tablet Comparison Blow-up

The drug we received has a different color and markings, and was manufactured in a different site, than King’s Altace. How can the products be the same if everything is different? Additionally, because there is no lot number and no identifying information on the bottle, it is impossible to identify who manufactured this product or where it was manufactured – much less under what conditions.

Slide Showing Two Pakistan Packages with Same Handwriting

In another purchase, we received a drug that we did not even order. After ordering “Levoxyl” and “Altace” by their brand names on DiscountMedsOnline.com, we received drugs known as “Eltroxin” from Fiji and “Tritace” in a handwritten package, shown here on the right, shipped from Pakistan. It gets worse – look to the left.

Slide With Green Box of Steroids

In the second Pakistani package we discovered this green, foreign-labeled box of steroids that we did not order.

Slide showing montage of four problems discussed

This brings me to a final concern. An important driver in this industry is the ability to contractually leverage discovery, manufacturing and marketing resources with other companies. Such contracts often include negotiated U.S. marketing rights. Companies like King negotiate for these rights with the expectation that U.S. patent and contractual rights will protect their investment.

For example, King's ownership of Altace® is limited to the United States and Puerto Rico. The importation of substitutes for King's Altace® undermines our U.S. intellectual property and contract rights. We urge the Task Force to take this into consideration as an integral part of the nature and value of drug development.

To add another perspective: King is headquartered in Bristol, Tenn. Our products are manufactured in more than a dozen U.S. sites, including Bristol; St. Petersburg, Florida; Kansas City, Missouri; Rochester, Michigan; and Middleton, Wisconsin. If this fundamental business model is put at risk, we could easily see imported drugs resulting in the loss of U.S. jobs.

Slide Showing Key Points

In summary, in none of our twenty-two Internet drug purchases did we receive an FDA approved drug manufactured by the applicant holder in an FDA approved facility. What we have learned so far is that importation is likely to:

- Compromise patient safety,

- Increase patient confusion,
- Undermine U.S. Intellectual property and contract rights, and
- Lead to the export of U.S. jobs

Slide showing King Logo and Name, Title and Contact Info

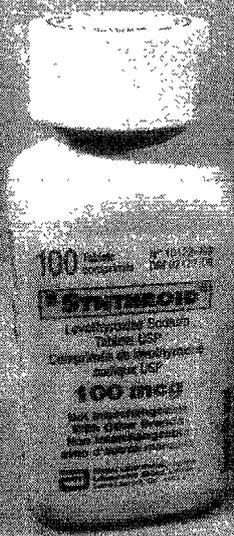
In conclusion, we thank you for your consideration. We are at your disposal as you continue to evaluate these issues and would be happy to meet with you privately to discuss our ongoing investigation in greater detail.



**DHHS – Task Force on Drug Importation
Public Meeting
April 14, 2004**

**James E. Green
Executive Vice President of Corporate Affairs
King Pharmaceuticals, Inc.**

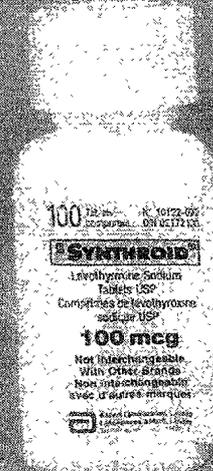
crossborderpharmacy.com



crossborderpharmacy.com

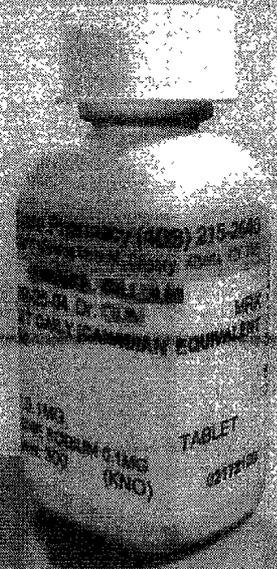


crossborderpharmacy.com

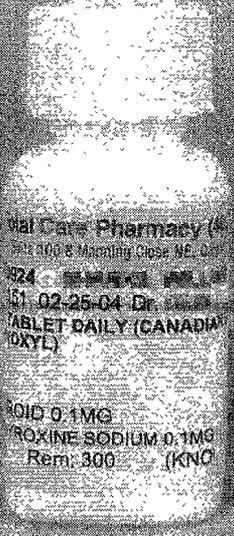


Total Care Pharmacy (403) 215-2640
 Suite 102 & Macdonald Drive NE, Calgary, Alberta T2C 1A5
 Rx# 420924
 TX# 751151-02-25-04 Dr. [Name] MRK
TAKE 1 TABLET DAILY (CANADIAN EQUIVALENT FOR LEVOXYL)
 SYNTHROID 0.1MG TABLET
 LEVOTHYROXINE SODIUM 0.1MG (KNO)
 Fill: 100 Rem: 300 22172100

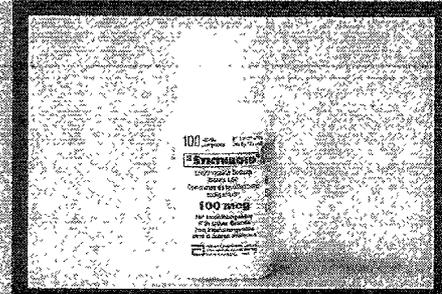
crossborderpharmacy.com



crossborderpharmacy.com

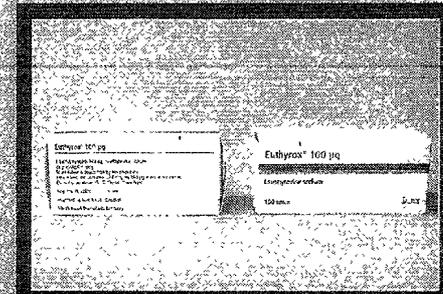


Drugs Substituted for Levoxyll® Prescriptions



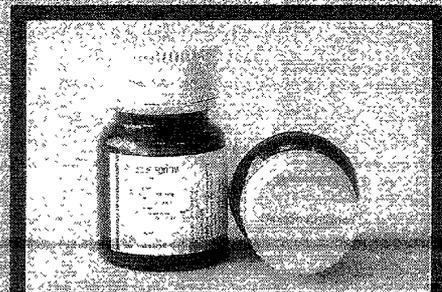
Canada

(Synthroid®)



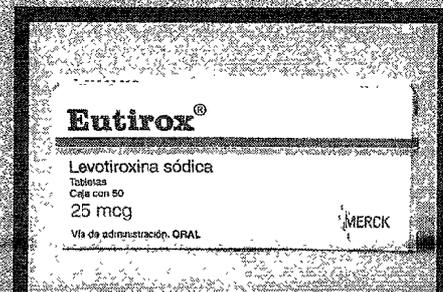
Thailand

(Euthyrox®)



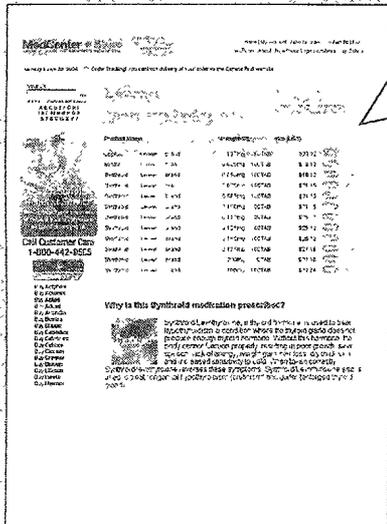
Fiji

(Eltroxin®)



Mexico

(Eutirox®)



MedCenter Store

AMERICA'S SOURCE OF AFFORDABLE MEDICATIONS

* * *

Levoxyl

“Levoxyl” from Canadian pharmacy
Levoxyl is known as Synthroid in Canada.

Product Name	Strength/Qty	Price (US\$)
Loprox Levoxyl brand	.137mg 100TAB	\$23.12 +Add

www.alliedprescriptions.com

ALLIEDPRESCRIPTIONS.COM HEALTH THROUGH CARE

ASSET CHEMIST LTD.
38 GROVEBURY ROAD
ABBEY WOOD
LONDON
SE2 5BS
UNITED KINGDOM

Dear Sir or Madam,

Thank you for having your medication filled by ASSET CHEMIST, your alliedprescriptions.com partner in England U.K

Your medication may appear different in shape, color or packaging from those you have received previously.

Please be assured that the products are the same and have been manufactured by the same company at FDA approved plants.

Should you have any questions or inquiries:

Please do not hesitate to contact us and speak to one of our Pharmacists who would be only too happy to answer any of your questions or contact the Customer service team toll free at:

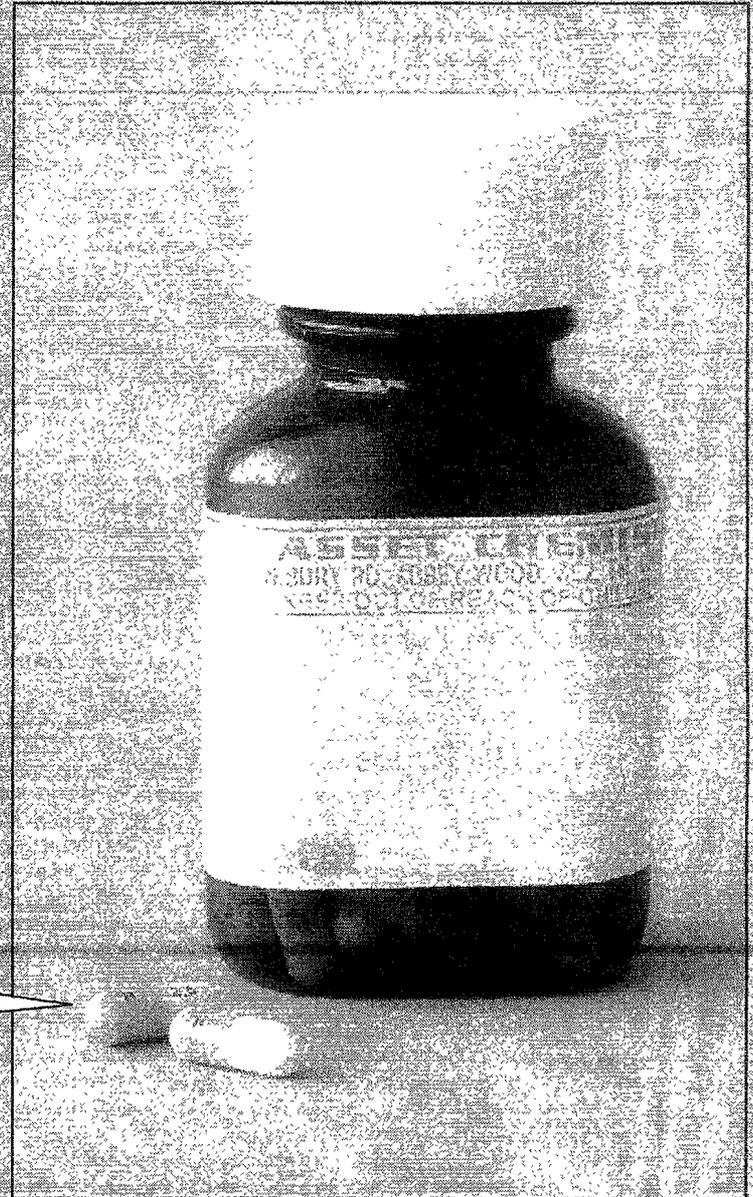
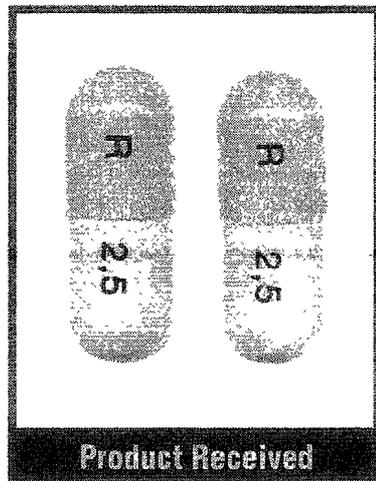
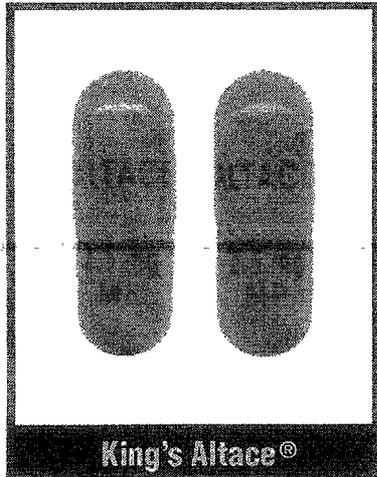
1-877-473-7056 or see all details at AlliedPrescriptions.com

Thank you and we look forward to servicing your future prescription needs

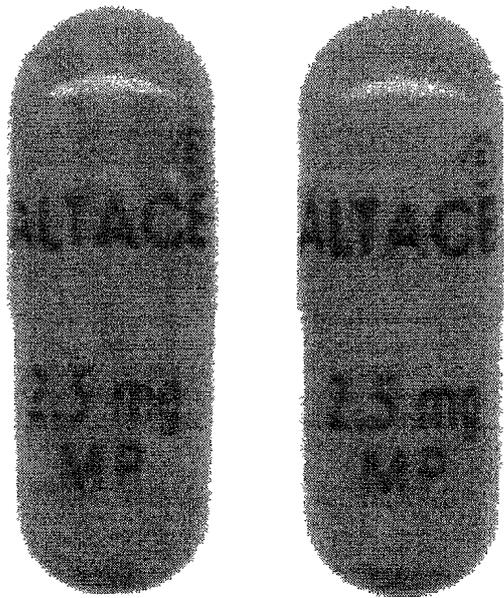
The Pharmacy Team at ASSET CHEMIST LTD.

Your medication may appear different in shape, color or packaging from those you have received previously.

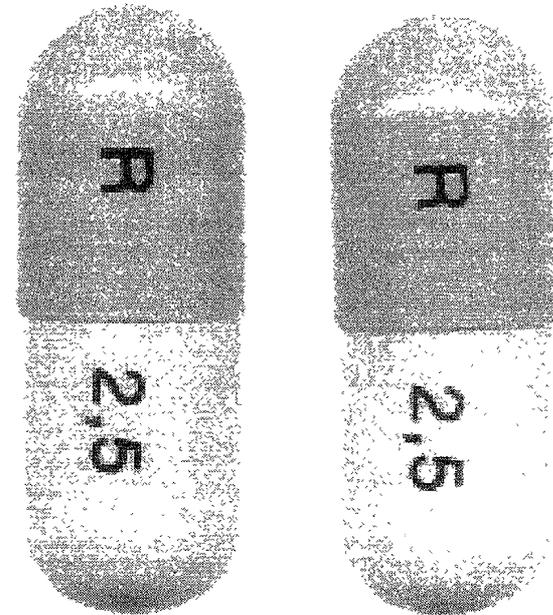
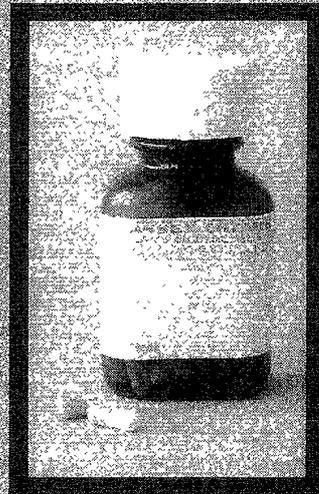
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www.alliedprescriptions.com

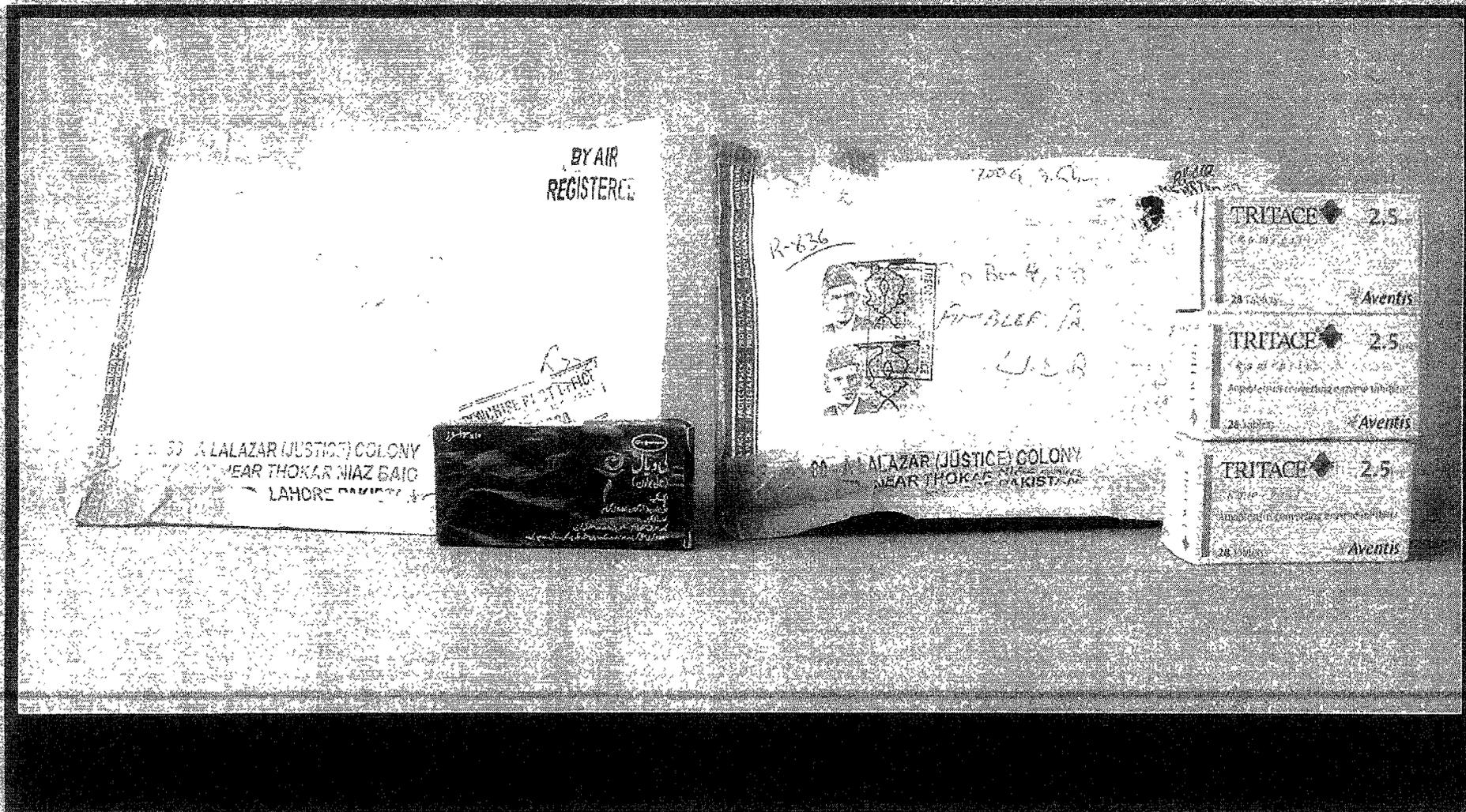


King's Altace®

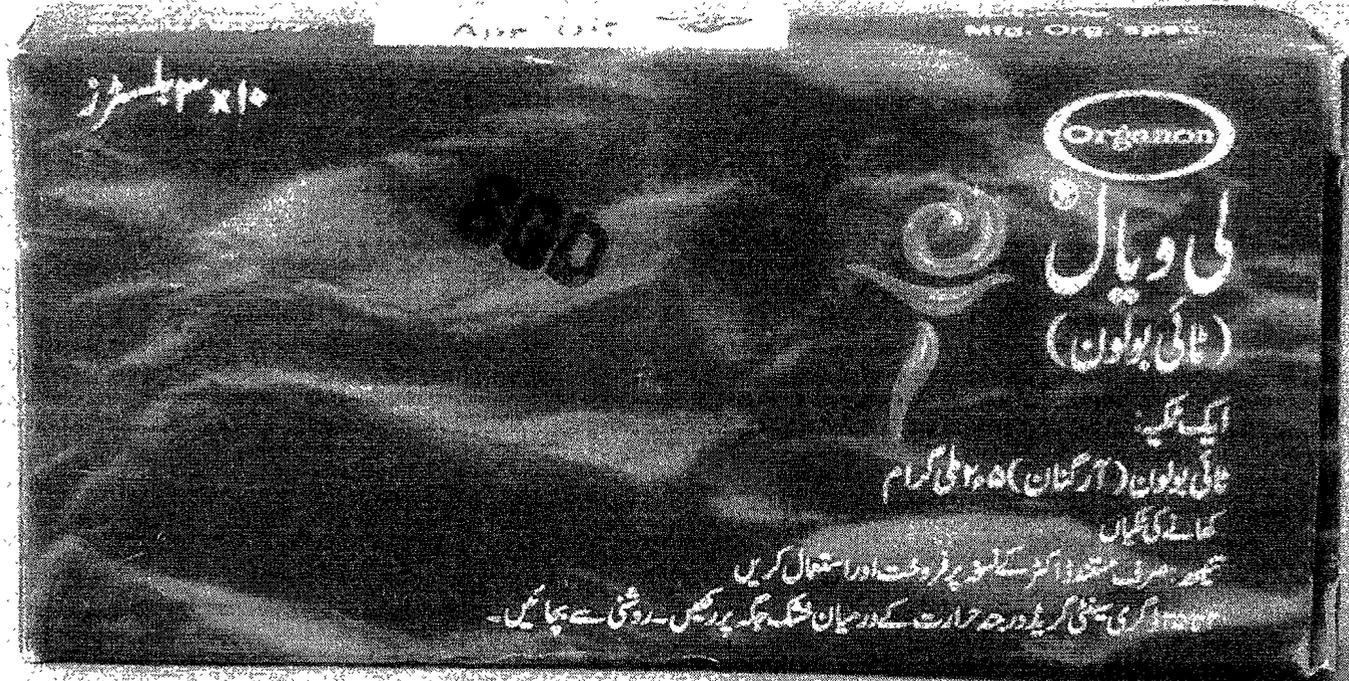


Product Received

www.discountmedsonline.com

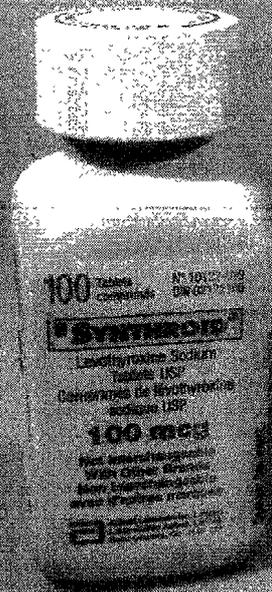


www.discountmedsonline.com

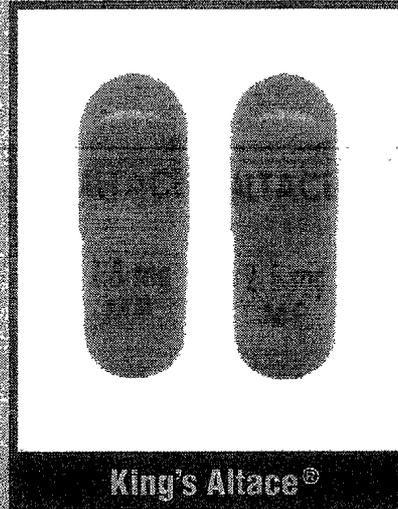


(Not Ordered)

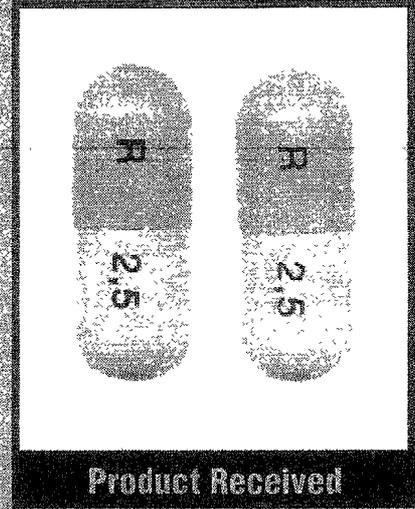
crossborderpharmacy.com



www.alliedprescriptions.com

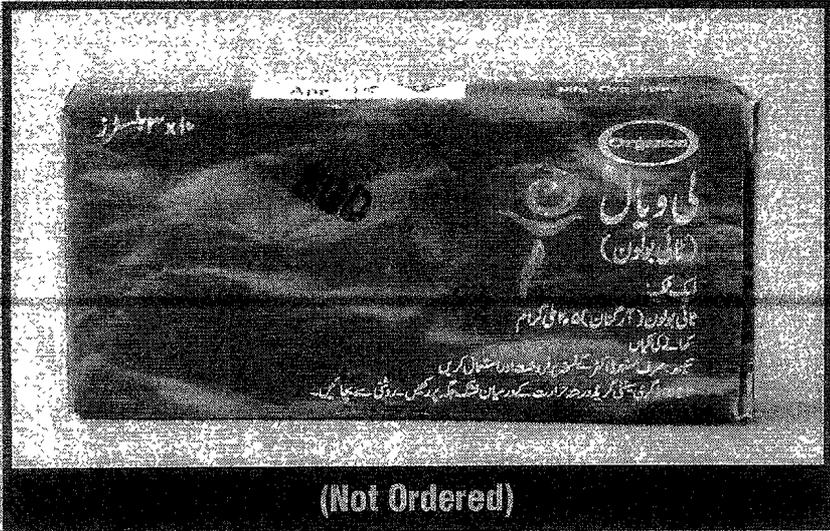


King's Altace®



Product Received

www.discountmedsonline.com



(Not Ordered)

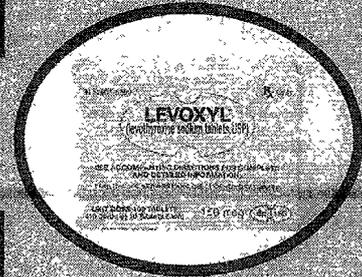
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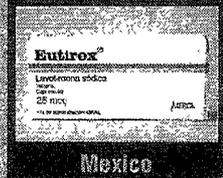
Canada
(Synthroid®)



Thailand
(Euthyrox®)



Fiji
(Eltroxin®)



Mexico
(Eutirox®)

Key Points

● **Compromise Safety**

● **Patient Confusion**

● **Damage IP/Contract Rights**

● **Effectively Exports U.S. Jobs**



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800-776-3637

James.Green@kingpharm.com
