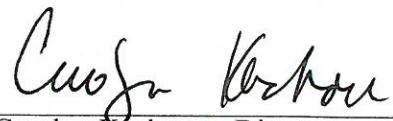


CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that Chih Shang J. Shen, Compliance Officer, Los Angeles District, Office of Regulatory Affairs, United States Food and Drug Administration, whose declaration is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provision of Title 42, United States Code, Section 3505, and FDA Staff Manual Guide 1410.23(1)(a)(6)(ii), hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this 11 day of May, 2009.



Carolyn Kachovec, Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management  
Food and Drug Administration

By direction of the Secretary of  
Health and Human Services

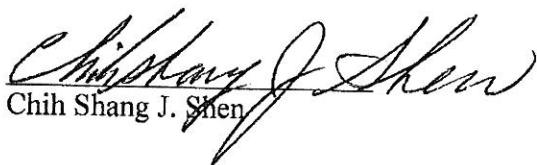
DECLARATION OF CHIH SHANG J. SHEN

Chih Shang J. Shen declares as follows:

1. I am a Compliance Officer, Los Angeles District, Office of Regulatory Affairs, United States Food and Drug Administration (FDA).
2. In this capacity, I have custody of official records of FDA relating to certain shipments of electronic cigarettes and accessories numbered DO7-1112223-7 and DO7-1112224-5.
3. Attached is a copy of an index to documents related to FDA's determinations on DO7-1112223-7 and DO7-1112224-5. In addition, I consulted with Kevin Budich of FDA's Center for Drug Evaluation and Research regarding these determinations.
4. Copies of the documents referenced in paragraph 3 above are part of the official records of FDA.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 7, 2009.

  
Chih Shang J. Shen

**Smoking Everywhere, Inc.**  
**Detention and Refusal of DO7-1112223-7 and DO7-11122245**  
**Index to Administrative Record**

| <b>Document Date</b>   | <b>Description</b>  | <b>Bates Number</b> |
|------------------------|---|---------------------|
| 12/17/2008             | Promotional materials from Smoking Everywhere website   | 000001-000053       |
| 12/17/2008             | User Manual for Electronic Cigarette  | 000054-000058       |
|                        |   |                     |
| 10/21/2008             | Notice of FDA Action - Hold Designated (DO7-1112223-7)  | 000059              |
| 10/21/2008             | Notice of FDA Action - Hold Designated (DO7-1112224-5)  | 000060              |
| 10/21/2008             | Photos of cartons of E-Cigarettes (DO7-1112223-7)   | 000061-000066       |
| 10/21/2008             | Photos of cartons of E-Cigarettes (DO7-1112224-5)   | 000067-000077       |
| 10/29/2008             | Notice of FDA Action - Detention (DO7-1112223-7)  | 000078-000079       |
| 10/29/2008             | Notice of FDA Action - Detention (DO7-1112224-5)  | 000080-000081       |
| 11/25/2008 - 2/11/2009 | Email exchange between Dr. Jim Shen, Rick Quinn, and Benjamin England, Esq. re: Extension Request for Entry Nos. D07-1112223-7, D07-1112224-5 and request for release | 000082-000088       |
| 12/10/2008             | Fax cover sheet from Benjamin England, Esq. to Dr. Jim Shen, Los Angeles District Imports Compliance, FDA attaching 11/25/2008 letter re: FDA and Customs Matters     | 000089-000090       |
| 12/19/2008             | Email exchange re: Extension Request for Entry Nos. D07-1112223-7, D07-1112224-5 and request for release  | 000091-000096       |
| 12/23/2008             | Notice of FDA Action - Correspondence (DO7-1112223-7)   | 000097-000099       |
| 12/23/2008             | Notice of FDA Action - Correspondence (DO7-1112224-5)   | 000100-000101       |
| 3/16/2009              | Notice of FDA Action - Refusal of Admission (DO7-1112223-7)   | 000102-000104       |
| 3/16/2009              | Notice of FDA Action - Refusal of Admission (DO7-1112224-5)   | 000105-000106       |

| <b>Document Date</b> | <b>Description</b>  | <b>Bates Number</b> |
|----------------------|---|---------------------|
| 4/6/2009             | Letter from Elicko Taleb, Chief Executive Officer, Smoking Everywhere LLC to Chih-Shang J. Shen, Compliance Officer, FDA re: Authorization for Thompson Hine LLP to communicate with FDA and other regulatory authorities on behalf of Smoking Everywhere LLC | 000107              |
| 10/16/2008           | Application for Entry/Immediate Delivery (DO7-1112223-7)  | 000108-000120       |
| 10/16/2008           | Application for Entry/Immediate Delivery (DO7-1112224-5)  | 000121-000134       |



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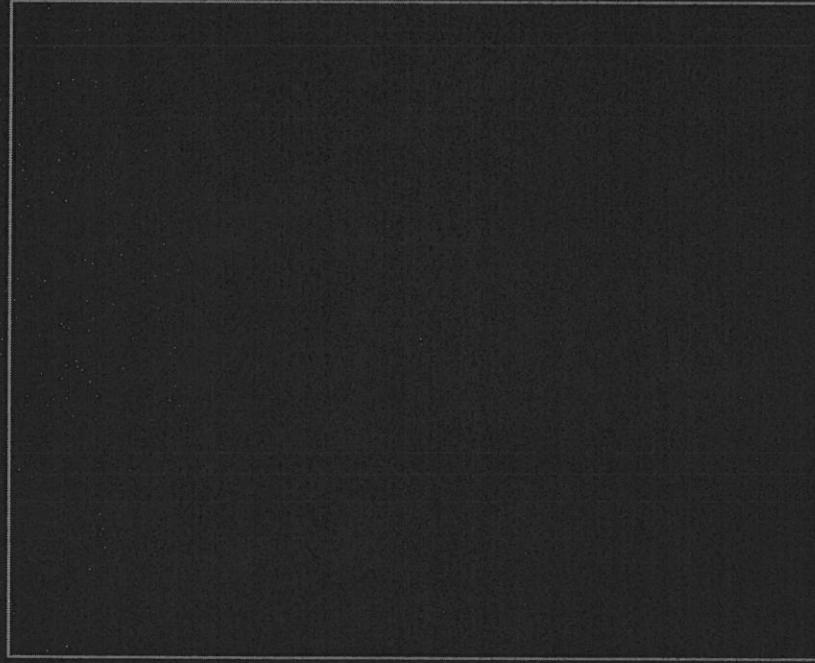
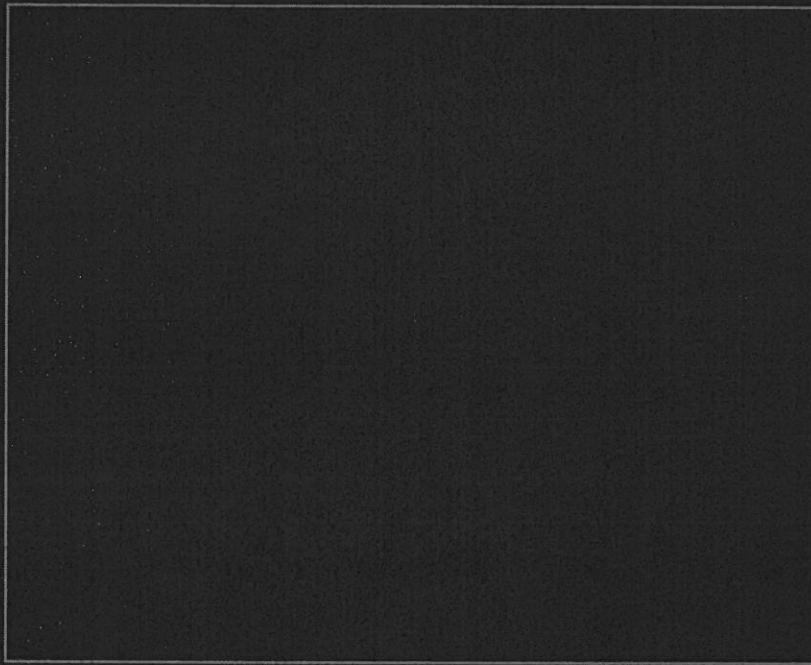
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## **Specialty Retail Magazine FALL 2008 Front Cover Feature: Smoking Everywhere E-Cigarette**

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## FAQ'S:

**Is Smoking Everywhere Electronic Cigarette safe?**

**What is a Cartridge?**

**How long will the cartridge last?**

**Who is Smoking Everywhere, LLC?**

**When do I have to replace a cartridge?**

**Do I need a lighter for the E-Cigarette?**

**How do I Turn-On the Smoking Everywhere E-Cigarette?**

**How long will the battery last before needing to recharge?**

**Is there a warranty with the purchase?**

**Can I get nicotine poisoning if I continue to smoke the Smoking Everywhere E-Cigarette?**

**Where can I buy the Smoking Everywhere E-Cigarette?**

**What is the smoke that is released from the E-Cigarette?**

**Does the Smoking Everywhere E-Cigarette have a smell?**

**Does the Smoking Everywhere E-Cigarette have a taste?**

**Can I use Smoking Everywhere E-Cigarette anywhere?**

**What does it mean when the indicator light flashes?**

**Can anyone use the Smoking Everywhere E-Cigarette?**

**Why people using Smoking Everywhere E-Cigarette?**



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## Smoking Everywhere E-Cigarette cheaper than traditional cigarettes?

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| Car Charger              | Can Be Smoked Everywhere | Join our MySpace    | Work From Home            | How to use the E-Cig? |
| Metal Case               | Cool Design              | Sawgrass Mills Mall | Affiliate Login           | Testimonials          |
|                          | Different Flavors        | Dr. Manny Fox News  |                           | Downloads             |
|                          | Rechargeable             | ABC News            |                           |                       |
|                          | Cheaper Then Cigarette   | Breaking News       |                           |                       |
|                          | Healthier Options        |                     |                           |                       |
|                          | Downloads                |                     |                           |                       |

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## How To Buy:

Smoking Everywhere Electronic Cigarette now open 2 locations at the Sawgrass Mills Mall in Sunrise Florida. and over 60 other location all over the U.S, with 55 more to open for Christmas 2009.

To purchase Smoking Everywhere E-Cigarette today please call 1-800-613-0337 to find out your nearest location, or buy online through one of our approved Resellers.

Or, click here to **BUY IT NOW**



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In order to gain use of the site (become a "user"), we require you to disclose the following information:

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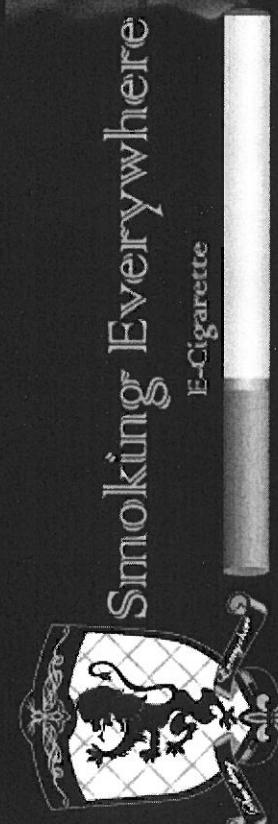
Address

Phone Number

Enroller ID

We may use the Information you provide to us to contact you about changes to our site, new services, features or products we offer, or other information we think you shall find valuable. If at any time you do not wish to receive such information, you may "opt-out" of doing so by sending an email to us at support@smokingeverywhere.com.

If you choose to post information on our site or maintain email, or telephone contact with us, we may retain such information also and its transmission via email



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is not secured.

### **Sharing Information with Advertisers or Other Third Parties**

We may disclose anonymous information about user habits, characteristics and user patterns, based on aggregate user statistics to advertisers on our site. The parties who perform services for us (credit card processors, merchant bank, our Internet Service Provider) may also have access to your information in performing such services. Should we buy or sell assets of our company, another company may need to review our company's assets, including your information, to make business decisions as to whether to acquire such assets. Sharing Information with the Government or As Otherwise Required by Law We may be required by subpoena, law or government agency to disclose both Active and Passive Information you have provided to us.

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### **Security**

Data security is important to Smoking Everywhere, LLC. and we have industry-

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## SATISFACTION GUARANTEE

If you're not completely satisfied with our product, please return it for an exchange ONLY to any other products within (even if used) within 30 days of your original purchase date (less shipping & handling) - NO REFUND!.

## 12 MONTH DEVICE LIMITED WARRANTY

Smoking Everywhere, LLC warrants to the original purchaser of the Smoking Everywhere Electronic Cigarette, that it will be free from defects in materials and workmanship for a period of ONE YEAR (12 months) from the date of original purchase. During the warranty period, Smoking Everywhere will, at its discretion, repair or replace (with a new or reconditioned unit) components that are defective. Exclusions to this warranty shall not apply to defects resulting from misuse, improper or inadequate maintenance or unauthorized modification. This Limited Warranty gives the original purchaser specific limited rights, in addition to those rights under applicable local law.

## TO REPLACE YOUR PRODUCT, PLEASE FOLLOW THE INSTRUCTION

### BELOW:

Pack the items to be returned securely (Shipping charges to Smoking Everywhere are your responsibility).

Please enclose your original bill of sale, your name, address, telephone numbers, email address and reason for returning the item.

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## Testimonials:

Hey my name is Celia and I heard about smoking everywhere e-cig and I though it was a great alternative to help me stop smoking real cigarettes.. For me I believe I will lower my strengths of nicotine very soon by smoking everywhere e-cig. I feel great since I've been using smoking everywhere e-cig.

*Celia (New York)*

Wow! What a concept.. I've been smoking real cigarettes for over 20 years and really wanted to stop because it was damaging my lungs... I heard about smoking everywhere e-cigarette from a friend who was using it for about a month, he told me that I should try it, and so I did and I've been using it for 3 weeks now and feel great..

*Z.U (California)*

Smoking everywhere electronic –cigarette is wonderful, I love the cherry flavor in medium strength..

*Jo-C (Florida)*

I'm going to refer all my friends about this wonderful product.. There is less health risk, and I can smoke anywhere and everywhere. Wow what a catchy name smoking everywhere, that's cool who ever thought of it... catchy name and easy to remember.

*Mike (Florida)*



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Car Charger

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Non Flammable

Can Be Smoked Everywhere

Cool Design

Different Flavors

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Reason for Inquiry

Name

Day time Phone

Evening Phone

Email

Notes, comments or Special  
requests?

**Office:**

Smoking Everywhere, LLC.

4500 North Hiatus Road. Suite 215

Sunrise, FL 33351 USA

**Phone:**

Toll Free: (800) 613-0337

Mon-Fri: 9:00 a.m. – 6:00 p.m. (EST)

**Fax:**

U.S Fax (954) 208-0696

**Email:**

support@SmokingEverywhere.com

Address

City

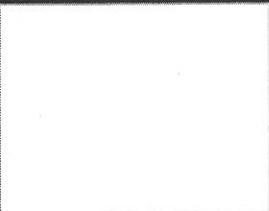
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## **Smoking Everywhere E-Cigarette Starter Kit:**

It looks like a cigarette, it tastes like a cigarette, it feels like a cigarette, but it isn't a cigarette, it contains no tobacco, and the "smoke" is vapor.

Containing state of the art micro-electronic technology this re-chargeable e-cigarette produces a real smoking experience without any of the deeply unpleasant side-effects of tobacco.

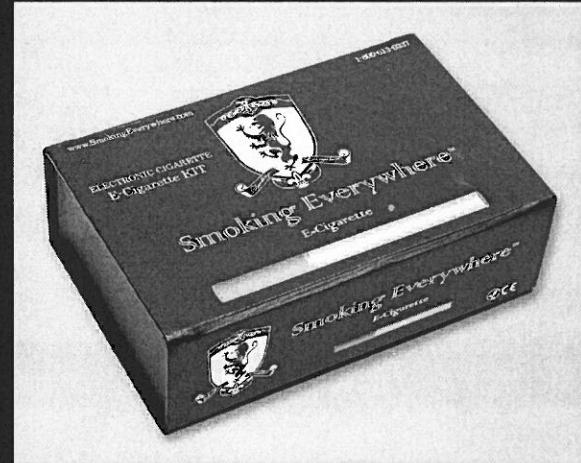
As you inhale, a tiny battery vaporizes liquid inside the cigarette producing smoke. You insert the Nicotine cartridges of your choice (it comes with a set of 5) that will release nicotine - or if you choose to skip the nicotine altogether, try our 0mg (None) Nicotine cartridges or you can choose from High Nicotine (16mg), Medium Nicotine (11mg) or Low Nicotine (6mg).

Of course some people may come up to you telling you to put your Electronic Cigarette out (it looks that real), but there's not much to worry about, it's NOT a real cigarette, there is NO real smoke, flame, tar or tobacco.

It comes with 2 batteries and a home electric charger, and since there is no flame or real tobacco, it's unaffected by the smoking ban... this e-cigarette is considerably better for you than traditional cigarettes, and will save you a fortune in the long run.

### **Smoking Everywhere E-Cigarette KIT Includes:**

- Two Electric Cigarette Rechargeable Batteries.
- 5 high-strength (16mg) tobacco flavored cartridges included in the kit.
- Mains Charger Adaptor.
- Power Lead (U.S plug).
- Manual (English).
- 12 MONTHS (ONE-YEAR) Manufacture Replacement WARRANTY\*.



Electronic Cigarette

### **Smoking Everywhere E-Cigarette KIT Features:**

- An electronic cigarette that's not a part of the smoking ban.
- The device has no flame, no tobacco and no harmful carcinogenic ingredients.
- The cigarette comes in two parts, the longest part contains micro electronic technology and a rechargeable battery and the shorter part is the flavored cartridge.

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Each cartridge is the equivalent of 20 cigarettes.

- The tip of the cigarette lights up as you inhale.
- Simulated smoke is emitted as you exhale. This is only vapor and evaporates in seconds.
- A full charge will last for approximately one day.
- Suitable for those STRICTLY over the age of 18 years.
- Not suitable for pregnant or breast feeding women.

\*Please note that as per our terms and conditions, we cannot accept returns on unwanted items once used.



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## Smoking Everywhere E-Cigarette Cartridges:

**The cartridges come in a pack of 5 and are available in four strengths:**

High (16mg Nicotine)

Medium (11mg Nicotine)

Low (6mg Nicotine) and

Non (0mg Nicotine)

Each cartridge is equivalent to 20 traditional cigarettes.

The taste of the Smoking Everywhere cartridge resembles that of tobacco.



**Smoking Everywhere is also launching the following new flavors:**

Tobacco flavor (just like real cigarette)

Apple

Cherry

Strawberry

Chocolate

Vanilla

Coffee

Mint

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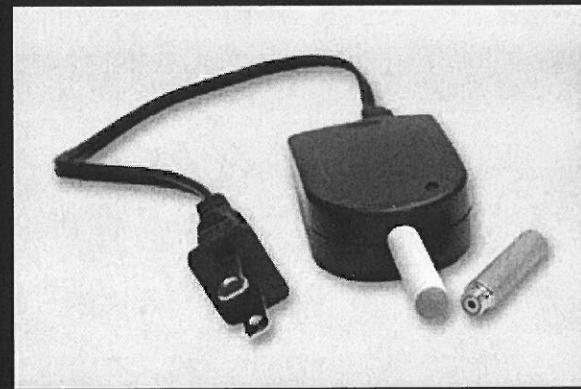
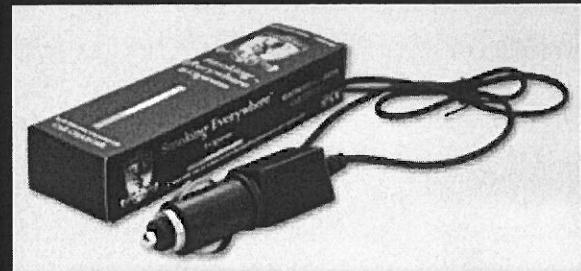
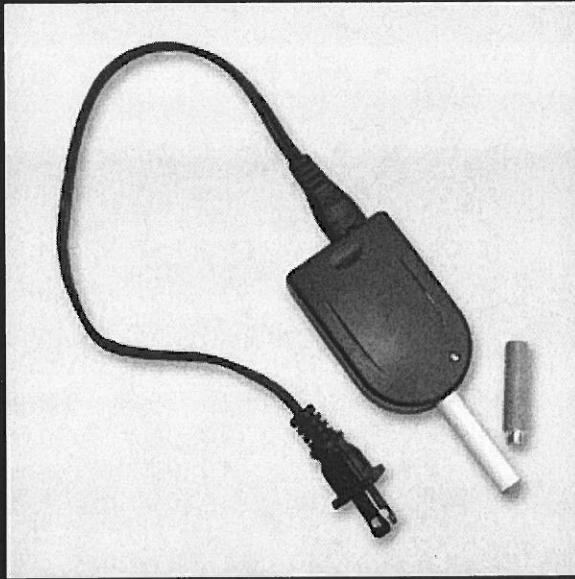
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## Smoking Everywhere E-Cigarette Car Charger:

The Smoking Everywhere Electronic Cigarette car charger, will let you charge your battery while driving, or on the road. A must to have if you travel a lot...

The electric home charger comes with the purchase of the Electronic Cigarette KIT.



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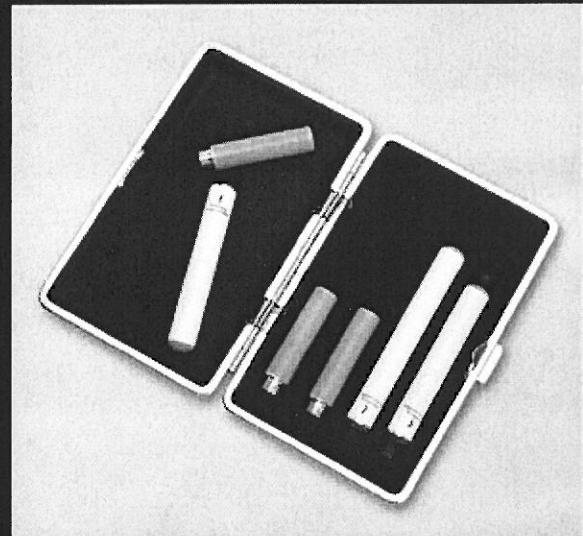
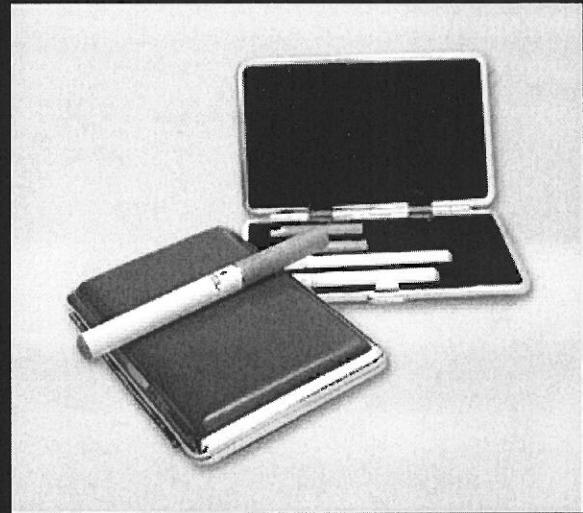
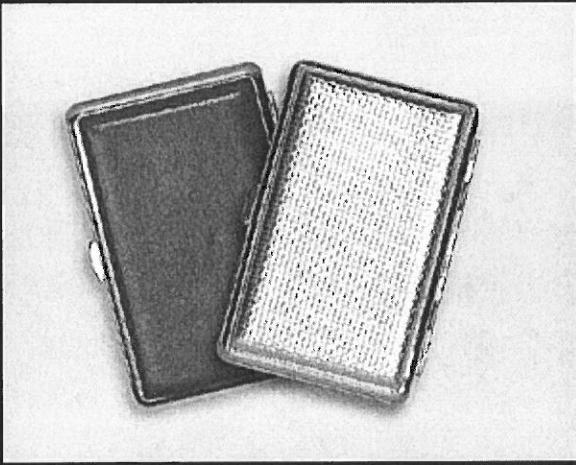
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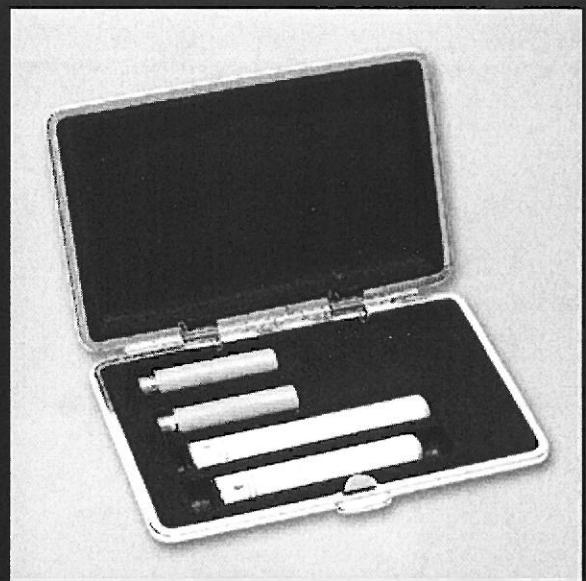
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News**Live Support!****BUY NOW!**Become an Affiliate | **Contact Us**[HOME](#) | [ABOUT OUR PRODUCTS](#) | [PRODUCTS](#) | [BENEFITS](#) | [OUR COMPANY](#) | [OPPORTUNITY](#) | [FAQ'S](#) | [HOWTO BUY?](#)**Smoking Everywhere E-Cigarette Metal Carrying Case:**

The Smoking Everywhere Electronic Cigarette metal carrying case is the most popular way to carry your electric cigarette with style and to keep everyone eyes looking when you pulling this beautiful shiny case from your pocket or bag...

A must have for people with style!



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## Smoking Everywhere Go Green with Eco-Friendly Electronic Cigarette :

We at Smoking Everywhere, LLC consider the Smoking Everywhere E-Cigarette as a GREEN Product, as also known as Eco-Friendly, and we have the goal of helping to create a smoke free environment, by offering smoking cigarettes, without tobacco, tar, smoke and the other chemicals found in the traditional cigarettes, and here is how:

- The Smoking Everywhere E-Cigarette produces vapor mist that looks like smoke, instead of real smoke, and there is no need for ashtrays, because there is no ash created from the Electronic Cigarette.
- There is no cigarette buds to dispose, and therefore much less to recycle.



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## **Smoking Everywhere E-Cigarette is Non-Flammable:**

The Smoking Everywhere E-Cigarette is a completely non-flammable electronic device. There is no danger of fire, anything burning and no substance in it lit. Smoking Everywhere E-Cigarette is a safe product and is CE & Rohs certified.



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## Smoking Everywhere E-Cigarette can be smoked anywhere and everywhere:

The Smoking Everywhere E-Cigarette can be used legally almost anywhere and everywhere, where traditional smoking is prohibited.

The Statutory Definitions of the Smoking Health Act Ban, refers to smoking tobacco or anything which contains tobacco, or being in possession of any other lit substances in a form in which it could be smoked.

The Smoking Everywhere E-Cigarette is not lit and smoke is not produced. The smoke that you see is strictly a harmless vapor mist, and therefore is no breach of the Health Act in using our Electronic Cigarette.

NOTE: There is no need to be concerned about the fact that nicotine is being used because the E-Cigarette is not lit and therefore not smoked.



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## **Smoking Everywhere E-Cigarette looks like a real cigarette:**

Smoking Everywhere E-Cigarette has been designed to look and feel like a traditional cigarette. We use the best quality of materials and technology to create our product and we stand behind it with ONE YEAR (12 months) replacement warranty.



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## Smoking Everywhere E-Cigarette comes in different flavors:

The Smoking Everywhere E-Cigarette cartridges come in various nicotine flavors including"

- Tobacco (just the real cigarette)
- Apple
- Cherry
- Strawberry
- Chocolate
- Coffee
- Vanilla
- Mint

The Smoking Everywhere E-Cigarette cartridges also come in various strengths of nicotine, such as:

- High (16mg nicotine)
- Medium (11mg nicotine)
- Low (6mg nicotine)
- Non (0mg nicotine).



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## **Smoking Everywhere E-Cigarette is rechargeable:**

The Smoking Everywhere E-Cigarette is rechargeable, so you can use it over and over...

With the Smoking Everywhere E-Cigarette starter kit you get two rechargeable batteries, which will give you never-ending smoking experience. The batteries and the atomization chamber come with a ONE YEAR (12 months) warranty and it have been certified by CE & ROHS.



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## **Smoking Everywhere E-Cigarette Is cheaper than real cigarette:**

The costs of smoking traditional cigarettes are becoming too expensive. A normal pack of cigarettes costs between \$4.00 to \$6.00 (average \$ 4.26). however, with Smoking Everywhere E-Cigarette you can enjoy massive savings (source: [http://www.cdc.gov/tobacco/data\\_statistics/factsheets/economic\\_facts.htm](http://www.cdc.gov/tobacco/data_statistics/factsheets/economic_facts.htm)).

After your initial investment of the Smoking Everywhere E-Cigarette starter kit, you will start to notice massive savings of up to 50-80 percent.

A single Smoking Everywhere cartridge is equivalent to a pack of 20 cigarettes but less than 1/2 of the price of a pack of cigarettes.



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## **Smoking Everywhere E-Cigarette Is a Much Healthier Option than Traditional Cigarette:**

Smoking Everywhere E-Cigarette has no tobacco, no tar, no real smoke and no other chemicals like traditional cigarette that can cause lung cancer. However, It looks like a real cigarette, feels like a real cigarette and tastes like a real cigarette, yet it isn't a real cigarette... It is also cheaper and healthier than real cigarettes!!!



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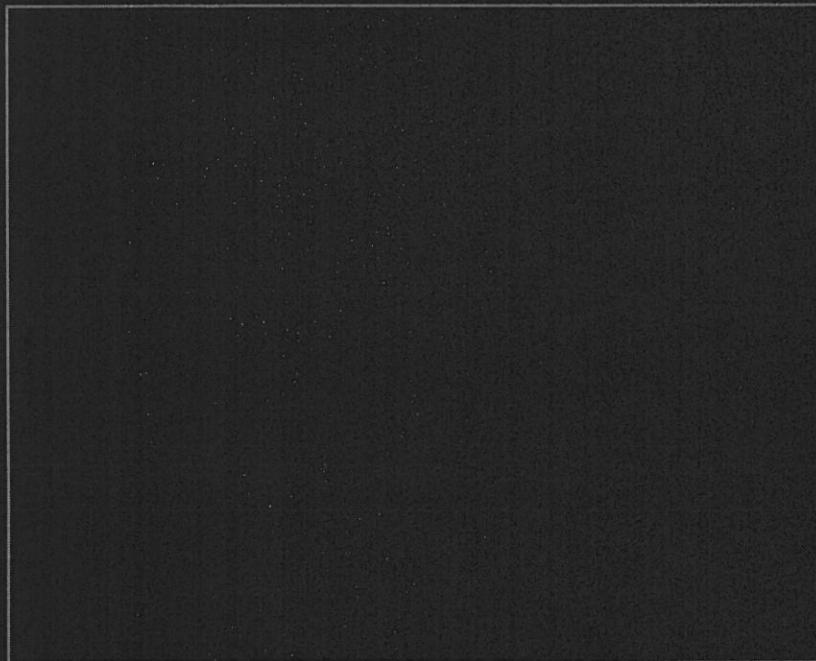
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Download the E-Cigarette Manual here



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## About Us :

Smoking Everywhere, LLC. is a Florida based company pioneering in electronic smoking products. For the past 12 months the team behind Smoking Everywhere E-Cigarette have been product testing and researching the possibility of a healthier alternative to smoking traditional cigarettes and are currently manufacturing a ground breaking electronic smoking devices.

Smoking Everywhere E-Cigarette is completely non-flammable and uses state of the art sophisticated micro-electronics device that gives the users the feeling they get when they smoke real cigarette.

The management of Smoking Everywhere E-Cigarette wants to create a smoke free environment by offering an option to smoke without tobacco, tar and all the other chemicals found in traditional cigarettes.

Join us today, and become a distributor or a user who wants to make a difference!



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## In The News:

Revolutionary Electronic Cigarette Offers a Real Smoking Pleasure & Nicotine

Delivery Without the Tobacco, Tar, Smoke, or Odor (PR.com)

*Now smokers can enjoy cigarettes at a cheaper price with less health risks – and*

*without offending or endangering others with secondhand smoke.*



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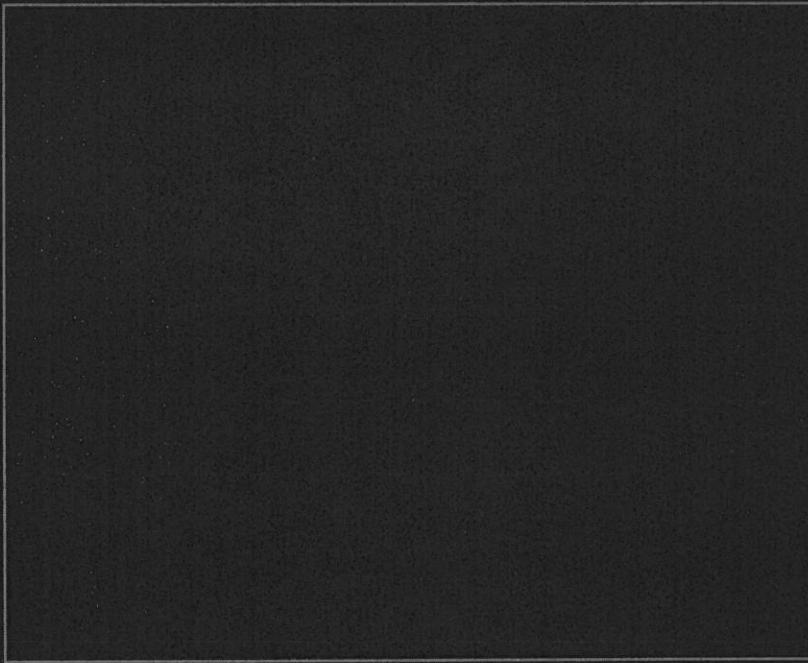
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## Dr. Manny Fox News on Smoking Everywhere Electronic Cigarettes:



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## **Become a Distributor :**

Smoking Everywhere E-Cigarette is expanding it's distribution channels both Resellers and Store Locations in Major Malls around the country. If you would like to learn more about Smoking Everywhere opportunities, please complete the form below and a Smoking Everywhere E-Cigarette representative will contact you within 24 hours.

Alternatively email us at Smoking Everywhere or call 1-800-613-0337

Company Name:

Address 1:

Address 2:

City:

Zip Code:

Country:

Contact Information:

\*Contact Name:

Job Title:

\*Telephone Number:

Fax Number:



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Email Address:

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## **International Distributor:**

Smoking Everywhere Electronic Cigarette is expanding it's distribution channels both nationally and internationally, and offers special distribution programs for resellers. If you would like to learn more about Smoking Everywhere reseller opportunities, please complete the form below and a Smoking Everywhere E-Cigarette representative will contact you within 24 hours.

Alternatively email us at Smoking Everywhere or call 1-800-613-0337

Company Name:

Address 1:

Address 2:

City:

Zip Code:

Country:

Contact Information:

\*Contact Name:

Job Title:

\*Telephone Number:

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**Work From Home:**

Smoking Everywhere, LLC is looking for qualified people who want to become reseller for the Smoking Everywhere Electronic Cigarettes...

If you think you got what it takes to become our reseller and make lots of money, while smoking anywhere and everywhere, please contact us for more details here.

Smoking Everywhere, LLC is the leader in Electronic Cigarettes, and we are rapidly growing rapidly all over the U.S and looking for additional affiliate resellers like yourself.

If you a smoker or someone who loves our product, and want to become your own boss, have a second unlimited source of income and make money while working from the comfort of your home, or while shopping, dining and traveling, contact us today.



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## **What is an Electronic Cigarette (E-Cigarette)?**

Smoking Everywhere Electronic Cigarette Looks like a traditional cigarette, Feels like a traditional cigarette, Taste like a traditional cigarette, But it isn't a traditional cigarette. It's just a much better way to smoke!

Smoking everywhere E-Cigarette is an electronic smoking device or an electronic cigarette which is also known as E-Cigarette. It is a non -flammable product that uses state of the art classy micro-electronic technology which provides smokers a real smoking experience without the fire, flame, tobacco, tar, carbon monoxide, ash, stub or smell found in real cigarettes.

Smoking Everywhere E-Cigarette offers smokers a chance of smoking in a much healthier way and the freedom to smoke everywhere. The smokers still get their nicotine, but don't get any harmful side effects of smoking traditional cigarettes which contains real tobacco.

Smoking Everywhere E-Cigarette offers it smokers many advantages over smoking traditional cigarettes. The product is free of tar & other chemical substances which is produced in traditional cigarettes. It is a non-flammable product and it is pollution free and harmless to other people. There is NO danger of second hand smoke and it is reusable (rechargeable by an electric outlet or car charger) so there is no problem with disposing of cigarette buds or ashes.

Most smokers enjoy the substantial and emotional feelings of smoking.

Smoking Everywhere E-Cigarette will provide smokers the same delight, physical and emotional feelings they get in smoking traditional cigarettes, but without all the problems that is related with traditional smoking. The main reasons people use Smoking Everywhere E-Cigarette includes: healthier way to smoke, freedom to smoke anywhere and everywhere, no first or second hand smoke, no smoke or odor, non-flammable, convenient and cheaper than traditional cigarettes.

We at Smoking Everywhere believes that the Electronic Cigarette is the future of smoking... have you tried it yet?



DET 000049

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#### products

Electronic Cigarette Kit

Cartridges

Car Charger

Metal Case

#### benefits

Eco Friendly

Non Flammable

Can Be Smoked Everywhere

Cool Design

Different Flavors

Rechargeable

Cheaper Then Cigarette

Healthier Options

Downloads

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Dr. Manny Fox News

ABC News

Breaking News

#### opportunity

Become a Distributor

International Distributor

Work From Home

Affiliate Login

#### faqs

What is it?

How Does it Work?

How to use the E-Cig?

Testimonials

Downloads

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Smoking Everywhere E-Cigarette is intended for use by adults and not intended for pregnant women or those who are sensitive to nicotine. Nicotine is highly addictive. Smoking Everywhere E-Cigarette is not intended as a smoking cessation device. Smoking Everywhere E-Cigarette is simply a healthier alternative to traditional smoking.

DET 000050



Smoking Everywhere  
E-Cigarette

Dr. Manny Fox  
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BENEFITS

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OPPORTUNITY

FAQ'S

HOW TO BUY?

## How Does the Electronic Cigarette Work?

Smoking Everywhere E-Cigarette performs just like a traditional cigarette. It looks like, feels like and tastes like a real cigarette and also distributes the same pleasures of smoking a traditional cigarette, but without all the harmful effects of a traditional cigarette.

The top secret to what makes Smoking Everywhere E-Cigarette better than traditional smoking is what is inside this innovative electronic device:

Smoking Everywhere E-Cigarette is driven by a micro-electronic technology. The actual cigarette body is made up of 3 parts: a nicotine cartridge, an atomization chamber, a smart chip with a lithium battery. In the front tip of the device there is an operating indicator light, that lights up when you use the Smoking Everywhere E-Cigarette (puff on), like a real cigarette gets red at the tip while smoking. One of the most attractive features of the Smoking Everywhere E-Cigarette is the atomization chamber that when puffed on creates a vapor like smoke, just like a real cigarette. Vapor is a result of the nicotine that is found in the cartridge, heating up the atomizer device and creating vapor smoke, but without any smell of smoking tobacco. This is what the smoker gets, the nicotine hit that smokers crave, a smoke like illusion, but without having to smoke a real cigarette.



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#### products

Electronic Cigarette Kit

Cartridges

Car Charger

Metal Case

#### benefits

Eco Friendly

Non Flammable

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#### faqs

What is it?

How Does it Work?

How to use the E-Cig?

Testimonials

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Smoking Everywhere E-Cigarette is intended for use by adults and not intended for pregnant women or those who are sensitive to nicotine. Nicotine is highly addictive. Smoking Everywhere E-Cigarette is not intended as a smoking cessation device. Smoking Everywhere E-Cigarette is simply a healthier alternative to traditional smoking.

DET 000052



**Smoking Everywhere**  
E-Cigarette

Dr. Manny Fox  
News



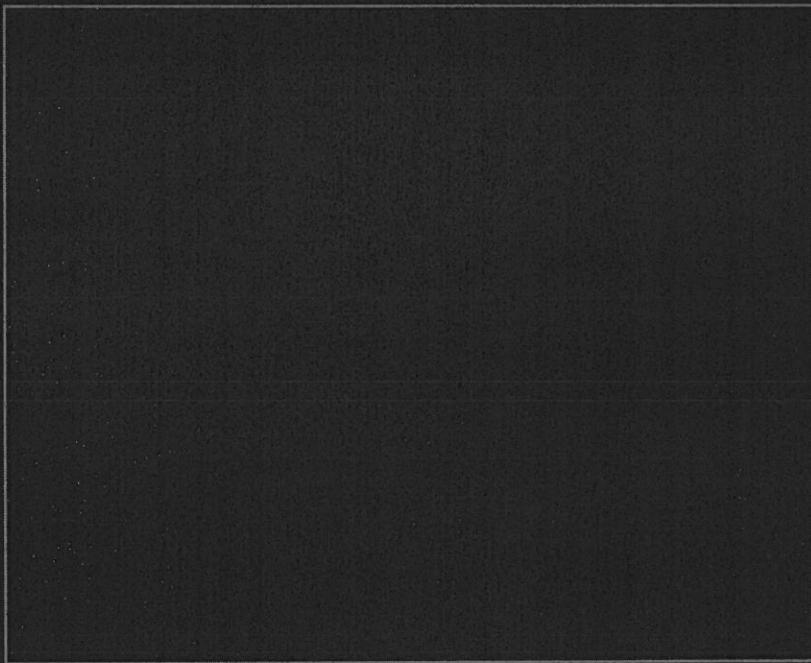
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**Watch the Video and learn how to use the Smoking Everywhere Electronic Cigarettes:**



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**benefits**

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**about us**

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**opportunity**

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**faqs**

Electronic Cigarette Kit

Eco Friendly

our company

Become a Distributor

What is it?

Cartridges

Non Flammable

In The News

International Distributor

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Cool Design

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Dr. Manny Fox News

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Rechargeable

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Cheaper Then Cigarette

Breaking News

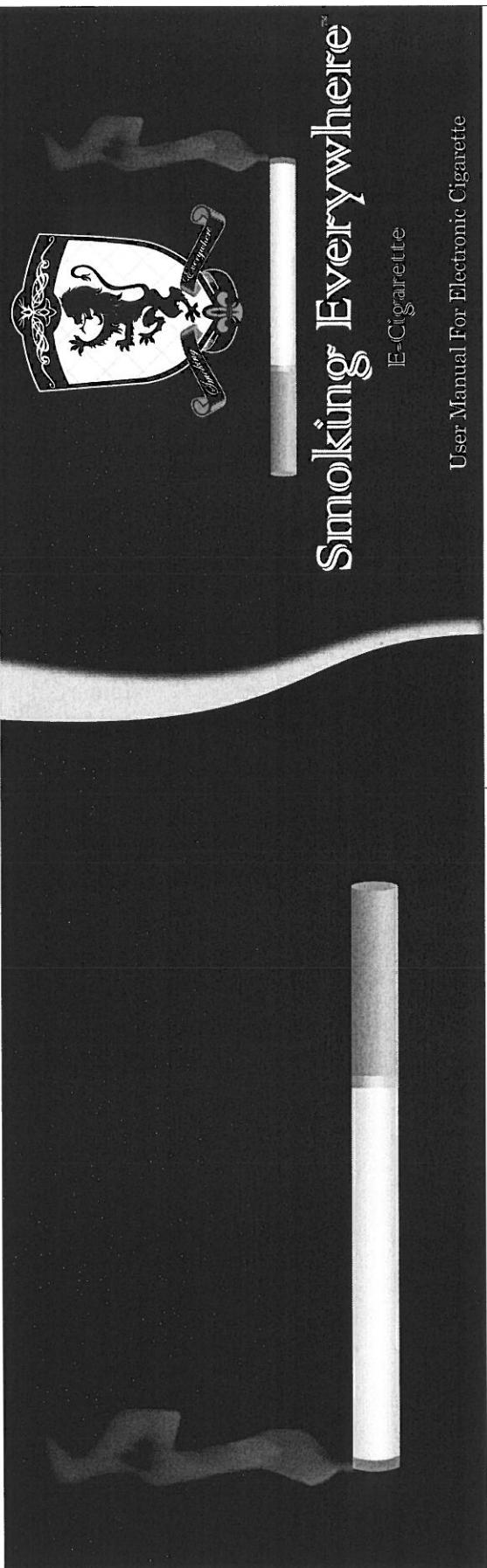
Healthier Options

Downloads

**Copyright © 2008 smokingeverywhere, LLC. All rights reserved.**

Smoking Everywhere E-Cigarette is intended for use by adults and not intended for pregnant women or those who are sensitive to nicotine. Nicotine is highly addictive. Smoking Everywhere E-Cigarette is not intended as a smoking cessation device. Smoking Everywhere E-Cigarette is simply a healthier alternative to traditional smoking.

DET 000053

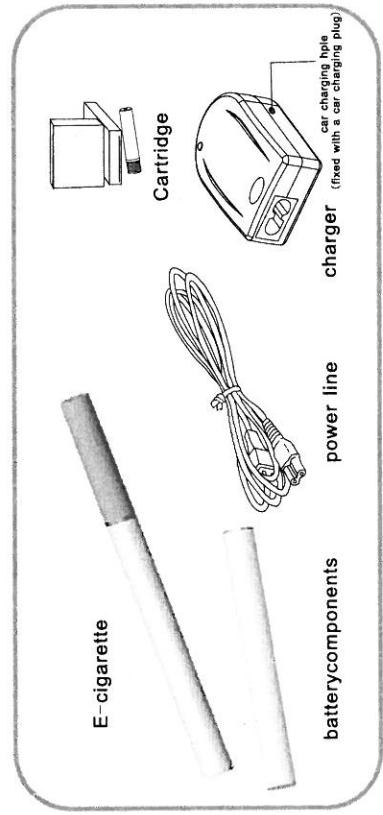


## Smoking Everywhere

E-Cigarette

User Manual For Electronic Cigarette

### Product components



- Congratulations on your beginning to choose a healthy lifestyle which will also create a healthy and environmental-friendly living space for both you and your family.
- Before you start to use this product, please read this user manual carefully so that its performances can be made best use of and this unit be used in accordance with the requirements herein.
- Please keep this manual properly for future reference.

DET 000054

## Catalog

- 01 Safety Information
- 02 Product Introduction
- 03 Structure of an "Electronic Cigarette"
- 04 Use Methods of "Electronic Cigarette"
- 05 Cautions
- 06 Use Method of Charge
- 07 Suitable and Forbidden People
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## Safety Information

01

For safe and effective use of “electronic cigarette” and its supporting products, please read through the following information carefully before use and follow the standard operating procedures strictly.

### Use of “Electronic Cigarette”

After installing new cartridge and battery correctly, the “electronic cigarette” entered its standby status and smoking action can be simulated through sucking the inhaler. Old cartridge will have to be replaced by a new one if smoke is reduced. When the power of the dedicated lithium battery is used up, the indicator in front of the cigarette body will flash continuously and this means that new dedicated lithium battery assembly will have to be used.

### Use of AC Charger

Please screw the dedicated lithium battery into electronic cigarette's dedicated charger. Charger can work normally with an AC100V-240V 50/60Hz voltage. To reduce the risk of electric shock, charger should be unplugged from its power source before cleaning it. Charger is prohibited to be used outdoors or in a damp environment.

## Safety Information

02

- Precautions for Pocket Carrying  
If you are carrying the “electronic cigarette” with you, please take care of the “electronic cigarette” separately and any collision or squeeze must be avoided.
- Electronic cigarette's fittings  
“Electronic cigarette” is a kind of high-tech product and its components such as cartridge, battery, and charger and so on are dedicated ones. The use of any undedicated components will lead to electronic cigarette's malfunction and damage of this product.
- Use in public places  
“Electronic cigarette” will not produce any second-hand smoke to others and does not cause harm to surrounding people and environment; meanwhile it does not need to be lit and will not have any fire risk so it can be used safely in most public places.

## Safety Information

03

No Use of “Electronic Cig” When Driving  
When driving, please ensure your strict compliance with the relevant laws and regulations of the country or region where you are staying; be concentrated on driving and pay attention to road conditions. Do not use “electronic cigarette” while driving and keep your electronic cigarette properly to avoid any damage to the product caused by collision.

### Precautions

When using or storing this product, avoid any hot and/or damp environment. Do not let children play “electronic cigarette” and its supporting components. Avoid improper operation that may cause damage to this product. Cigarette should be taken care of properly and kept away from children's reach. When using this “electronic cigarette”, it would be appropriate that the time and frequency of your continuous sucking action should not exceed that of smoking a traditional cigarette in normal times.

DET 000055

## 04 Product Introduction

### Product Introduction

#### Principle of "Electronic Cigarette"

"Electronic cigarette" uses advanced microelectronic technology and supercritical physical atomization technology to atomize the high-purity and exciting nicotine dilution extracted from tobacco into smoke for smoker's sucking and accordingly meet the needs of those smokers. The nicotine dilution used contains nicotine, tobacco flavor and so on.

The birth of "electronic cigarette" is a revolution of mankind's smoking history. Undoubtedly, its birth will bring a gospel to mankind, especially the vast smokers and will have extremely far-reaching impact on human being's lifestyle. We believe that "electronic cigarette" will certainly be able to eradicate evil tobacco's hazards to human being.

"Electronic cigarette" is a kind of non-flammable electronic cigarette with similar functions to those of a common cigarette which is to refresh smokers and satisfy their smoking addiction, thus making them happy and relaxed. So "electronic cigarette" is the best substitute to common cigarette.

#### Significant Advantages of "Electronic Cigarette"

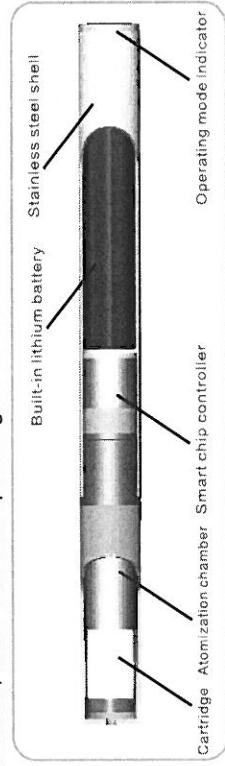
1. Free of tar and other carcinogenic substances harmful to human body;
2. Non-flammable, without the danger of over 4,000 chemical substances produced by the common cigarette;
3. Harmless to others and pollution-free to environment caused by "second-hand smoking";
4. Without the hidden danger of fire accident and can be used in most public places;
5. Wide serviceable range and be able to work normally between -5 degrees to 42 degrees.
6. Humanely designed, similar simulated smoke temperature to body temperature;
7. Shielded electromagnetic, free of electromagnetic radiation;
8. The nicotine content of each liquid container is less than that of 20 ordinary cigarettes.

## 05

### Structure of an "Electronic Cigarette"

#### Cigarette body

The cigarette body is an integrated structure consisting of stainless steel shell, lithium ion battery assembly, smart chip and program controlled circuits, atomization chamber and cartridge and so on. In the front of it, there exists an operating mode indicator.



## 07

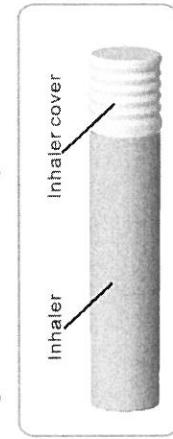
### Structure of an "Electronic Cigarette"

#### Atomization cartridge

The atomization cartridge of an "electronic cigarette" is composed of an inhaler and a liquid container. The nicotine dilution to be atomized is stored in this liquid container and is free of ingredients harmful to human body, such as tar and carcinogenic substance.

The inhaler is for one-time-only use.

The nicotine content in cartridge is classified into high, medium, low, and zero with various tastes to meet the needs of different people.

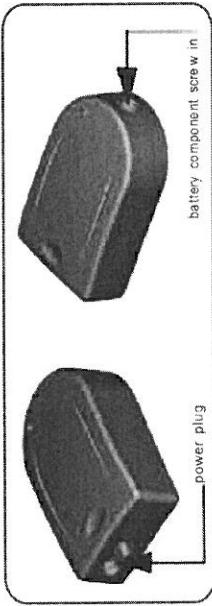


08

## Structure of an "Electronic Cigarette"

### Battery and Charger

"Electronic cigarette" uses a 3.7V special-purpose lithium ion battery and the supporting charger is also a special device for this and both battery and charter cannot be substituted by other lithium battery or charger. The input supply voltage of the charger is AC100V~240V 50/60HZ. During traveling, attention shall be paid to if the rated value of local supply voltage is accordant to that of electronic cigarette's charger.



09

## Use Methods of "Electronic Cigarette"

### 1. Installation:

Step one: unpack the cigarette cartridge and remove the inhaler cover of the cartridge;  
Step two: insert the cartridge into the cigarette body.

### 2. Operating Mode:

When placing the "electronic cigarette" into lips and sucking it, circuit will be activated and the indicator in front of the cigarette body will light up immediately; when inhaling ended, atomization will stop accordingly and its operating mode changes into standby. The best angle of using this unit is horizontal and it is not appropriate to use it upwards to prevent any small amount of liquid from flowing into the mouth which may cause stimulation to oral mucositis. The built-in micro-computer controlled programs have self-cleaning function; when accumulated number of "electronic cigarette" suction has reached 1,500, the indicator in front of the cigarette body will keep on lighting for 6 seconds, which means that the micro-computer controlled programs are cleaning the unit automatically.

10

## Use Methods of "Electronic Cigarette"

### 3. Battery Replacement:

During the use of this unit, if indicator in front of the cigarette body is found to be flashing slowly for consecutive 20 times, it means that the battery may have to be replaced.

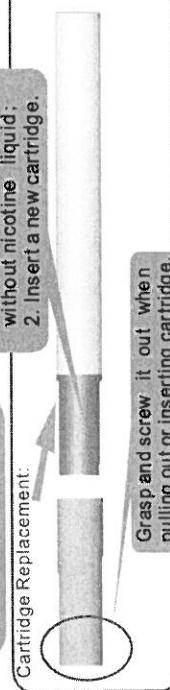
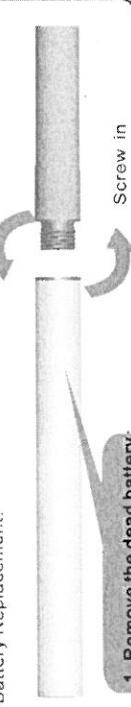
### 4. Cartridge Replacement:

During the use of this unit, if smoke is found to be significantly reduced, please replace the cartridge accordingly.

11

## Use Methods of "Electronic Cigarette"

### Battery Replacement:

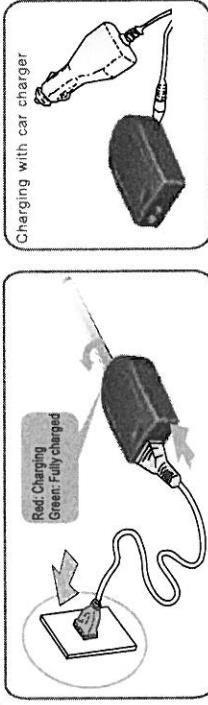


### Installation:



## 12 Use Method of Charge

During the use of this unit, if indicator in front of the cigarette body is found to be flashing, the accompanying charger of this unit should be used to charge the battery assembly. In order to charge, please connect the power cord to the charger and the plug into a socket, screw the battery into the charger jack. After charging for 3-4 hours, the charger indicator will turn from red to green, which means that the battery has been fully charged and please remove the battery and disconnect the power source of the charger accordingly.



## 13 Cautions

It is prohibited that battery is charged near a high-temp heat source. It is prohibited that battery is welded directly or pierced by nails or any other sharp objects.

If battery is found to be emitting any odor or heat or be discolored or deformed or have any abnormality during charging, please cut off the power source immediately and remove the battery from cigarette body or charger and suspend the use of it.

This charger can only be used to charge electronic cigarette's dedicated lithium ion battery. Do not try to use this charger to charge other kind of battery.

Please keep this "electronic cigarette" and cartridge from the reach of children.

This unit can only use the accompanying charger and battery provided by our company.

## 14 Cautions

The first charging must be kept for 8 hours and the charging for regular use be kept for 3-4 hours.

The nicotine dilution contained in the cartridge of this "electronic cigarette" is prohibited from direct contact with mucositis. No direct entrance to mouth is allowed.

This is a high-tech electronic product and knocking or collision must be avoided.

In order to prevent too frequent use of the product, the front indicator will flash for 10 seconds for reminding if the cigarette is sucked for consecutive 15 times within one minute.

## 15 Suitable and Forbidden People

### Suitable People:

People with long smoking history suffering from uncomfortable feeling without smoking cigarette  
People working in no-smoking areas for long time but having habit of smoking

### Forbidden People:

Minors under the age of 18  
People without the habit of smoking  
People allergic to nicotine or any components of inhalants  
Pregnant and breastfeeding women

**United States Food and Drug Administration**  
Los Angeles District Office  
**Notice of FDA Action**

Entry Number: DO7-1112223-7

Notice Number: 1  
October 21, 2008

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

>

<

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

Carrier: (b) (4);

Date Received: October 16, 2008

Arrival Date: September 29, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

**HOLD DESIGNATED**

Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                  | Quantity | Current Status                |
|--------------|--------------------------------------|----------|-------------------------------|
| 001/001      | ATOMIZER DEVICE                      | 36 BX    | Line Split                    |
| 001/001A     | Electronic Cigarette E-Cigarette Kit | 1000 PCS | Pending FDA Review 10-21-2008 |
| 001/001B     | Electronic Cigarette Cartridges      | 600 BX   | Pending FDA Review 10-21-2008 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration  
Notice Prepared By: CJS

DET 000059

# United States Food and Drug Administration

Los Angeles District Office

## Notice of FDA Action

Entry Number: DO7-1112224-5

Notice Number: 1  
October 21, 2008

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

>

<

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

Carrier: (b) (4)

Date Received: October 16, 2008

Arrival Date: September 28, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

## HOLD DESIGNATED

### Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                  | Quantity | Current Status                |
|--------------|--------------------------------------|----------|-------------------------------|
| 001/001      | Electronic Cigarette E-Cigarette Kit | 12 BX    | Pending FDA Review 10-21-2008 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration

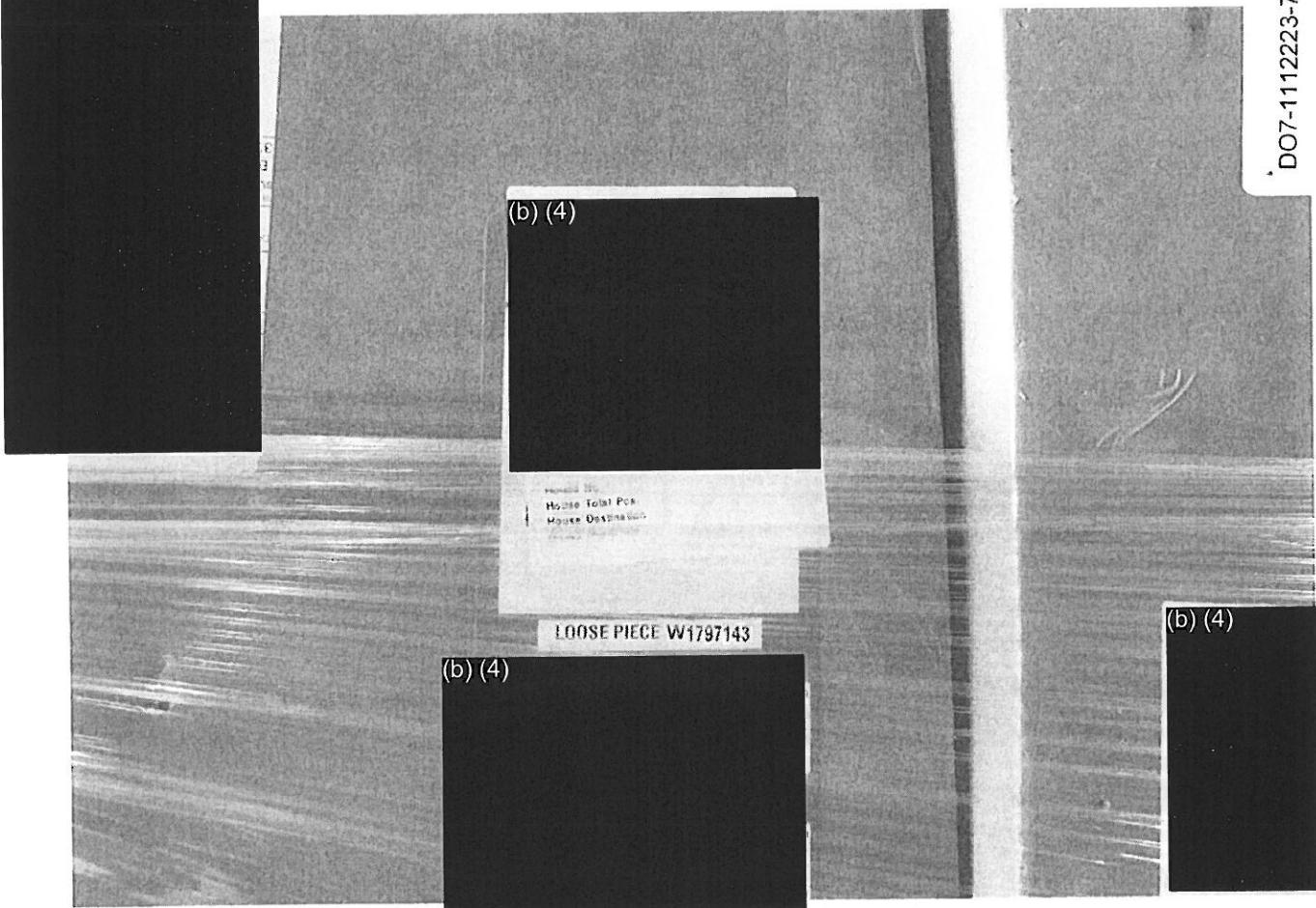
Notice Prepared By: CJS

DET 000060



DO7-1112223-7 1/A 1/B JM 10/21/08

Top - View of Master Cartons  
Bottom - Master AWB Label

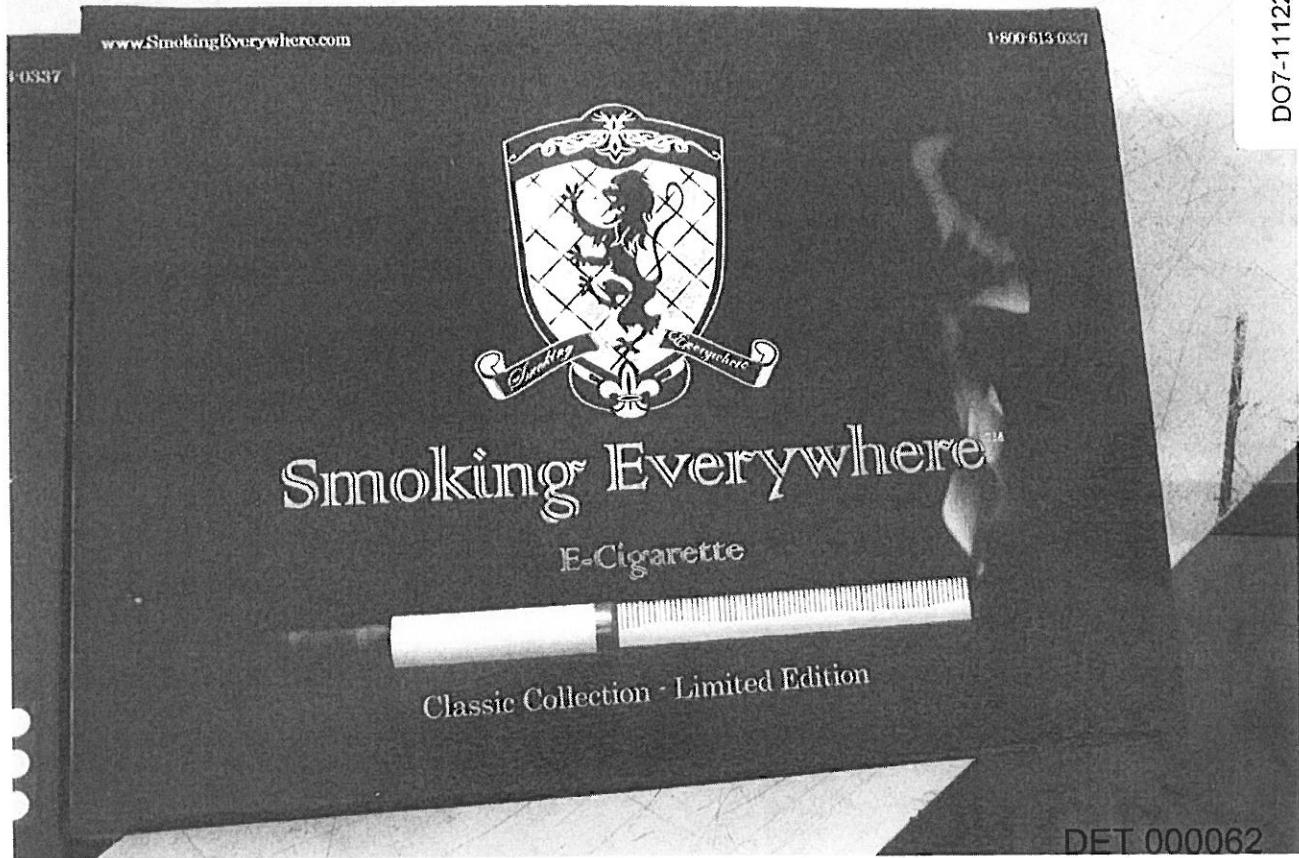


DET 000061

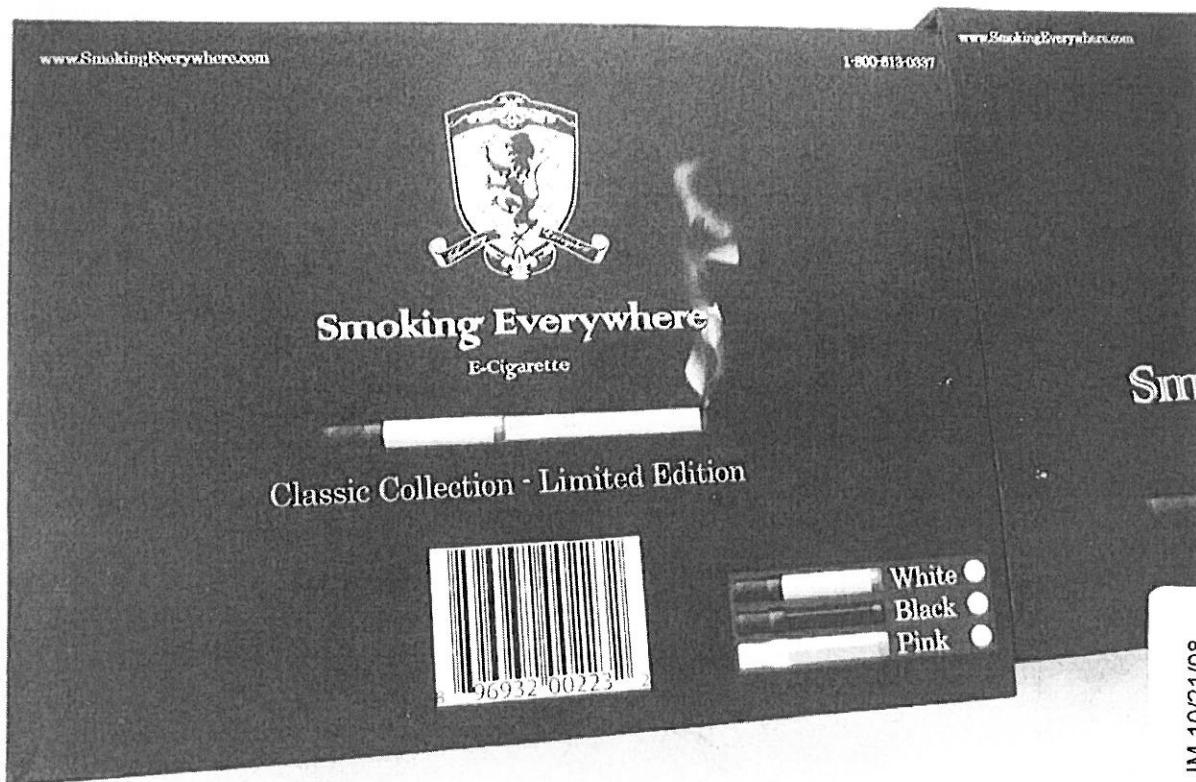


DO7-1112223-7 1/A JM 10/21/08

Top - Classic Collection Kit  
Bottom - Top view of Kit



DET 000062

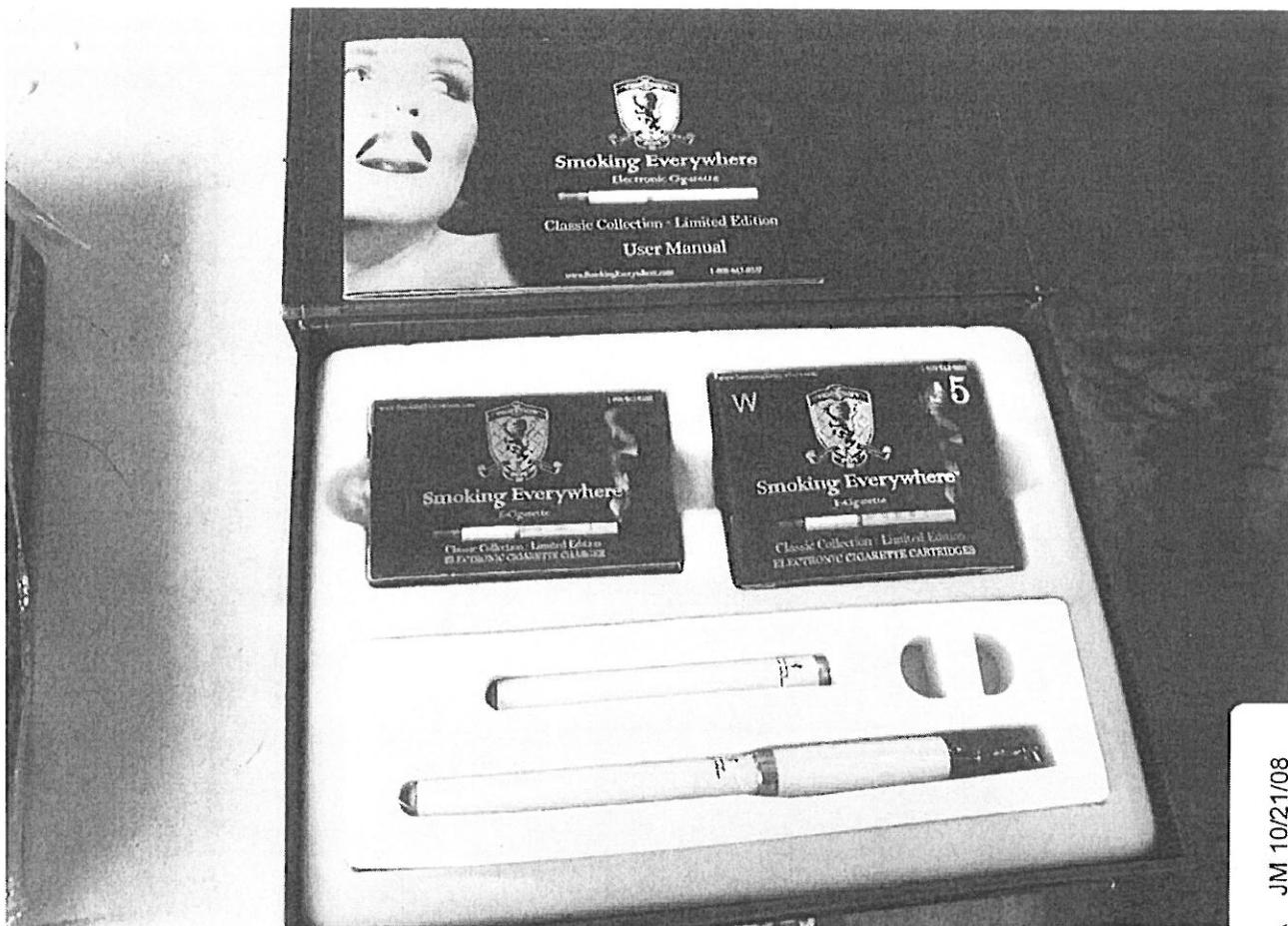


DO7-1112223-7 1/A JM 10/21/08

Top - Bottom view of Kit  
Bottom - Side view of Kit



DET 000063



DO7-1112223-7 1/A JM 10/21/08

Top - Open view of Kit  
Bottom - Contents of Kit

DET 000064



DO7-112223-7 1/B JM 10/21/08

Top - Cartridges  
Bottom - Cartridges

DET 000065



DO7-1112223-7 1/B JM 10/21/08

Top - Cartridges  
Bottom - Side view of cartridge boxes

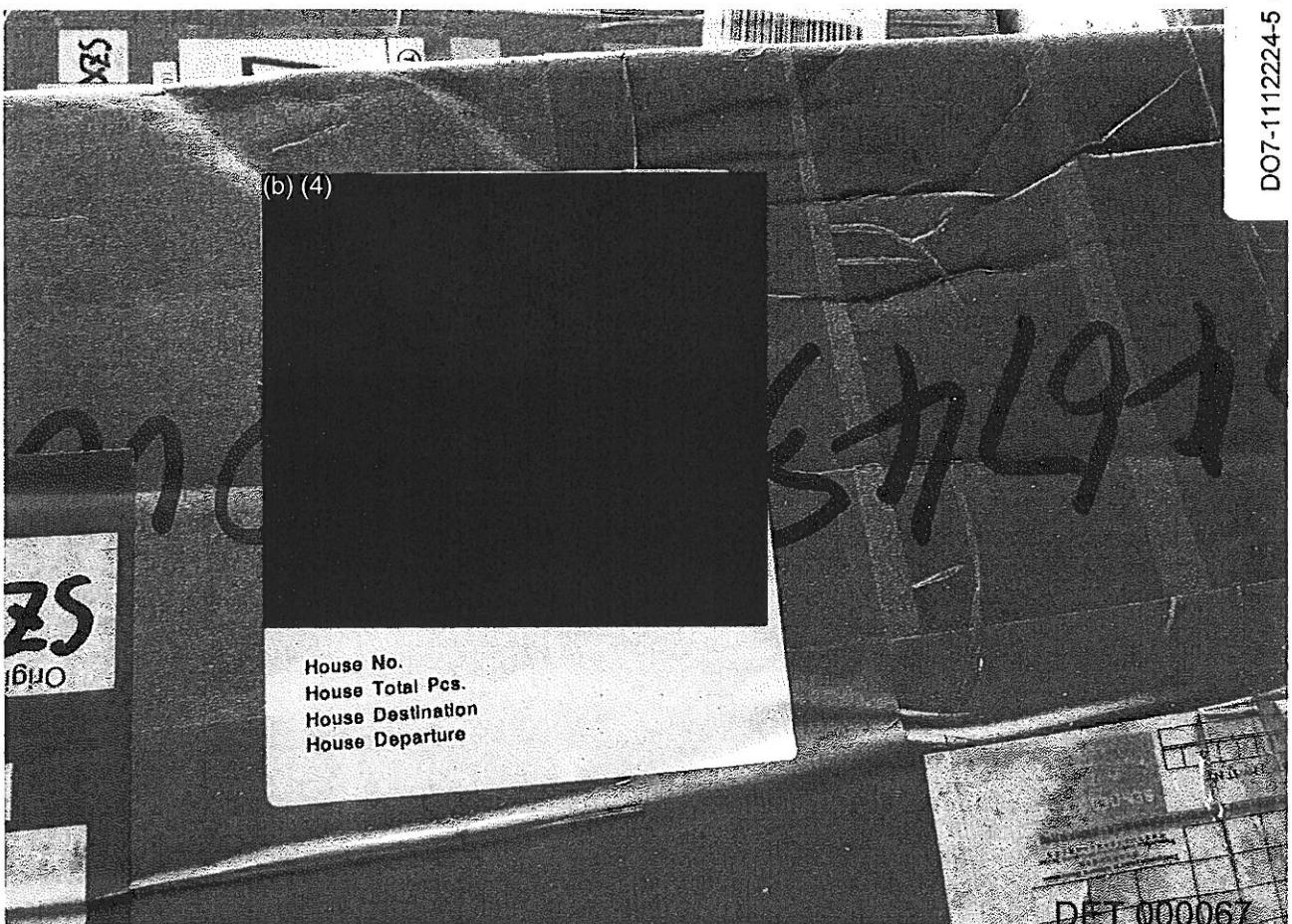


DET 000066



DO7-1112224-5 JM 10/21/08

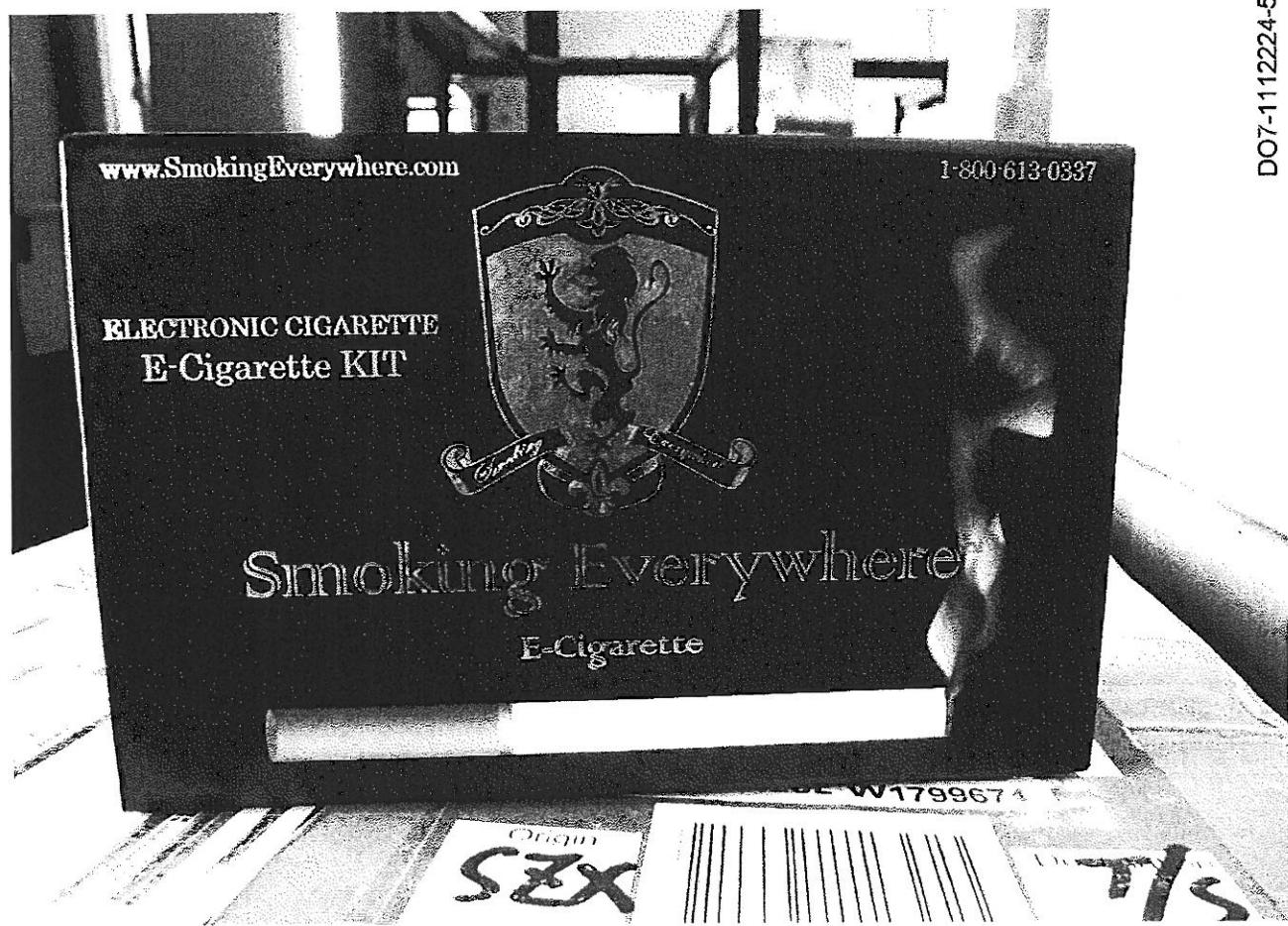
Top: View of Master Cartons  
Bottom: Master AWB Label





DO7-1112224-5 JM 10/21/08

Top - View of open carton  
Bottom - View of top of Kit



DET 000068

[www.SmokingEverywhere.com](http://www.SmokingEverywhere.com)

1-800-613-0337



Smoking Everywhere™

E-Cigarette



E-Cigarette Kit Includes:  
Electronic Cigarette  
2 Rechargeable Batteries  
Main Charger  
Power Lead (US Plug)  
5 Cartridges

DO7-1112224-5 JM 10/21/08

Top - View of bottom of Kit  
Bottom - View of sides of Kit



Smoking Everywhere™

E-Cigarette



To order refill, visit our website at [www.SmokingEverywhere.com](http://www.SmokingEverywhere.com) or call 1-800-613-0337



Smoking Everywhere™

E-Cigarette



DET 000069



DO7-1112224-5 JM 10/21/08

Top - Open view of Kit  
Bottom - Contents of Kit



DET 000070



DO7-1112224-5 JM 10/21/08



Top - Cartridges  
Bottom - Charger

DET 000071

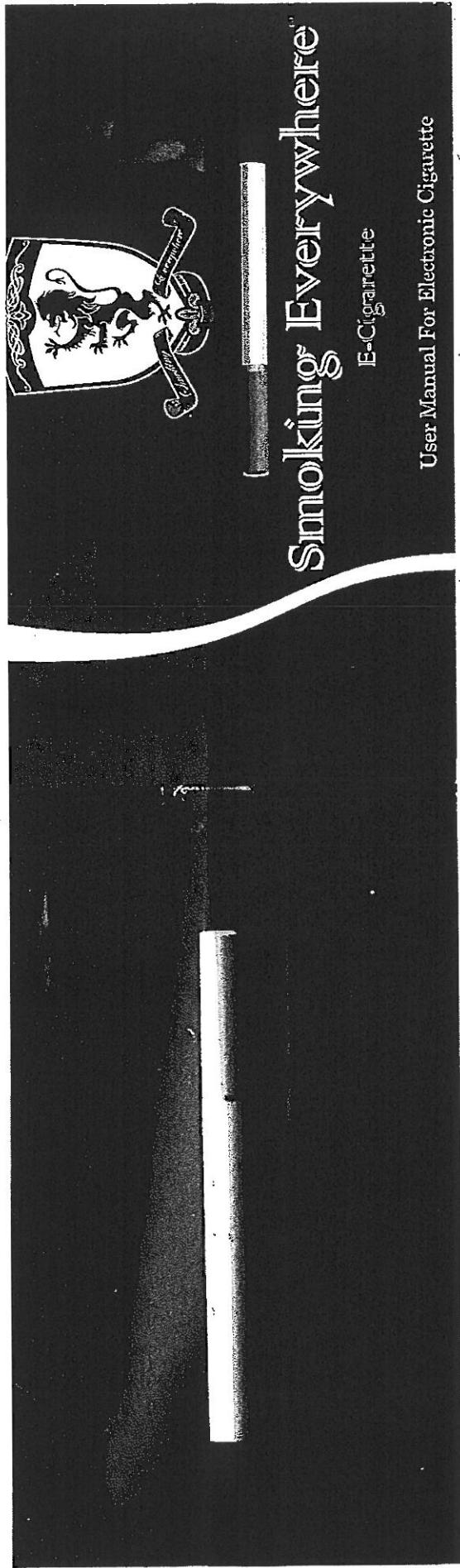


DO7-1112224-5 JM 10/21/08

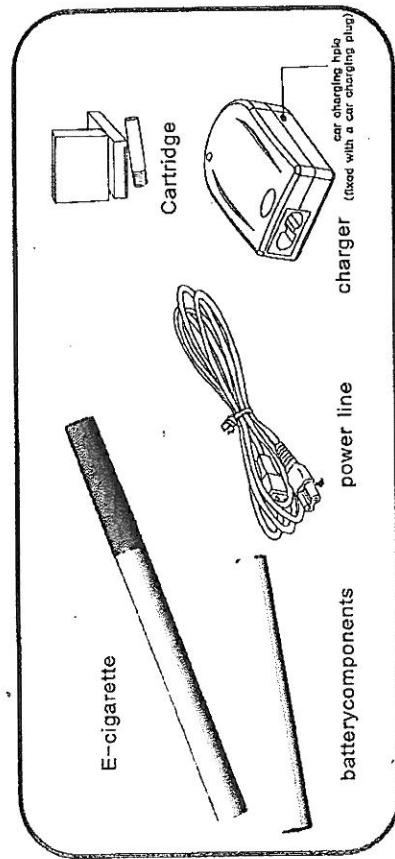
Top - Power cord.

DET 000072

DET-11112224-5



### Product components



- Congratulations on your beginning to choose a healthy lifestyle which will also create a healthy and environmental-friendly living space for both you and your family.
- Before you start to use this product, please read this user manual carefully so that its performances can be made best use of and this unit be used in accordance with the requirements herein.
- Please keep this manual properly for future reference.

DET 000073

## Catalog

### Safety Information

#### Product Introduction

#### Structure of an "Electronic Cigarette"

#### Use Methods of "Electronic Cigarette"

#### Use Method of Charge

#### Cautions

#### Suitable and Forbidden People

## Safety Information

For safe and effective use of "electronic cigarette" and its supporting products, please read through the following information carefully before use and follow the standard operating procedures strictly.

### Use of "Electronic Cigarette"

After installing new cartridge and battery correctly, the "electronic cigarette" entered its standby status and smoking action can be simulated through sucking the inhaler. Old cartridge will have to be replaced by a new one if smoke is reduced. When the power of the dedicated lithium battery is used up, the indicator in front of the cigarette body will flash continuously and this means that new dedicated lithium battery assembly will have to be used.

### Use of AC Charger

Please screw the dedicated lithium battery into electronic cigarette's dedicated charger. Charger can work normally with an AC100V-240V 50/60HZ voltage. To reduce the risk of electric shock, charger should be unplugged from its power source before cleaning it. Charger is prohibited to be used outdoors or in a damp environment.

## Safety Information

### Precautions for Pocket Cigarette

If you are carrying the "electronic cigarette" with you, please take care of the "electronic cigarette" separately and any collision or squeeze must be avoided.

### Electronic cigarette Precautions

"Electronic cigarette" is a kind of high-tech product and its components such as cartridge, battery, and charger and so on are dedicated ones. The use of any undedicated components will lead to electronic cigarette's malfunction and damage of this product.

### Use in public places

"Electronic cigarette" will not produce any second-hand smoke to others and does not cause harm to surrounding people and environment; meanwhile it does not need to be lit and will not have any fire risk so it can be used safely in most public places.

## Safety Information

### No Use of "Electronic Cig" When Driving

When driving, please ensure your strict compliance with the relevant laws and regulations of the country or region where you are staying; be concentrated on driving and pay attention to road conditions. Do not use "electronic cigarette" while driving and keep your electronic cigarette properly to avoid any damage to the product caused by collision.

### Precautions

When using or storing this product, avoid any hot and/or damp environment.

Do not let children play "electronic cigarette" and its supporting components. Avoid improper operation that may cause damage to this product. Cigarette should be taken care of properly and kept away from children's reach.

When using this "electronic cigarette", it would be appropriate that the time and frequency of your continuous sucking action should not exceed that of smoking a traditional cigarette in normal times.

## 04 Product Introduction

### Principle of "Electronic Cigarette"

"Electronic cigarette" uses advanced microelectronic technology and supercritical physical atomization technology to atomize the high-purity and exciting nicotine dilution extracted from tobacco into smoke for smoker's sucking and accordingly meet the needs of those smokers. The nicotine dilution used contains nicotine, tobacco flavor and so on.

The birth of "electronic cigarette" is a revolution of mankind's smoking history. Undoubtedly, its birth will bring a gospel to mankind, especially the vast smokers and will have extremely far-reaching impact on human being's lifestyle. We believe that "electronic cigarette" will certainly be able to eradicate evil tobacco's hazards to human being.

"Electronic cigarette" is a kind of non-flammable electronic cigarette with similar functions to those of a common cigarette which is to refresh smokers and satisfy their smoking addiction, thus making them happy and relaxed. So "electronic cigarette" is the best substitute to common cigarette.

## 05 Product Introduction

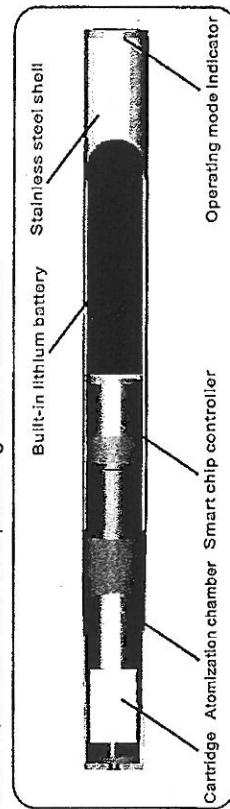
### Significant Advantages of "Electronic Cigarette"

1. Free of tar and other carcinogenic substances harmful to human body;
2. Non-flammable, without the danger of over 4,000 chemical substances produced by the common cigarette;
3. Harmless to others and pollution-free to environment caused by "second-hand smoking";
4. Without the hidden danger of fire accident and can be used in most public places;
5. Wide serviceable range and be able to work normally between -5 degrees to 42 degrees;
6. Humanely designed, similar simulated smoke temperature to body temperature;
7. Shielded electromagnetic, free of electromagnetic radiation;
8. The nicotine content of each liquid container is less than that of 20 ordinary cigarettes.

## 06 Structure of an "Electronic Cigarette"

### Cigarette body

The cigarette body is an integrated structure consisting of stainless steel shell, lithium ion battery assembly, smart chip and program controlled circuits, atomization chamber and cartridge and so on. In the front of it, there exists an operating mode indicator.



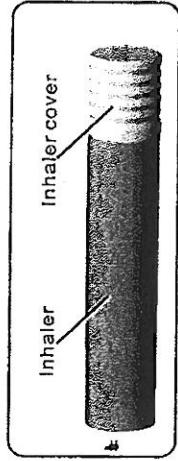
## 07 Structure of an "Electronic Cigarette"

### Atomization cartridge

The atomization cartridge of an "electronic cigarette" is composed of an inhaler and a liquid container. The nicotine dilution to be atomized is stored in this liquid container and is free of ingredients harmful to human body, such as tar and carcinogenic substance.

The inhaler is for one-time-only use.

The nicotine content in cartridge is classified into high, medium, low, and zero with various tastes to meet the needs of different people.

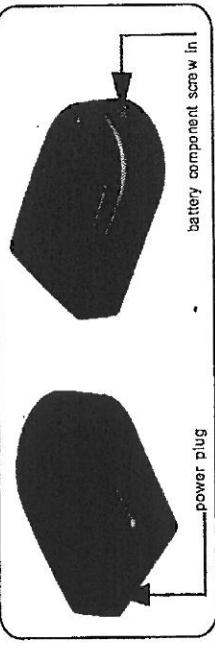


08

## Structure of an "Electronic Cigarette"

### Battery and Charger

"Electronic cigarette" uses a 3.7V special-purpose lithium ion battery and the supporting charger is also a special device for this and both battery and charger cannot be substituted by other lithium battery or charger. The input supply voltage of the charger is AC100V~240V 50/60HZ. During traveling, attention shall be paid to if the rated value of local supply voltage is accordant to that of electronic cigarette's charger.



09  
Use Methods of "Electronic Cigarette"

1. Installation:  
Step one: unpack the cigarette cartridge and remove the inhaler cover of the cartridge;  
Step two: insert the cartridge into the cigarette body;

### 2. Operating Mode

When placing the "electronic cigarette" into lips and sucking it, circuit will be activated and the indicator in front of the cigarette body will light up immediately; when inhaling ended, atomizing will stop accordingly and its operating mode changes into standby. The best angle of using this unit is horizontal and it is not appropriate to use it upwards to prevent any small amount of liquid from flowing into the mouth which may cause stimulation to oral mucositis. The built-in micro-computer controlled programs have self-cleaning function; when accumulated number of "electronic cigarette" suction has reached 1,500, the indicator in front of the cigarette body will keep on lighting for 6 seconds, which means that the micro-computer controlled programs are cleaning the unit automatically.

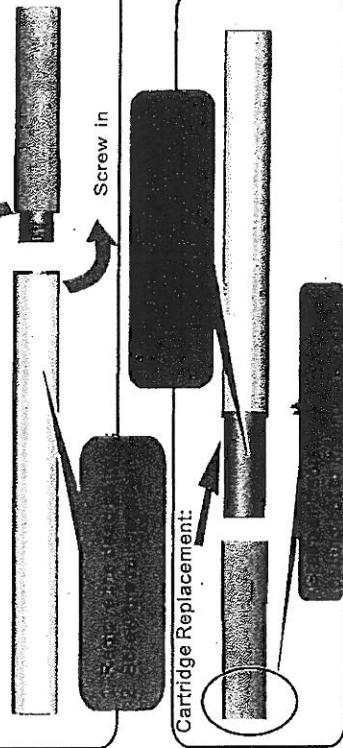
10  
Use Methods of "Electronic Cigarette"

3. Battery Replacement:  
During the use of this unit, if indicator in front of the cigarette body is found to be flashing slowly for consecutive 20 times, it means that the battery may have to be replaced.
4. Cartridge Replacement:  
During the use of this unit, if smoke is found to be significantly reduced, please replace the cartridge accordingly.



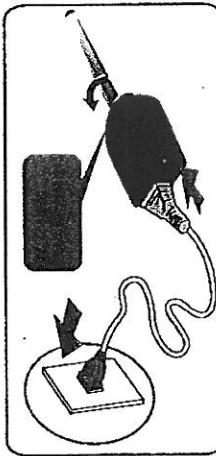
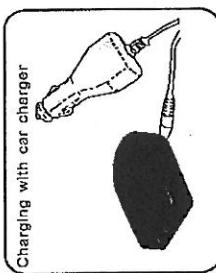
11  
Use Methods of "Electronic Cigarette"

### Battery Replacement:



## 12 Use Method of Charge

During the use of this unit, if indicator in front of the cigarette body is found to be flashing, the accompanying charger of this unit should be used to charge the battery assembly. In order to charge, please connect the power cord to the charger and the plug into a socket, screw the battery into the charger jack. After charging for 3-4 hours, the charger indicator will turn from red to green, which means that the battery has been fully charged and please remove the battery and disconnect the power source of the charger accordingly.



## 13 Cautions

It is prohibited that battery is charged near a high-temp heat source. It is prohibited that battery is welded directly or pierced by nails or any other sharp objects.

If battery is found to be emitting any odor or heat or be discolored or deformed or have any abnormality during charging, please cut off the power source immediately and remove the battery from cigarette body or charger and suspend the use of it.

This charger can only be used to charge electronic cigarette's dedicated lithium ion battery. Do not try to use this charger to charge other kind of battery.

Please keep this "electronic cigarette" and cartridge from the reach of children.

This unit can only use the accompanying charger and battery provided by our company.

## 14 Cautions

The first charging must be kept for 8 hours and the charging for regular use be kept for 3-4 hours.  
The nicotine dilution contained in the cartridge of this "electronic cigarette" is prohibited from direct contact with mucositis. No direct entrance to mouth is allowed.  
This is a high-tech electronic product and knocking or collision must be avoided.  
In order to prevent too frequent use of the product, the front indicator will flash for 10 seconds for reminding if the cigarette is sucked for consecutive 15 times within one minute.

## 15 Suitable and Forbidden People

### Suitable People:

People with long smoking history suffering from uncomfortable feeling without smoking cigarette  
People working in no-smoking areas for long time but having habit of smoking

### Forbidden People:

Minors under the age of 18  
People without the habit of smoking  
People allergic to nicotine or any components of inhalants  
Pregnant and breastfeeding women

# United States Food and Drug Administration

Los Angeles District Office

## Notice of FDA Action

Entry Number: DO7-1112223-7

Notice Number: 2

October 29, 2008

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

> <

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

Carrier: (b) (4)

Date Received: October 16, 2008

Arrival Date: September 29, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

## HOLD DESIGNATED

### Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                           | Quantity | Current Status      |
|--------------|---|----------|---------------------|
| 001/001      | ATOMIZER DEVICE                               | 36 BX    | Line Split          |
| *            | 001/001A Electronic Cigarette E-Cigarette Kit | 1000 PCS | Detained 10-29-2008 |
| *            | 001/001B Electronic Cigarette Cartridges      | 600 BX   | Detained 10-29-2008 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

## DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or

DET 000078

Notice of FDA Action  
Entry Number: DO7-1112223-7

Notice Number 2  
Page: 2

otherwise in violation as indicated below:

| Line ACS/FDA | Product Description  | Respond By        |
|--------------|--|-------------------|
| 001/001A     | Electronic Cigarette E-Cigarrette Kit  | November 19, 2008 |
|              | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).  |                   |
|              | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).                  |                   |
|              | <b>FD&amp;CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG</b><br>The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA. |                   |
|              | <b>FD&amp;CA Section 801(a)(3); 502(o) Misbranding</b><br>It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.  |                   |
| 001/001B     | Electronic Cigarette Cartridges  | November 19, 2008 |
|              | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).  |                   |
|              | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).                  |                   |
|              | <b>FD&amp;CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG</b><br>The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA. |                   |
|              | <b>FD&amp;CA Section 801(a)(3); 502(o) Misbranding</b><br>It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.  |                   |

Please direct your response to:

Chih-Shang J. Shen, Compliance Officer  
(Region/District)  
U.S. Food and Drug Administration  
222 W. 6th St., Suite 700  
San Pedro, CA 90731  
(310) 971-2353  
(310) 971-2363 (FAX)  
JIM.SHEN@FDA.HHS.GOV

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.

Notice Prepared For: The District Director, U.S. Food and Drug Administration  
Notice Prepared By: CJS

DET 000079

# United States Food and Drug Administration

Los Angeles District Office

## Notice of FDA Action

Entry Number: DO7-1112224-5

Notice Number: 2  
October 29, 2008

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

>

<

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

Carrier: (b) (4)

Date Received: October 16, 2008

Arrival Date: September 28, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

## HOLD DESIGNATED

### Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                          | Quantity | Current Status      |
|--------------|--|----------|---------------------|
| *            | 001/001 Electronic Cigarette E-Cigarette Kit | 12 BX    | Detained 10-29-2008 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

## DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

| Line ACS/FDA | Product Description | Respond By |
|--------------|---------------------|------------|
|              |                     | DET 000080 |

001/001                    Electronic Cigarette E-Cigarette Kit       November 19, 2008

**FD&CA Section 502(o), 801(a)(3); MISBRANDING**

It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).

**FD&CA Section 502(o), 801(a)(3); MISBRANDING**

It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).

**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. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA.

**FD&CA Section 801(a)(3); 502(o) Misbranding**

It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.

Please direct your response to:

|   |  |
|---|--|
| Chih-Shang J. Shen, Compliance Officer<br>(Region/District)                           | (310) 971-2353<br>(310) 971-2363 (FAX)<br>JIM.SHEN@FDA.HHS.GOV |
| U.S. Food and Drug Administration<br>222 W. 6th St., Suite 700<br>San Pedro, CA 90731 |  |

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.

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Notice Prepared For: The District Director, U.S. Food and Drug Administration

Notice Prepared By: CJS

Shen, Jim

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**From:** Shen, Jim  
**Sent:** Wednesday, February 11, 2009 4:29 PM  
**To:** 'blengland@fdaimports.com'  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Hi, Ben:

I apologize for the delay of my response.

I have consulted with CDER/OC. We believe that when originally offered for importation, this product was explicitly labeled and promoted for "drug" use. In addition, and as described in 21 C.F.R. 201.128, this product is clearly intended for "drug" use by "the circumstances surrounding the distribution of the article." These circumstances include the product's conventional cigarette appearance; its design, formulation, and function to deliver to the body through inhalation of a smoke-like aerosol (resembling conventional cigarette smoke) various volatile chemical substances, including nicotine, produced by the article; and how the product is intended to be manipulated and used like conventional cigarettes to affect the body's structures and functions and/or to treat/mitigate the symptoms of nicotine addiction. In addition, the intended distribution of "Smoking Everywhere E-Cigarette" is targeted to current and potential conventional cigarette smokers, who are knowledgeable about the effects that nicotine has on the structure and function of the body. Moreover, it is clear that the product is intended to deliver nicotine and/or other volatilized chemical substances for inhalation. Thus, as described further in 21 C.F.R. 201.128, we think that "[i]t may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, [to be] offered and used for a [drug] purpose . . . ."

We do not believe that this product can be relabeled to make it anything other than an article which, in accordance with section 801(a) of the Act (21 U.S.C. 381(a)), appears to be a drug-device combination product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(g)(1)) where its marketing in the United States would appear to violate sections 505 of the Act and 501(f)(1)(B) of the Act (21 U.S.C. 355 and 351(f)(1)(B)). Nonetheless, the importer may submit a relabeling proposal on FDA Form 766 to this office. I will forward it to CDER for review.

James

*C. James Shen, Ph.D.  
Compliance Officer  
Import Operations Branch, Los Angeles District  
FDA*

---

**From:** Benjamin England [mailto:[blengland@fdaimports.com](mailto:blengland@fdaimports.com)]  
**Sent:** Monday, February 09, 2009 9:26 AM  
**To:** Shen, Jim  
**Cc:** [blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Jim

Again, we want to make revisions to all labels and websites to satisfy FDA that this product is intended

2/11/2009

DET 000082

solely for recreational use and not as a drug or device (not intended to affect the structure or function of the body and not intended to treat, cure, mitigate or treat a disease).

Should I negotiate this issue with you (under a 766) or directly with CDRH?

Thanks

Ben England

***Benjamin L. England\****

Benjamin L. England & Associates, LLC  
FDAlimports.com, Inc.  
8775 Centre Park Dr.  
Suite 265  
Columbia, MD 21045  
410-740-3403 (dir)  
443-583-1464 (fax)  
[blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
[www.fdaimports.com](http://www.fdaimports.com)

\*Admitted to bars of the states of Maryland and Florida and the District of Columbia

---

**From:** Benjamin England [mailto:[blengland@fdaimports.com](mailto:blengland@fdaimports.com)]

**Sent:** Tuesday, February 03, 2009 1:26 PM

**To:** 'Shen, Jim'

**Cc:** [blengland@fdaimports.com](mailto:blengland@fdaimports.com)

**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

James

I want to make revisions to all labels and websites to satisfy FDA that this product is intended solely for recreational use. Who did you discuss this with at HQ?

Ben

**\*\*\* PLEASE NOTE NEW OFFICE TELEPHONE NUMBER BELOW\*\*\***

***Benjamin L. England\****

Benjamin L. England & Associates, LLC  
FDAlimports.com, Inc.  
8775 Centre Park Dr.  
Suite 265  
Columbia, MD 21045  
410-740-3403 (dir)  
443-538-1940 (mob)  
443-583-1464 (fax)  
[blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
[www.fdaimports.com](http://www.fdaimports.com)

\*Admitted to bars of the states of Maryland and Florida and the District of Columbia

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**From:** Shen, Jim [mailto:[jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov)]

**Sent:** Tuesday, January 13, 2009 6:52 PM

2/11/2009

DET 000083

**To:** blengland@fdaimports.com  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Hi, Ben:

Please see the attached Notices. Wish you a nice day.

James

*C. James Shen, Ph.D.  
Compliance Officer  
Import Operations Branch, Los Angeles District  
FDA*

---

**From:** Benjamin England [mailto:[blengland@fdaimports.com](mailto:blengland@fdaimports.com)]  
**Sent:** Monday, January 12, 2009 9:35 PM  
**To:** Shen, Jim  
**Cc:** [blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Dr. Shen

I am following up on your prior telephone call regarding these two entries. You indicated CDRH was reviewing the matter. Can I please have a status on these two entries? Thank you and best regards.

Ben England

**\*\*\* PLEASE NOTE NEW OFFICE TELEPHONE NUMBER BELOW\*\*\***

**Benjamin L. England\***  
Benjamin L. England & Associates, LLC  
FDAlimports.com, Inc.  
8775 Centre Park Dr.  
Suite 265  
Columbia, MD 21045  
410-740-3403 (dir)  
443-538-1940 (mob)  
443-583-1464 (fax)  
[blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
[www.fdaimports.com](http://www.fdaimports.com)

\*Admitted to bars of the states of Maryland and Florida and the District of Columbia

---

**From:** Benjamin England [mailto:[blengland@fdaimports.com](mailto:blengland@fdaimports.com)]  
**Sent:** Monday, December 15, 2008 2:06 PM  
**To:** 'Shen, Jim'  
**Cc:** [blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Dr. Shen

I would like to discuss these entries with you, as I believe I misunderstood where the importer was regarding their marketing and advertising plans. Apparently the relevant site is up because they sell

2/11/2009

DET 000084

This product around the world – meaning it is available for review here in the U.S.

We want to discuss any review you might undertake of the relevant website ([smokingeverywhere.com](http://smokingeverywhere.com)) and make any revisions you believe are necessary to ensure the consumer understands the article is not intended to affect the structure or function of the body or to diagnose, treat, cure, mitigate or prevent disease in man or other animals.

Are you available to discuss this today?

Ben England

**\*\*\* PLEASE NOTE NEW OFFICE TELEPHONE NUMBER BELOW\*\*\***

**Benjamin L. England\***

Benjamin L. England & Associates, LLC

FDAImports.com, Inc.

8775 Centre Park Dr.

Suite 265

Columbia, MD 21045

410-740-3403 (dir)

443-538-1940 (mob)

443-583-1464 (fax)

[blengland@fdaimports.com](mailto:blengland@fdaimports.com)

[www.fdaimports.com](http://www.fdaimports.com)

\*Admitted to bars of the states of Maryland and Florida and the District of Columbia

---

**From:** Shen, Jim [mailto:[jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov)]

**Sent:** Tuesday, December 09, 2008 7:18 PM

**To:** [blengland@fdaimports.com](mailto:blengland@fdaimports.com)

**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

At the present time, for security reasons and as a matter of policy, this office does not accept e-mail communications and responses to the FDA notices. Please submit your response either by mail if the original signature in the document is required or by FAX (310-971-2363). All incoming written responses will be logged in and filed by the technician and then reviewed by a Compliance Officer by the order as they are received.

If you need to know whether we have received your submissions or the status of your entry, please call status line at 310-971-2399. Please make sure that you leave your name, phone number and entry number clearly.

Please see FDA website at [www.fda.gov](http://www.fda.gov) for regulations, requirements, instructions and forms.

Thank you.

*C. James Shen, Ph.D.*

*Compliance Officer*

*Import Operations Branch, Los Angeles District*

*FDA*

---

**From:** Benjamin England [mailto:[blengland@fdaimports.com](mailto:blengland@fdaimports.com)]

**Sent:** Tuesday, December 09, 2008 3:39 PM

**To:** Shen, Jim

2/11/2009

DET 000085

**Cc:** blengland@fdaimports.com

**Subject:** Extension request D07-1112223-7 & D07-1112224-5 and request for release

Dr. Shen

My associate, Rick Quinn, sent to you a fax on November 25, 2008 indicating I represent the importer of record for the above two entry numbers and requesting an extension of time. I have not heard back from you so I am just confirming you received that fax.

Additionally, these articles are not labeled in any fashion that would bring them into the jurisdiction of FDA. They are for adult entertainment purposes only and their labels/labeling make no structure or function claims and make no disease claims. Moreover, the only labeling associated with the article is in the kit or on the various boxes within the kit. The website that is identified on the labeling is not in operation at all.

Your detention notice states that the articles appear to be a combination drug/device products. For that to be true, the articles must be intended for a use that falls within the definition of either the term "drug" or "device". In both instances, the relevant definitions require that the article be intended to affect the structure or any function of the body of man or other animals or to diagnose, cure, treat, mitigate, or prevent disease in man or other animals. (21 USC 321(g)(1) and (h)(

This is a brand new product. Therefore, these particular products are being imported as complimentary samples for testing the adult entertainment market into which they may be intended for distribution. For that reason, the website referenced on the product label is not active – because these articles are not yet for sale as commercial items. Consequently, the articles are not sold or held for sale by the importer. Companies that do not sell or hold for sale medical devices (or drugs, for that matter) are not required to register with FDA or list their drugs or devices (See 21 CFR 807.20(a) in conjunction with 807.3(b); and 21 CFR 207.20(a) in conjunction with 207.3(b)). Consequently, even if these articles were drugs, devices or combination drug/devices, the importer is not subject to drug or device registration and the manufacturer is not subject to device or drug registration or required to list the article as a drug or device.

Consequently, the articles are not subject to admission.

If you have any evidence that the articles are intended for sale or are held for sale, please provide that to me.

In the alternative, please release the entries with comment if necessary.

Thank you and best regards,

Ben England

***Benjamin L. England\****

Benjamin L. England & Associates, LLC

FDALimports.com, Inc.

8775 Centre Park Dr.

Suite 265

Columbia, MD 21045

410-740-3403 (dir)

443-538-1940 (mob)

443-583-1464 (fax)

[blengland@fdaimports.com](mailto:blengland@fdaimports.com)

[www.fdaimports.com](http://www.fdaimports.com)

\*Admitted to bars of the states of Maryland and Florida and the District of Columbia

----- Forwarded message -----

2/11/2009

DET 000086

From: Rick D. Quinn (b) (6)  
Date: Tue, Nov 25, 2008 at 5:34 PM  
Subject: D07-1112223-7 and D07-1112224-5  
To: [jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov)

CONFIDENTIAL COMMUNICATION

ATTORNEY-CLIENT PRIVILEGED

November 25, 2008

Mr. Chi-Shang J. Shen, Compliance Officer  
U.S. Food and Drug Administration  
222 W. 6th Street, Suite 7000  
San Pedro, CA 90731  
Telephone: (310) 971-2353  
Facsimile: (310) 971-2363

*VIA E-MAIL:* [jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov)

**Re: Extension Request for Entry Nos. D07-1112223-7, D07-1112224-5.**

Dear Mr. Shen:

Benjamin L. England & Associates represents Smoking Everywhere, LLC, importer of record in the above referenced entries.

Mr. England is responsible for handling matters related to this client and is on vacation until Monday, December 1<sup>st</sup>. Thus, I respectfully ask that you grant an extension until December 9, 2008, in order for him to address the above matters.

At 5:20pm on November 25, 2008, I sent this request including a copy of the client's Letter of Authorization and a copy of the two Notices of FDA Action to your attention via facsimile to (310) 971-2363.

Thank you for your consideration and reply.

If you should have any questions about this request, please call me directly at (410) 740-3403.

Sincerely

Rick D. Quinn, Esq.

## FAX COVER SHEET

TO Dr. Jim Shen  
COMPANY LOS-DO Imports Compliance  
FAX NUMBER 13109712363  
FROM Benjamin England, Esq.  
DATE 2008-12-10 02:07:23 GMT  
RE D07-1112223-7 & D07-1112224-5

### COVER MESSAGE

CORRECTED Follow up to prior fax.

Dr. Shen:

There was a significant typographical error in the fax I sent you. I asserted these articles are not subject to admission. What I meant was,

"These articles are not subject to refusal of admission".

Sorry for the confusion. The attached has the corrected language in it.

Thanks

Ben England  
410-740-3403

# Smoking Everywhere, LLC

4500 North Hiatus Road, Suite 215

Sunrise, FL 33351

954-675-8400

November 25, 2008

To Whom it May Concern:

RE: FDA and Customs matters

Please be advised that we have retained the law firm of Benjamin L. England & Assoc., LLC and the consulting practice of (b) (4) to assist us in addressing various issues related to the manufacture, distribution, exportation, and importation of FDA regulated products. Mr. England will be primarily handling such matters for us.

This letter authorizes you to discuss our FDA and Customs related issues with Mr. England (410-740-3403, [bengland@fdaimports.com](mailto:bengland@fdaimports.com), FAX: 410-583-1164). If you have any questions regarding this authorization, please do not hesitate to contact me at (954) 675-8400.

Sincerely,

Elcko Taieb  
President / CEO  
Smoking Everywhere, LLC

{WD002976.1}

DET 000090

Shen, Jim

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**From:** Budich, Kevin M  
**Sent:** Friday, December 19, 2008 7:32 AM  
**To:** Shen, Jim  
**Cc:** Bormel, Frances Gail; Heller, Robert; Batista, Huascar R  
**Subject:** FW: Extension request D07-1112223-7 & D07-1112224-5 and request for release  
**Attachments:** do7-1112223-7.pdf; do7-1112224-5.pdf; do7-1112224-5q.pdf

James,

I have reviewed the import entry documents (attached) for Entry Nos. DO7-1112224-5 and DO7-1112223-7 regarding articles identified in part as "Atomizer device" and "Accessories." These documents further identify "Smoking Everywhere, LLC, 4500 North Hiatus Road, Suite 215, Sunrise, Florida, 33351" as the importer and consignee. I reviewed copies of the photographs included with these documents showing the actual package labeling for these imported articles. I have also reviewed a user manual entitled "Smoking Everywhere E-Cigarette User Manual For Electronic Cigarette" which is included in the referenced import entries.

The package labeling for the "Atomizer device" kits identify the product as "Smoking Everywhere E-Cigarette." That labeling also references the Internet website "[www.SmokingEverywhere.com](http://www.SmokingEverywhere.com)" and the telephone number "1-800-613-0337." That telephone number is identified on the website as the number for Smoking Everywhere, LLC.

I reviewed the referenced website ([www.SmokingEverywhere.com](http://www.SmokingEverywhere.com)), which features a nicotine delivery system marketed under the name "Smoking Everywhere E-Cigarette." According to the website, this product is constructed with a rechargeable battery-operated heating element and a replaceable cartridge that contains water, propylene glycol, flavoring, and it may or may not contain nicotine. The nicotine-containing cartridges are available in three strengths: "High (16mg nicotine) . . . Medium (11mg nicotine) . . . [and] Low (6 mg nicotine)." Nicotine and other chemicals are intended to be volatilized when the user inhales through the product, just as they would when using conventional tobacco-containing cigarettes. The "Smoking Everywhere E-Cigarette" product is intended to heat air as it is drawn through it by the user. This heated air purportedly volatilizes the chemicals contained in the replaceable cartridges. The volatilized chemicals are then inhaled by the user. According to the web site, this product is designed to look like, feel like, taste like, and to be used (inhaled) in the same way that a smoker uses conventional cigarettes. And, just like the conventional tobacco products, the package labeling and the website state that the product delivers nicotine.

The package labeling and the [www.SmokingEverywhere.com](http://www.SmokingEverywhere.com) website include the following statements:

- ""Electronic cigarette" uses advanced microelectronic technology and supercritical physical atomization technology to atomize the high-purity and exciting nicotine dilution extracted from tobacco into smoke for smoker's sucking and accordingly meet the needs of those smokers. The nicotine dilution used contains nicotine, tobacco flavor and so on."
- ""Electronic cigarette" is a kind of non-flammable electronic cigarette with similar functions to those of a common cigarette which is to refresh smokers and satisfy their smoking addiction, thus making them happy and relaxed. So "electronic cigarette" is the best substitute to common cigarette [sic]."
- "The nicotine content in cartridge is classified into high, medium, low, and zero with various tastes to meet the needs of different people."
- "Suitable People [for using Smoking Everywhere E-Cigarette]: People with long smoking history suffering from uncomfortable feeling without smoking cigarette . . . People working in no-smoking areas for long time but having habit of smoking . . ."
- "Smoking Everywhere E-Cigarette will provide smokers the same delight, physical and emotional feelings they get in smoking traditional cigarettes, but without all the problems that is related with traditional smoking [sic]."
- "Smoking Everywhere E-Cigarette performs just like a traditional cigarette. It looks like, feels like and tastes like

DET 000091

a real cigarette and also distributes the same pleasures of smoking a traditional cigarette, but without all the harmful effects of a traditional cigarette."

- "The actual cigarette body is made up of 3 parts: a nicotine cartridge, an atomization chamber, a smart chip with a lithium battery . . . the most attractive part of the Smoking Everywhere E-Cigarette is the atomization chamber device that when puffed on creates a vapor like smoke, just like a real cigarette. The vapor is a result of the nicotine that is found in the cartridge, heating up by the atomizer device and creating vapor smoke, but without any smell of smoking real tobacco. This is what the smoker gets, the nicotine hit that smokers crave, and the smoke like illusion, but without having to smoke a real cigarette"
- "Testimonials . . . a great alternative to help me stop smoking real cigarettes . . ."
- "Smoking Everywhere E-Cigarette Cartridges . . . Each cartridge is equivalent to 20 traditional cigarettes."
- "In The News . . . Revolutionary Electronic Cigarette Offers a Real Smoking Pleasure & Nicotine Delivery Without the Tobacco, Tar, Smoke, or Odor . . . FOX News ASK Dr. Manny August 25, 2008 VIDEO: New Way to Stop Smoking"

Based on the foregoing, "Smoking Everywhere E-Cigarette" and its component parts appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. Thus, this product appears to be a drug-device combination product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(g)(1)).

Since we are not aware of any data establishing "Smoking Everywhere E-Cigarette" as generally recognized among scientific experts as safe and effective for the uses described above and in the labeling, this product appears to be a "new drug," as defined by section 201(p) of the Act (21 U.S.C. 321(p)). "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. 355) to be legally marketed in the United States. The "Smoking Everywhere E-Cigarette" product is not so approved and its marketing in the United States would violate this section of the Act.

The "Smoking Everywhere E-Cigarette" product also appears to be an adulterated device under section 501(f)(1)(B) of the Act (21 U.S.C. 351(f)(1)(B)), because there is no approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act (21 U.S.C. 360e(a)), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act (21 U.S.C. 360j(g)).

Therefore, in accordance with section 801(a) of the Act (21 U.S.C. 381(a)), the marketing of "Smoking Everywhere E-Cigarette" and its component parts appears to violate sections **505** and **501(f)(1)(B)** of the Act (21 U.S.C. 355 and 21 U.S.C. 351(f)(1)(B)), as described above, and we support the District's detention of the referenced import entries citing these violations.

Please note that our assessment of the "Smoking Everywhere E-Cigarette" product and its component parts considered the existing statutes affecting tobacco products, i.e., the Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 15 U.S.C. §§ 1331 et seq., and the Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 98-474 (1986), 15 U.S.C. §§ 4401 et seq. Since the "Smoking Everywhere E-Cigarette" products and its component parts do not appear to contain any tobacco leaf or stem, they would not be subject to these statutes.

You may share the content of this e-mail with the importer and consignee, Smoking Everywhere, LLC, and with that firm's consultant, Mr. Benjamin L. England.

If you have any questions, or would like to discuss, please let me know.

Kevin

Kevin M. Budich  
Compliance Officer  
Food and Drug Administration  
CDER/Office of Compliance  
Division of New Drugs & Labeling Compliance  
OTC Drugs Team  
10903 New Hampshire Ave.

DET 000092

12/23/2008

WO51-5174  
Silver Spring, MD 20993

301-796-3304  
[kevin.budich@fda.hhs.gov](mailto:kevin.budich@fda.hhs.gov)

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**From:** Shen, Jim  
**Sent:** Tuesday, December 16, 2008 4:57 PM  
**To:** Budich, Kevin M  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Hi, Kevin:

Please discard the earlier e-mail. Thanks.

James

---

**From:** Budich, Kevin M  
**Sent:** Tuesday, December 16, 2008 12:40 PM  
**To:** Shen, Jim  
**Subject:** RE: Extension request D07-1112223-7 & D07-1112224-5 and request for release

James,

Before I comment, please send me all of the labeling, product information, and entry documents for my review.  
Thanks.

Kevin

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**From:** Shen, Jim  
**Sent:** Tuesday, December 16, 2008 12:50 PM  
**To:** Budich, Kevin M  
**Subject:** FW: Extension request D07-1112223-7 & D07-1112224-5 and request for release

Good morning, Kevin:

Please comment. Thanks.

James

---

**From:** Benjamin England [mailto:[blengland@fdimports.com](mailto:blengland@fdimports.com)]  
**Sent:** Tuesday, December 09, 2008 3:39 PM  
**To:** Shen, Jim  
**Cc:** [blengland@fdimports.com](mailto:blengland@fdimports.com)  
**Subject:** Extension request D07-1112223-7 & D07-1112224-5 and request for release

Dr. Shen

My associate, Rick Quinn, sent to you a fax on November 25, 2008 indicating I represent the importer of record for the above two entry numbers and requesting an extension of time. I have not heard back from you so I am just confirming you received that fax.

DET 000093

12/23/2008

Additionally, these articles are not labeled in any fashion that would bring them into the jurisdiction of FDA. They are for adult entertainment purposes only and their labels/labeling make no structure or function claims and make no disease claims. Moreover, the only labeling associated with the article is in the kit or on the various boxes within the kit. The website that is identified on the labeling is not in operation at all.

Your detention notice states that the articles appear to be a combination drug/device products. For that to be true, the articles must be intended for a use that falls within the definition of either the term "drug" or "device". In both instances, the relevant definitions require that the article be intended to affect the structure or any function of the body of man or other animals or to diagnose, cure, treat, mitigate, or prevent disease in man or other animals. (21 USC 321(g)(1) and (h)(

This is a brand new product. Therefore, these particular products are being imported as complimentary samples for testing the adult entertainment market into which they may be intended for distribution. For that reason, the website referenced on the product label is not active – because these articles are not yet for sale as commercial items. Consequently, the articles are not sold or held for sale by the importer. Companies that do not sell or hold for sale medical devices (or drugs, for that matter) are not required to register with FDA or list their drugs or devices (See 21 CFR 807.20(a) in conjunction with 807.3(b); and 21 CFR 207.20(a) in conjunction with 207.3(b)). Consequently, even if these articles were drugs, devices or combination drug/devices, the importer is not subject to drug or device registration and the manufacturer is not subject to device or drug registration or required to list the article as a drug or device.

Consequently, the articles are not subject to admission.

If you have any evidence that the articles are intended for sale or are held for sale, please provide that to me.

In the alternative, please release the entries with comment if necessary.

Thank you and best regards,

Ben England

***Benjamin L. England\****

Benjamin L. England & Associates, LLC  
FDAlimports.com, Inc.  
8775 Centre Park Dr.  
Suite 265  
Columbia, MD 21045  
410-740-3403 (dir)  
443-538-1940 (mob)  
443-583-1464 (fax)  
[blengland@fdaimports.com](mailto:blengland@fdaimports.com)  
[www.fdaimports.com](http://www.fdaimports.com)

\*Admitted to bars of the states of Maryland and Florida and the District of Columbia

----- Forwarded message -----

From: Rick D. Quinn <(b) (6)>  
Date: Tue, Nov 25, 2008 at 5:34 PM  
Subject: D07-1112223-7 and D07-1112224-5  
To: [jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov)

CONFIDENTIAL COMMUNICATION

ATTORNEY-CLIENT PRIVILEGED

12/23/2008

DET 000094

November 25, 2008

Mr. Chi-Shang J. Shen, Compliance Officer

U.S. Food and Drug Administration

222 W. 6th Street, Suite 7000

San Pedro, CA 90731

Telephone: (310) 971-2353

Facsimile: (310) 971-2363

*VIA E-MAIL: [jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov)*

**Re: Extension Request for Entry Nos. D07-1112223-7, D07-1112224-5.**

Dear Mr. Shen:

Benjamin L. England & Associates represents Smoking Everywhere, LLC, importer of record in the above referenced entries.

Mr. England is responsible for handling matters related to this client and is on vacation until Monday, December 1<sup>st</sup>. Thus, I respectfully ask that you grant an extension until December 9, 2008, in order for him to address the above matters.

At 5:20pm on November 25, 2008, I sent this request including a copy of the client's Letter of Authorization and a copy of the two Notices of FDA Action to your attention via facsimile to (310) 971-2363.

Thank you for your consideration and reply.

DET 000095

12/23/2008

If you should have any questions about this request, please call me directly at (410) 740-3403.

Sincerely

Rick D. Quinn, Esq.

DET 000096

12/23/2008

# United States Food and Drug Administration

Los Angeles District Office

## Notice of FDA Action

Entry Number: DO7-1112223-7

Notice Number: 3

December 23, 2008

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

>

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

Carrier: (b) (4) ;

Date Received: October 16, 2008

Arrival Date: September 29, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

## HOLD DESIGNATED

### Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                  | Quantity | Current Status                        |
|--------------|--------------------------------------|----------|---------------------------------------|
| 001/001      | ATOMIZER DEVICE                      | 36 BX    | Line Split                            |
| * 001/001A   | Electronic Cigarette E-Cigarette Kit | 1000 PCS | Correspondence received<br>12-23-2008 |
| * 001/001B   | Electronic Cigarette Cartridges      | 600 BX   | Correspondence received<br>12-23-2008 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

## CORRESPONDENCE

DET 000097

| Line ACS/FDA | Product Description                  |
|--------------|--------------------------------------|
| 001/001A     | Electronic Cigarette E-Cigarette Kit |

Comments : We have reviewed your response, the entry documents and product labeling including the [www.smokingeverywhere.com](http://www.smokingeverywhere.com) website.

We concluded that "Smoking Everywhere E-Cigarette?" and its component parts appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. Thus, this product appears to be a drug-device combination product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(g)(1)).

Since we are not aware of any data establishing ?Smoking Everywhere E-Cigarette? as generally recognized among scientific experts as safe and effective for the uses described above and in the labeling, this product appears to be a "new drug," as defined by section 201(p) of the Act (21 U.S.C. 321(p)). "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. 355) to be legally marketed in the United States. The ?Smoking Everywhere E-Cigarette? product is not so approved and its marketing in the United States would violate this section of the Act.

The ?Smoking Everywhere E-Cigarette? product also appears to be an adulterated device under section 501(f)(1)(B) of the Act (21 U.S.C. 351(f)(1)(B)), because there is no approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act (21 U.S.C. 360e(a)), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act (21 U.S.C. 360j(g)).

Therefore, in accordance with section 801(a) of the Act (21 U.S.C. 381(a)), the marketing of ?Smoking Everywhere E-Cigarette? and its component parts appears to violate sections 505 and 501(f)(1)(B) of the Act (21 U.S.C. 355 and 21 U.S.C. 351(f)(1)(B)), as described above.

|          |                                 |
|----------|---------------------------------|
| 001/001B | Electronic Cigarette Cartridges |
|----------|---------------------------------|

Comments : We have reviewed your response, the entry documents and product labeling including the [www.smokingeverywhere.com](http://www.smokingeverywhere.com) website.

We concluded that ?Smoking Everywhere E-Cigarette? and its component parts appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. Thus, this product appears to be a drug-device combination product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(g)(1)).

Since we are not aware of any data establishing ?Smoking Everywhere E-Cigarette? as generally recognized among scientific experts as safe and effective for the uses described above and in the labeling, this product appears to be a "new drug," as defined by section 201(p) of the Act (21 U.S.C. 321(p)). "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. 355) to be legally marketed in the United States. The ?Smoking Everywhere E-Cigarette? product is not so approved and its marketing in the United States would violate this section of the Act.

The ?Smoking Everywhere E-Cigarette? product also appears to be an adulterated device under section 501(f)(1)(B) of the Act (21 U.S.C. 351(f)(1)(B)), because there is no approved application

Notice of FDA Action  
Entry Number: DO7-1112223-7

Notice Number 3  
Page: 3

for premarket approval (PMA) in effect pursuant to section 515(a) of the Act (21 U.S.C. 360e(a)), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act (21 U.S.C. 360j(g)).

Therefore, in accordance with section 801(a) of the Act (21 U.S.C. 381(a)), the marketing of ?Smoking Everywhere E-Cigarette? and its component parts appears to violate sections 505 and 501(f)(1)(B) of the Act (21 U.S.C. 355 and 21 U.S.C. 351(f)(1)(B)), as described above.

Chih-Shang J. Shen, Compliance Officer  
(Region/District)  
U.S. Food and Drug Administration  
222 W. 6th St., Suite 700  
San Pedro, CA 90731

(310) 971-2353  
(310) 971-2363 (FAX)  
JIM.SHEN@FDA.HHS.GOV

Notice Prepared For: The District Director, U.S. Food and Drug Administration  
Notice Prepared By: CJS

DET 000099

# United States Food and Drug Administration

Los Angeles District Office

## Notice of FDA Action

Entry Number: DO7-1112224-5

Notice Number: 3  
December 23, 2008

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

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<

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

Carrier: (b) (4);

Date Received: October 16, 2008

Arrival Date: September 28, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

## HOLD DESIGNATED

### Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                  | Quantity | Current Status                        |
|--------------|--------------------------------------|----------|---------------------------------------|
| * 001/001    | Electronic Cigarette E-Cigarette Kit | 12 BX    | Correspondence received<br>12-23-2008 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

## CORRESPONDENCE

| Line ACS/FDA | Product Description                  |
|--------------|--------------------------------------|
| 001/001      | Electronic Cigarette E-Cigarette Kit |

DET 000100

Comments : We have reviewed your response, the entry documents and product labeling including the [www.smokingeverywhere.com](http://www.smokingeverywhere.com) website.

We concluded that ?Smoking Everywhere E-Cigarette? and its component parts appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. Thus, this product appears to be a drug-device combination product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(g)(1)).

Since we are not aware of any data establishing ?Smoking Everywhere E-Cigarette? as generally recognized among scientific experts as safe and effective for the uses described above and in the labeling, this product appears to be a "new drug," as defined by section 201(p) of the Act (21 U.S.C. 321(p)). "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. 355) to be legally marketed in the United States. The ?Smoking Everywhere E-Cigarette? product is not so approved and its marketing in the United States would violate this section of the Act.

The ?Smoking Everywhere E-Cigarette? product also appears to be an adulterated device under section 501(f)(1)(B) of the Act (21 U.S.C. 351(f)(1)(B)), because there is no approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act (21 U.S.C. 360e(a)), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act (21 U.S.C. 360j(g)).

Therefore, in accordance with section 801(a) of the Act (21 U.S.C. 381(a)), the marketing of ?Smoking Everywhere E-Cigarette? and its component parts appears to violate sections 505 and 501(f)(1)(B) of the Act (21 U.S.C. 355 and 21 U.S.C. 351(f)(1)(B)), as described above.

Chih-Shang J. Shen, Compliance Officer  
(Region/District)  
U.S. Food and Drug Administration  
222 W. 6th St., Suite 700  
San Pedro, CA 90731

(310) 971-2353  
(310) 971-2363 (FAX)  
[JIM.SHEN@FDA.HHS.GOV](mailto:JIM.SHEN@FDA.HHS.GOV)

Notice Prepared For: The District Director, U.S. Food and Drug Administration  
Notice Prepared By: CJS

**United States Food and Drug Administration**  
Los Angeles District Office  
**Notice of FDA Action**

Entry Number: DO7-1112223-7

Notice Number: 4  
March 16, 2009

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

>

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

Carrier: (b) (4)

Date Received: October 16, 2008

Arrival Date: September 29, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

**HOLD DESIGNATED**

Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                  | Quantity | Current Status    |
|--------------|--------------------------------------|----------|-------------------|
| 001/001      | ATOMIZER DEVICE                      | 36 BX    | Line Split        |
| * 001/001A   | Electronic Cigarette E-Cigarette Kit | 1000 PCS | Refuse 03-13-2009 |
| * 001/001B   | Electronic Cigarette Cartridges      | 600 BX   | Refuse 03-13-2009 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

**REFUSAL OF ADMISSION**

**REDELIVERY WITH FDA VERIFICATION REQUESTED**

DET 000102

Notice of FDA Action  
Entry Number: DO7-1112223-7

Notice Number 4  
Page: 2

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

| Line ACS/FDA   | Product Description  |
|--|--|
| 001/001A   | Electronic Cigarette E-Cigarette Kit   |
| Refused :  | 1,000 PCS  |
|  | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).  |
|  | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).                  |
|  | <b>FD&amp;CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG</b><br>The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA. |
|  | <b>FD&amp;CA Section 801(a)(3); 502(o) Misbranding</b><br>It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.  |
| 001/001B   | Electronic Cigarette Cartridges  |
| Refused :  | 3,000 PCS  |
|  | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).  |
|  | <b>FD&amp;CA Section 502(o), 801(a)(3); MISBRANDING</b><br>It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).                  |
|  | <b>FD&amp;CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG</b><br>The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA. |
|  | <b>FD&amp;CA Section 801(a)(3); 502(o) Misbranding</b><br>It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.  |
| For the District Director of Customs:  |  |
| Chih-Shang J. Shen, Compliance Officer<br>(Region/District)<br>U.S. Food and Drug Administration<br>222 W. 6th St., Suite 700<br>San Pedro, CA 90731 |  |
| (310) 971-2353<br>(310) 971-2363 (FAX)<br>JIM.SHEN@FDA.HHS.GOV   |  |

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this

DET 000103

Notice of FDA Action  
Entry Number: DO7-1112223-7

Notice Number 4  
Page: 3

notice, or within such additional time as the District Director of Customs specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF-3499, along with any other documents required by Customs, and a copy of this notice to:

CBP LAX  
11099 S. La Cienega Blvd.  
Los Angeles, CA 90045-6115

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

---

Notice Prepared For: The District Director, U.S. Food and Drug Administration  
Notice Prepared By: CJS

DET 000104

# United States Food and Drug Administration

Los Angeles District Office

## Notice of FDA Action

Entry Number: DO7-1112224-5

Notice Number: 4

March 16, 2009

Importer:

Smoking Everywhere Llc  
4500 N Hiatus Rd  
Ste 215  
Fort Lauderdale, FL 33351

>

<

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

Carrier: (b) (4);

Date Received: October 16, 2008

Arrival Date: September 28, 2008

Filer of Record: (b) (4)

Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

## HOLD DESIGNATED

### Summary of Current Status of Individual Lines

| Line ACS/FDA | Product Description                          | Quantity | Current Status    |
|--------------|--|----------|-------------------|
| *            | 001/001 Electronic Cigarette E-Cigarette Kit | 12 BX    | Refuse 03-13-2009 |

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

## REFUSAL OF ADMISSION

## REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

DET 000105

Notice of FDA Action  
Entry Number: DO7-1112224-5

Notice Number 4  
Page: 2

Line ACS/FDA                          Product Description

001/001                          Electronic Cigarette E-Cigarette Kit

Refused :                          7,200 NO

FD&CA Section 502(o), 801(a)(3); MISBRANDING

It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).

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. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA.

For the District Director of Customs:

Chih-Shang J. Shen, Compliance Officer                          (310) 971-2353  
(Region/District)                          (310) 971-2363 (FAX)  
U.S. Food and Drug Administration                          JIM.SHEN@FDA.HHS.GOV  
222 W. 6th St., Suite 700  
San Pedro, CA 90731

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

CBP LAX  
11099 S. La Cienega Blvd.  
Los Angeles, CA 90045-6115

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

---

Notice Prepared For: The District Director, U.S. Food and Drug Administration  
Notice Prepared By: CJS

DET 000106



Smoking Everywhere®

Electronic Cigarette

April 6, 2009

Refused  
3/13/09

Chih-Shang J. Shen  
Compliance Officer  
U.S. Food and Drug Administration  
222 West 6th Street, Suite 700  
San Pedro, CA 90731

*via U.S. mail and via email ([jim.shen@fda.hhs.gov](mailto:jim.shen@fda.hhs.gov))*

RE: Authorization for Thompson Hine LLP to communicate with FDA and other regulatory authorities on behalf of Smoking Everywhere LLC

Dear Dr. Shen,

Thompson Hine LLP, including attorneys Walt Linscott and Elizabeth Gobeil, is representing Smoking Everywhere LLC in relation to the following Notices of FDA Action and related regulatory matters: Entry Number D07-1112223-7 and D07-1112224-5.

Accordingly, and by way of this letter, as a duly authorized representative of Smoking Everywhere LLC, I hereby grant Thompson Hine LLP, including attorneys Walt Linscott and Elizabeth Gobeil, permission to speak with you and other regulatory authorities on behalf of Smoking Everywhere LLC regarding the above-referenced regulatory matters.

If you need additional information, please feel free to contact me at [elicko@yahoo.com](mailto:elicko@yahoo.com) or (954) 675-8400 or contact Elizabeth Gobeil at (404) 541-2912 or [elizabeth.gobeil@thompsonhine.com](mailto:elizabeth.gobeil@thompsonhine.com).

Best regards,

Elicko Taleb  
Chief Executive Officer  
Smoking Everywhere LLC

5600 NW 102<sup>nd</sup> Ave, Suite A-F • Sunrise, FL 33351

Toll Free: 1-800-613-0337 • International: 1-954-749-9269 • Fax: 1-954-208-0696

Email: [support@SmokingEverywhere.com](mailto:support@SmokingEverywhere.com) • Website: [www.SmokingEverywhere.com](http://www.SmokingEverywhere.com)

DET 000107

## ENTRY/IMMEDIATE DELIVERY

(b) (4)

EDA

COT # 744

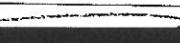
19 CFR 142.3, 142.16, 142.22, 142.24 \*\*\* ABI CERTIFIED \*\*\*

|   |                                     |  |                                   |
|---|-------------------------------------|--|-----------------------------------|
| 1. ARRIVAL DATE<br>092908   | 2. ELECTED ENTRY DATE<br>101608     | 3. ENTRY TYPE CODE/NAME<br>01                    | 4. ENTRY NUMBER<br>D07-1112223-7  |
| 5. PORT<br>2720   | 6. SINGLE TRANS. BOND<br>\$458      | 7. BROKER/IMPORTER FILE NUMBER<br>(b) (4)        |                                   |
|   | 8. CONSIGNEE NUMBER<br>80-020570700 |  | 9. IMPORTER NUMBER<br>SAME        |
| 10. ULTIMATE CONSIGNEE NAME<br>SHOKING EVERYWHERE LLC<br>4500 N HIATUS RD<br>SUNRISE, FL 33351-7984 |                                     | 11. IMPORTER OF RECORD NAME<br>SAME              |                                   |
| 12. CARRIER CODE<br>CX  | 13. VOYAGE/FLIGHT/TRIP<br>884       | 14. LOCATION OF GOODS-CODE(S)/NAME(S)<br>(b) (4) |                                   |
| 15. VESSEL CODE/NAME  |                                     |  |                                   |
| 16. U.S. PORT OF UNLADING<br>2720   | 17. MANIFEST NUMBER                 | 18. G.O. NUMBER                                  | 19. TOTAL VALUE<br>(b) (4)        |
| 20. DESCRIPTION OF MERCHANDISE<br>ATOMIZER DEVICE   |                                     |  |                                   |
| 21. ITAWB CODE<br>N   | 22. IT/BL/AWB NO.<br>(b) (4)        | 23. MANIFEST QUANTITY<br>(b) (4)                 | 24. H.S. NUMBER<br>(b) (4)        |
|   |                                     |  | 25. CARRIER/CONTRACTOR<br>(b) (4) |
|   |                                     |  | 26. MANUFACTURER NO.<br>(b) (4)   |
|   |                                     |  |                                   |
|   |                                     |  |                                   |
|   |                                     |  |                                   |
|   |                                     |  |                                   |

## 27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT



PHONE NO.

(b) (4)

DATE

10/16/2008

## 28. CBP USE ONLY

 OTHER AGENCY ACTION REQUIRED, NAMELY: CBP EXAMINATION REQUIRED. ENTRY REJECTED, BECAUSE:29. BROKER OR OTHER GOVT. AGENCY USE  
EXAM DATE: 2420 DATE: 2420

\*\*\* COUNTER FACILITY \*\*\*

|                      |           |      |
|----------------------|-----------|------|
| DELIVERY AUTHORIZED: | SIGNATURE | DATE |
|----------------------|-----------|------|

DET 000108

Paperwork Reduction Act Notice: This information is to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary. The estimated average burden associated with this collection of information is 15 minutes per respondent depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to Bureau of Customs and Border Protection, Information Services Branch, Washington, DC 20229, and to the Office of Management and Budget, Paperwork Reduction Project (1651-0024), Washington, DC 20503.

## ENTRY/IMMEDIATE DELIVERY

(b) (4)

FDA

CST # 744

19 CFR 142.3, 142.16, 142.22, 142.24 \*\*\* ABI CERTIFIED \*\*\*

|   |                                     |   |                                  |
|---|-------------------------------------|---|----------------------------------|
| 1. ARRIVAL DATE<br>092908   | 2. ELECTED ENTRY DATE<br>101608     | 3. ENTRY TYPE CODE/NAME<br>01   | 4. ENTRY NUMBER<br>D07-1112223-7 |
| 5. PORT<br>2720   | 6. SINGLE TRANS. BOND<br>X458       | 7. BROKER/IMPORTER FILE NUMBER<br>S8-07985  |                                  |
|   | 8. CONSIGNEE NUMBER<br>80-020570700 |   | 9. IMPORTER NUMBER<br>SAME       |
| 10. ULTIMATE CONSIGNEE NAME<br>SMOKING EVERYWHERE LLC<br>4500 N HIATUS RD<br>SUITE 100 33351-7904   |                                     | 11. IMPORTER OF RECORD NAME<br>SAME   |                                  |
| 12. CARRIER CODE<br>CX  | 13. VOYAGE/FLIGHT/TRIP<br>884       | 14. LOCATION OF GOODS-CODE(S)/NAME(S)<br>(b) (4)  |                                  |
| 15. VESSEL CODE/NAME  |                                     |   |                                  |
| 16. U.S. PORT OF UNLADING<br>2720   | 17. MANIFEST NUMBER                 | 18. G.O. NUMBER   | 19. TOTAL VALUE<br>(b) (4)       |
| 20. DESCRIPTION OF MERCHANDISE<br>ATOMIZER DEVICE   |                                     |   |                                  |
| 21. IT/BL/AWB CODE<br>X   | 22. IT/BL/AWB NO.<br>(b) (4)        | 23. MANIFEST QUANTITY<br>(b) (4)  | 24. H.S. NUMBER<br>(b) (4)       |
|   |                                     |   | 25. OWNER/GEN<br>(b) (4)         |
|   |                                     |   | 26. MANUFACTURER NO.<br>(b) (4)  |
|   |                                     |   |                                  |
|   |                                     |   |                                  |
|   |                                     |   |                                  |
| 27. CERTIFICATION   |                                     | 28. CBP USE ONLY  |                                  |
| I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met. |                                     | <input type="checkbox"/> OTHER AGENCY ACTION REQUIRED, NAMELY:<br><br><input type="checkbox"/> CBP EXAMINATION REQUIRED.<br><br><input type="checkbox"/> ENTRY REJECTED, BECAUSE: |                                  |
| SIGNATURE OF APPLICANT<br><br>X   |                                     |   |                                  |
| PHONE NO<br>(b) (4)   | DATE<br>10/16/2008                  |   |                                  |
| 29. BROKER OR OTHER GOVT. AGENCY USE<br>EARN 31112428 TIRRS 2420  |                                     |   |                                  |

\*\*\* AIRPORT AND COURIER FACILITY \*\*\*

DELIVERY AUTHORIZED: SIGNATURE DATE

DET 000109

Paperwork Reduction Act Notice: This information is to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary. The estimated average burden associated with this collection of information is 15 minutes per respondent depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to Bureau of Customs and Border Protection, Information Services Branch, Washington, DC 20229, and to the Office of Management and Budget, Paperwork Reduction Project (1651-0024), Washington, DC 20503.

# **Smoking Everywhere, LLC**

**4500 North Hiatus Road, Suite 215  
Sunrise, FL 33351  
954-675-8400**

---

To whom it may concern,

Here is a brief description on atomizer device:

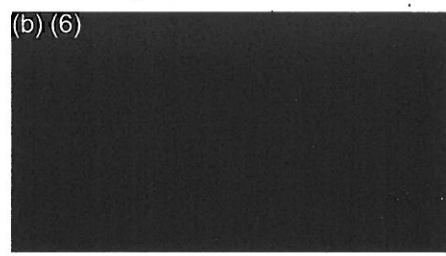
The Atomizer device is driven by modern microelectronic technology, a small rechargeable battery and a unique, safe replaceable cartridge containing water, propylene glycol, nicotine or non-nicotine (depending on cartridges), a scent and other flavorings.

Any questions, please feel free to contact me anytime.

Regards,  
Elcko Taleb  
Smoking Everywhere, LLC

*Fax To:*

(b) (6)



DET 000110

Manufacturer

Original

(b) (4)

INVOICE

NO6166373 IN date september 26 2008

| Consignee |   |
|-----------|---|
| Attn      | Contact Name: Mr elicko tareb<br>Company: Smoking Everywhere, LLC.<br>Address: 4500 North Hiatus Road, Suite 215, Sunrise, Florida, 33351 USA<br>Country/Region: United States<br>Business Email: elicko@yahoo.com<br>Telephone: 954-675-8400 |

Terms of Delivery: (b) (4)

Means of Transportation: By Air

Shipping time : 4-5days

Payment Term : TT

Shipping cost : prepaid

Per FDT  
9018-90-8000  
FDT# 80M--SN

Order detail

| Quantity<br>Unit No. | Description  | Country<br>of<br>Origin | Unit<br>Value | Sub. Value  |
|----------------------|--|-------------------------|---------------|-------------|
| (b) (4)              | Atomizer device for 108<br>HTS#8419.89.9585          | CHINA                   | (b) (4)       | (b) (4) EV  |
| (b) (4)              | Accessories for 108<br>HTS#4819.40.0040 8419 90 9580 | CHINA                   | (b) (4)       | (b) (4) NDC |
|                      | Shipping cost  |                         |               | (b) (4) ✓   |
| Totally              |  |                         | (USD)         | (b) (4) ✓   |

Go BK  
HK HON BRO GIO HON

DET 000111

|  |   |          |
|--|---|----------|
| 1. Sender's Account Number<br>发件人帐号  |   |          |
| 2. Invoice to Receiver 收件人付费   | RECIPIENT LIABLE FOR UNPAID CHARGES 收件人须付费用 |          |
| <input type="checkbox"/>   | Receiver's account number<br>收件人帐号          |          |
| 3. Customer Reference 客户参考号  |   |          |
| <b>4. Item (Collective Address) 货物项目 (单件填空)</b>  |   |          |
| Name 公司名称:   |   |          |
| Address 地址:  |   |          |
| City 城市:   | Postal / Zip Code 邮政编码:                     |          |
| Province/Region 省份/地区:   | Country 国家:                                 |          |
| Contact Name 联系人姓名:  | Tel No 联系电话:                                |          |
| <b>5. To (Recipient) 收件人信息</b>   |   |          |
| Name 公司名称:   |   |          |
| Address 地址:  |   |          |
| City 城市:   | Postal / Zip Code 邮政编码:                     |          |
| Province/Region 省份/地区:   | Country 国家:                                 |          |
| Contact Name 联系人姓名:  | Tel No 联系电话:                                |          |
| <b>6. Delivery Address 交货地址</b>  |   |          |
| Name 公司名称:   |   |          |
| Address 地址:  |   |          |
| City 城市:   | Postal / Zip Code 邮政编码:                     |          |
| Province/Region 省份/地区:   | Country 国家:                                 |          |
| Contact Name 联系人姓名:  | Tel No 联系电话:                                |          |
| <b>7. Dangerous Goods 危险品</b>  |   |          |
| Does this consignment contain any dangerous goods? 本托运货物内是否含有危险品?                            |   |          |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |   |          |
| Your Signature 发件人签名   |   |          |
| Received by (b) (4)  |   |          |
| Date: 1/1/11 (Day/Month/Year)<br>日期: 日月年   | Date: 1/1/11<br>日期: 日月                      | Time: 时日 |

| Sending Depot<br>发件地  | Receiving Depot<br>收件地 | (b) (4)   |               |                         |         |
|---|------------------------|-----------|---------------|-------------------------|---------|
| Bobag   |                        |           |               |                         |         |
| <br><b>GD 227 207 582 WW</b><br>Please quote this Number if you have an enquiry. 如有任何查询请出示此号码   |                        |           |               |                         |         |
| To China Mainland/China Post/China Air Mail<br><input checked="" type="checkbox"/> Special Express<br>全方位服务<br>9:00 Express<br>朝九快遞<br><input checked="" type="checkbox"/> 10:00 Express<br>朝十快遞<br><input checked="" type="checkbox"/> 12:00 Express<br>中午快遞<br><input checked="" type="checkbox"/> Express<br>全球快遞<br><input checked="" type="checkbox"/> Economy Express<br>经济快递 |                        |           |               |                         |         |
| Documents 文件 <input type="checkbox"/> Non-Documents 非文件 <input type="checkbox"/><br><b>Priority 优先服务</b> <input type="checkbox"/><br><b>Insurance 保险</b> <input type="checkbox"/><br>Currency 货币 <input type="checkbox"/><br>Volume 体积 <input type="checkbox"/>   |                        |           |               |                         |         |
| A Goods Delivery Document 快递单据  |                        |           |               |                         |         |
| 4. Goods Description 货物描述   |                        |           |               |                         |         |
| General Description 货物描述  | Number of Items 件数     | Weight 重量 | Dimensions 体积 |                         |         |
|   |                        | Kilos 公斤  | Grams 克       | Length 长                | Width 宽 |
|   |                        |           |               |                         |         |
|   |                        |           |               |                         |         |
|   |                        |           |               |                         |         |
|   |                        |           |               |                         |         |
| Stat. No. 过计数量  | Total 共计               | 36.1      | 379169        | Volume 体积:              |         |
| OPS verify 操作部确认:   | 36.1                   |           |               | Volume<br>Weights 体积重量: |         |
| Declaration of Value for Insurance<br>声明价值保价声明<br>Amount of Value 保价金额<br>V.A.T./V.A.W./Postage<br>金额<br>保价<br>邮资   |                        |           |               |                         |         |
| Signature<br>签名<br>Name 姓名<br>Name<br>Name  |                        |           |               |                         |         |
| <b>INVOICE COPY</b><br><b>发票联</b>   |                        |           |               |                         |         |

DET 000112

(b) (4)

## Full Manifest

MAWB: 16066319105  
(Totals for Master)

Origin: HKG

Flight: CX884

Date: 09/29/2008

Total Houses: (b)  
Total Pieces: (4)

Total Value: (b) (4)

Total MBags: (b) (4)

(Totals by Entry Type)

Entry Type: 01-Formal

Total Houses: (b)  
Total Pieces: (4)

"INBOUND MANIFEST FINAL"

Total Value: (b) (4)

Total MBags: (b) (4)

Total Weight: 842.00

HAWB: 227207582

PCS: (b) (4)

WGT: 812.000

VALUE: (b) (4)

DESC: ALORMIZER

DEVICE/ACCESSORIES/

HTS:

BAG #: W1799615

FILE #: LS0804832

SH. ORIG: CXO

SHIPPER: (b) (4)

CN. DEST:MIA

CONSIGNEE:SMOKING EVERYWHERE LLC

4500 NOTH HIATUS RD SUITE 215

SUNRISE FLORIDA

SUNRISE, FL 33304

HAWB: 463543313

PCS: (b) (4)

WGT: 30.000

VALUE: (b) (4)

DESC: BONDED

HTS:

BAG #: P8479516

FILE #: LS0804831

SH. ORIG: CTU

SHIPPER: (b) (4)

CN. DEST:SFO

CONSIGNEE: (b) (4)

FDA OASIS v5.6.01 Web Application . Production - WebUtil - Microsoft Internet Explorer

Window

Line Details

**Line Information**

|           |               |                     |   |
|-----------|---------------|---------------------|---|
| Entry No: | DO7-1112223-7 | Importer of Record: | Smoking Everywhere Llc, 4500 N Hiatus Rd Ste 215, Fort Lauderdale, FL 33308 |
| Doc/Line# | 1             | Suffix:             | 0   |
| HTS:      | 9018906000    |                     |   |

**Date Available Information**

|           |            |         |  |                 |           |
|-----------|------------|---------|--|-----------------|-----------|
| Expected: | 09-29-2008 | Actual: |  | Storage status: | 401-A-100 |
|-----------|------------|---------|--|-----------------|-----------|

**Product Information**

|                    |                                 |                    |                                      |
|--------------------|---------------------------------|--------------------|--------------------------------------|
| Product Code :     | 80-1M-1-SN                      | Country of Origin: | China                                |
| Product Code Desc: | Cigarettes (containing Tobacco) |                    |                                      |
| Importer Desc:     | ATOMIZER DEVICE                 |                    |                                      |
| Corrected Desc:    | Electronic Cigarette Cartridges |                    |                                      |
| Brand Name:        | SMOKING EVERYWHERE E-Cigarettes | Package/Can Codes: | Classic Collection - Limited Edition |
| Quantity:          | (b) (4)                         | Value of Goods:    | (b) (4)                              |
| A of C:            | (b) (4)                         | A:                 | (b) (4)                              |

**Firm Information**

|               |  |
|---------------|--|
| Manufacturer: | (b) (4)  |
| Shipper:      |  |
| Consignee:    | 3007182091 Smoking Everywhere Llc, 4500 N Hiatus Rd Ste 215, Fort Lauderdale, FL 33308 |

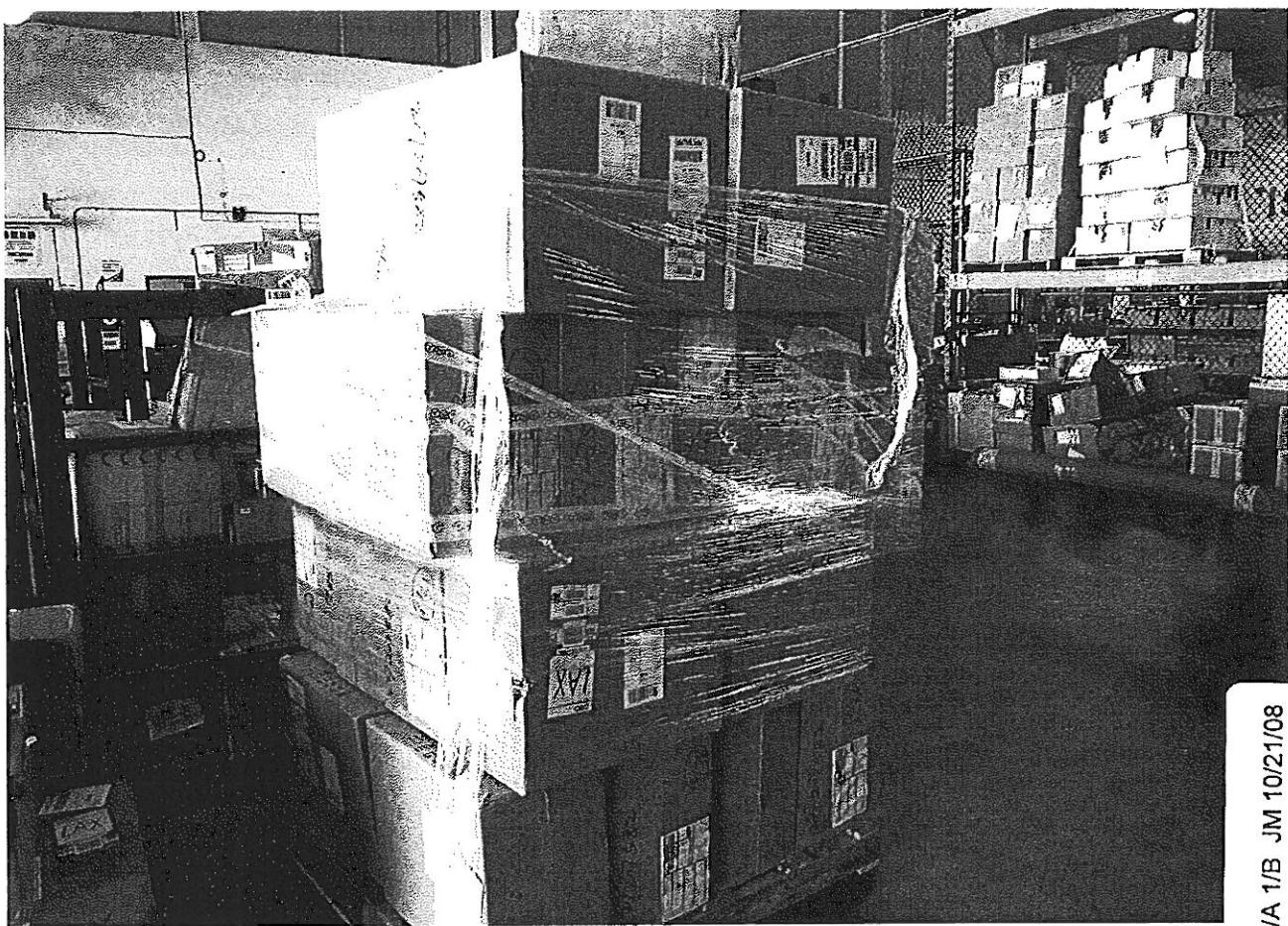
TransCont Id's:

Location of Goods:

Help  
View Update  
Cancel  
PruRec  
NextRec  
Entry Details

Start | Inbox - Microsoft Outlook | 3 Internet Explorer | IC General.doc - Microsoft Word | 3:20 PM

DET 000114



DO7-1112223-7 1/A 1/B JM 10/21/08

Top - View of Master Cartons  
Bottom - Master AWB Label

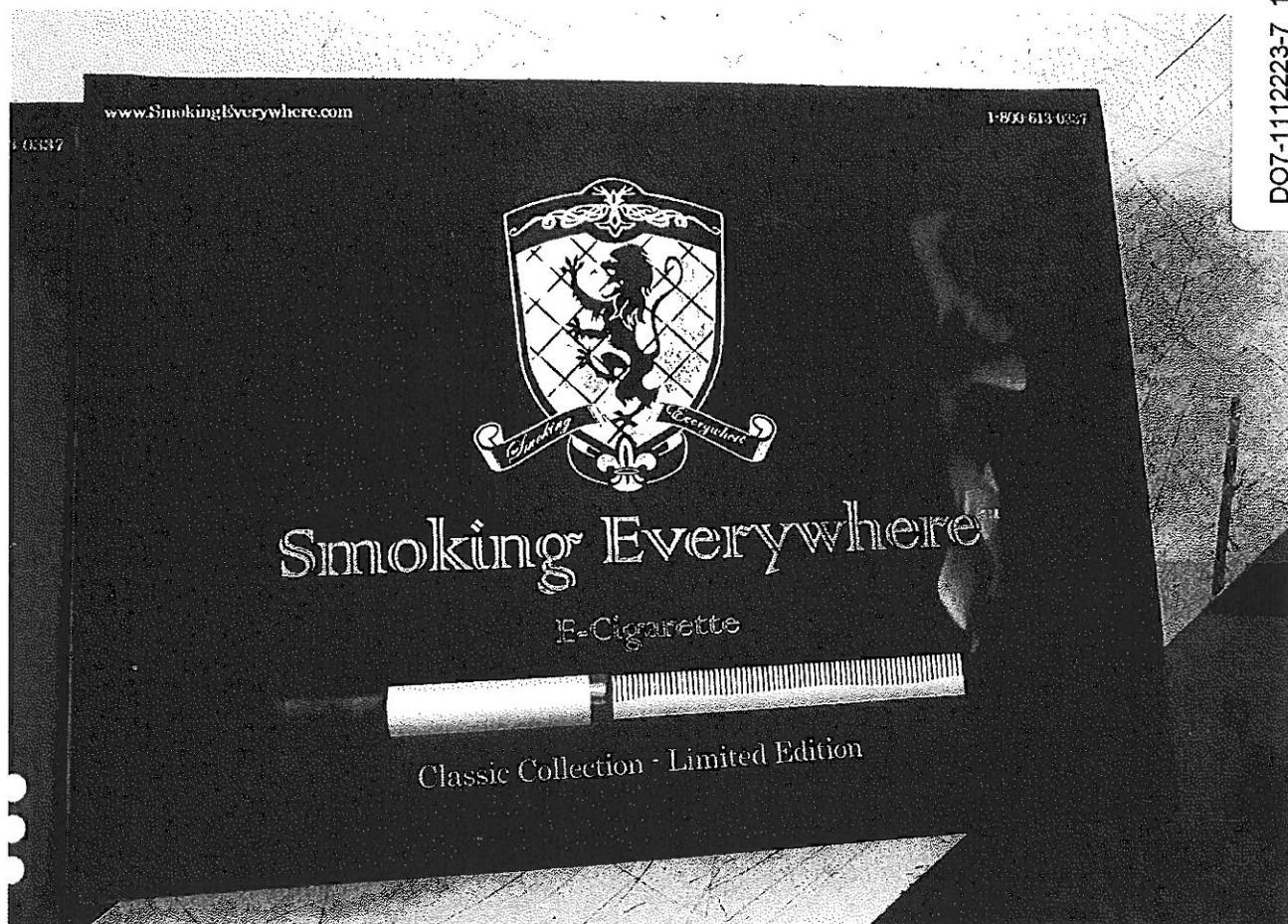


DET 000115

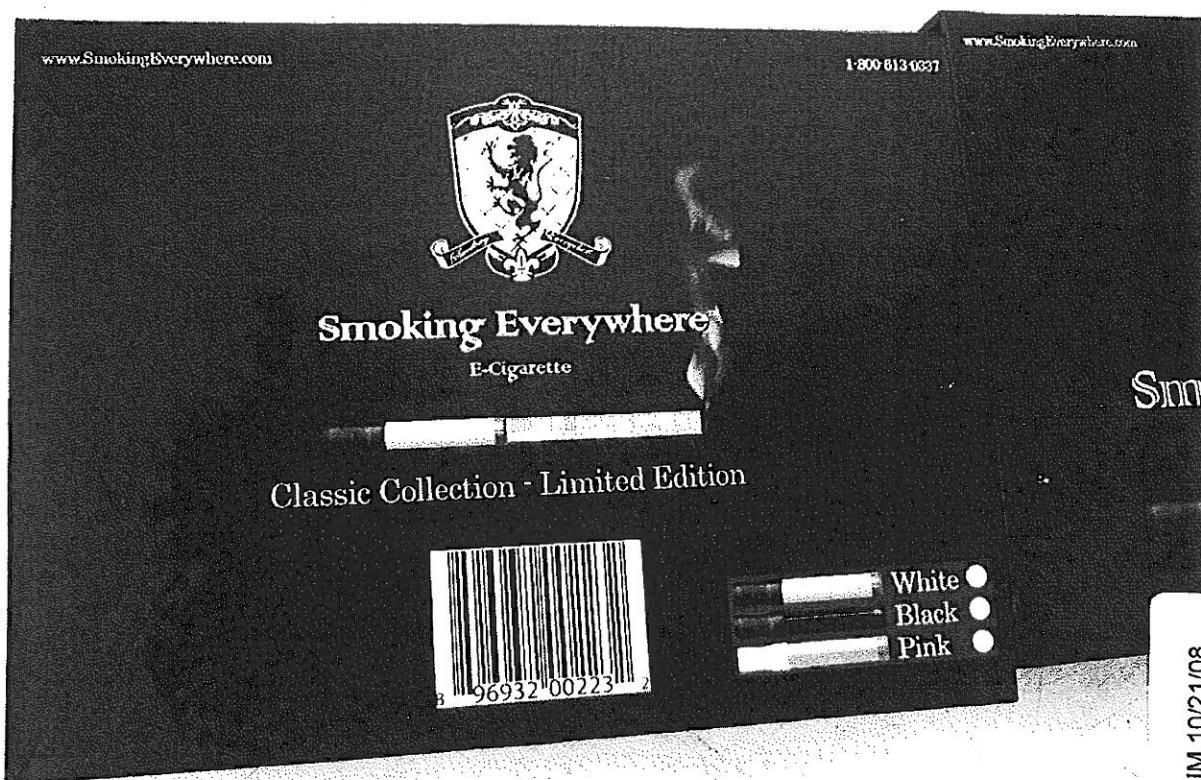


DET-1112223-7 1/A JM 10/21/08

Top - Classic Collection Kit  
Bottom - Top view of Kit

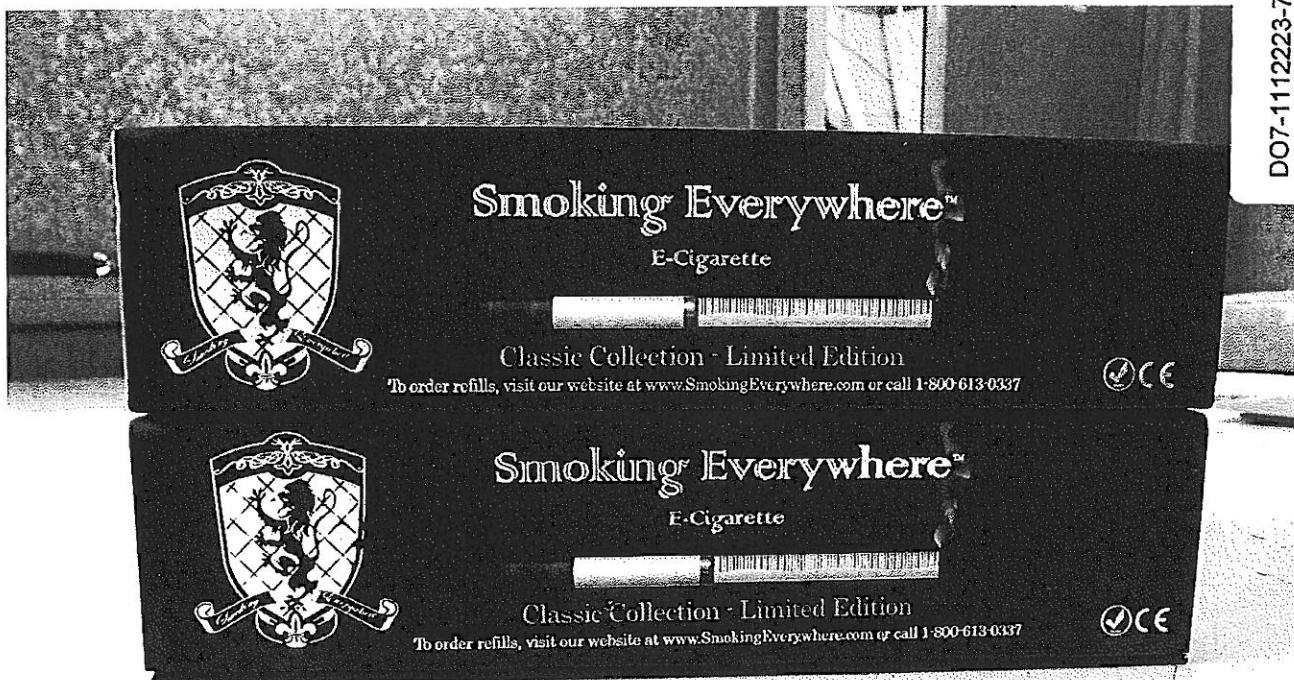


DET 000116



DO7-1112223-7 1/A JM 10/21/08

Top - Bottom view of Kit  
Bottom - Side view of Kit



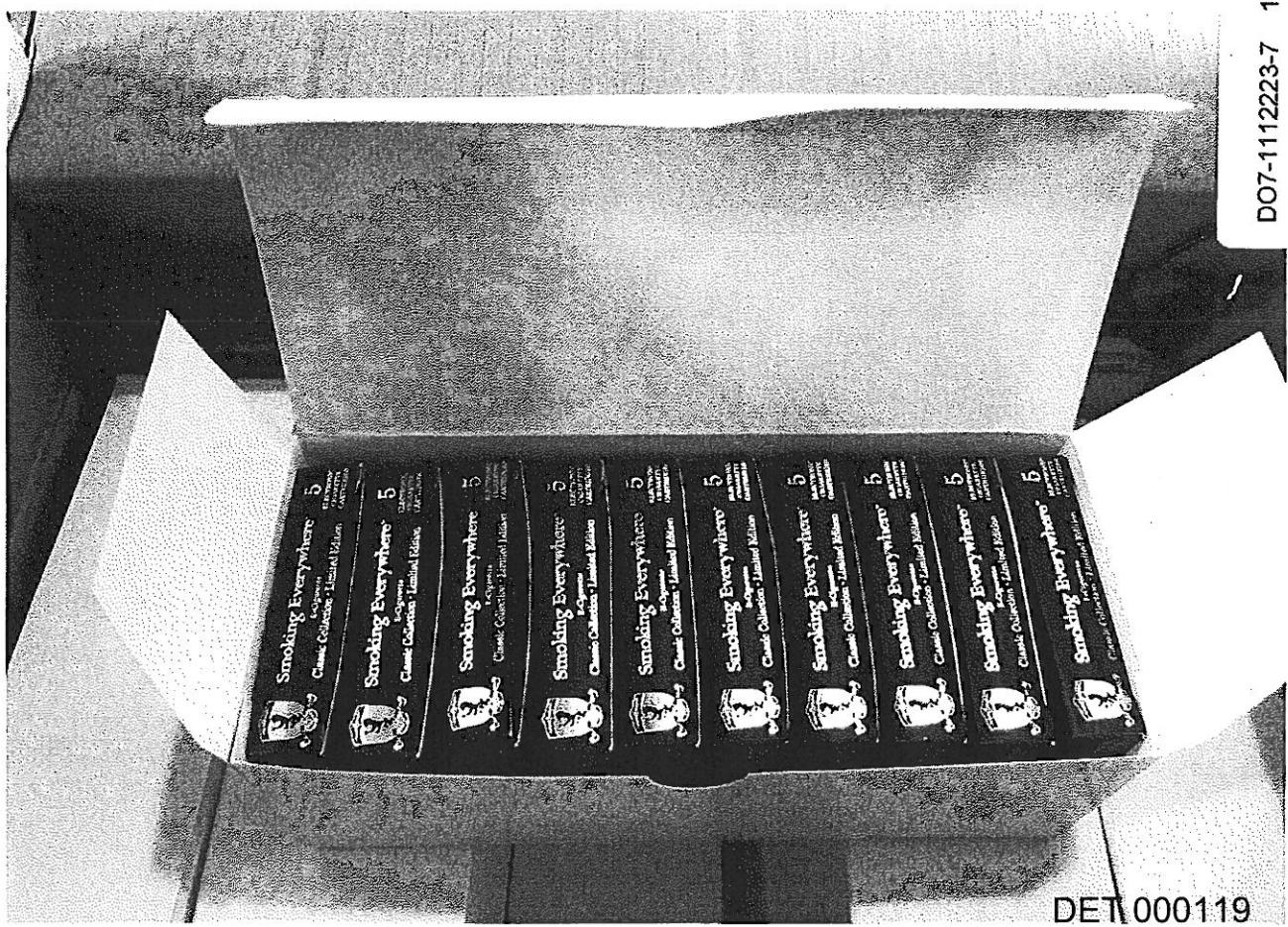
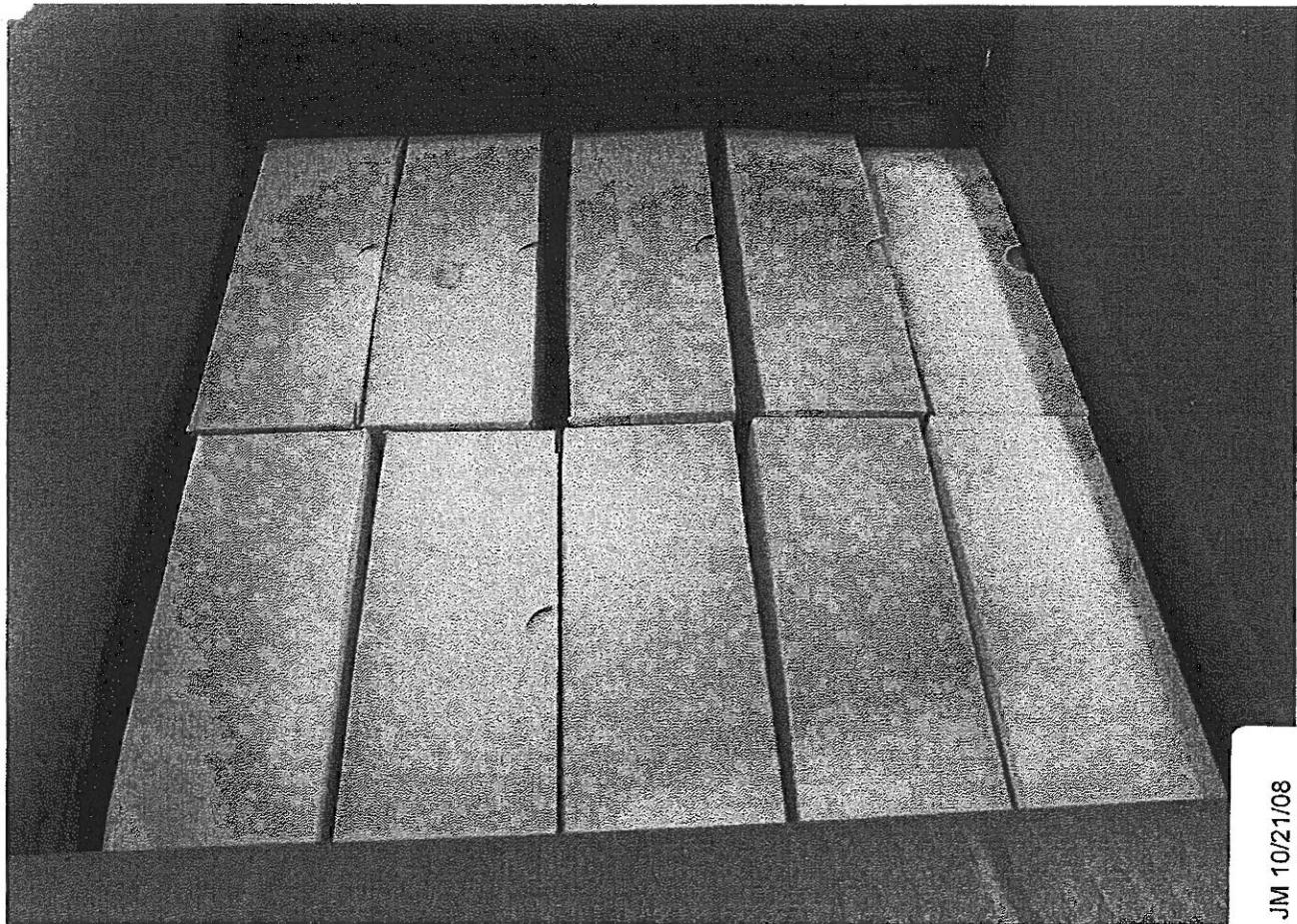
DET 000117



DO7-1112223-7 1/A JM 10/21/08

Top - Open view of Kit  
Bottom - Contents of Kit

DET 000118



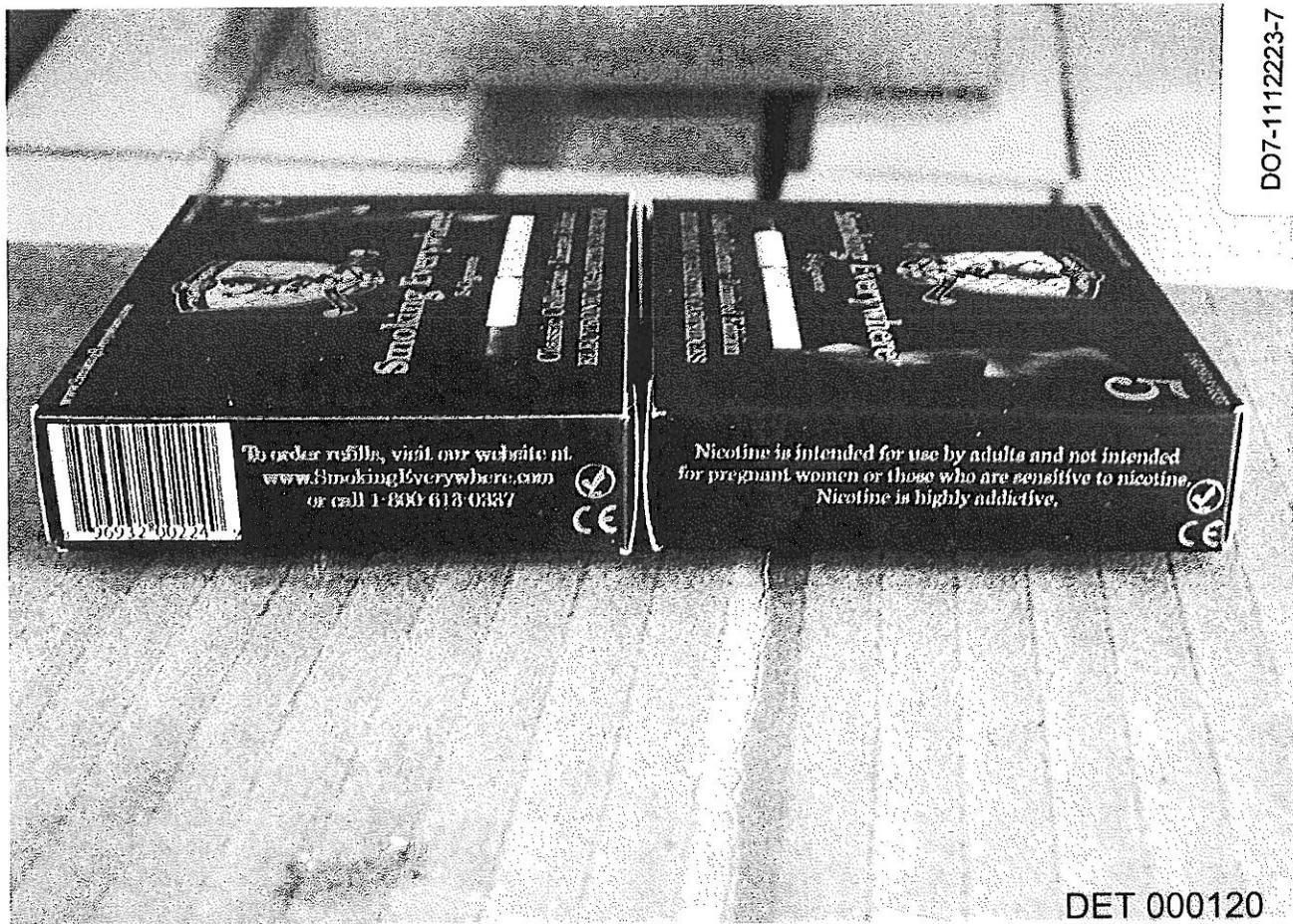
DO7-1112223-7 1/B JM 10/21/08

Top - Cartridges  
Bottom - Cartridges

DET 000119



DO7-1112223-7 1/B JM 10/21/08



Top - Cartridges  
Bottom - Side view of cartridge boxes

DET 000120

FEBR 177

U.S. DEPARTMENT OF HOMELAND SECURITY  
Bureau of Customs and Border ProtectionForm Approved  
OMB No. 1651-0024**ENTRY/IMMEDIATE DELIVERY**

(b) (4)

FDA

CST # 744

19 CFR 142.3, 142.16, 142.22, 142.24 \*\*\* ABI CERTIFIED \*\*\*

|   |                                     |  |                                  |
|---|-------------------------------------|--|----------------------------------|
| 1. ARRIVAL DATE<br>092808   | 2. ELECTED ENTRY DATE<br>301608     | 3. ENTRY TYPE CODE/NAME<br>01                    | 4. ENTRY NUMBER<br>D07-1112224-5 |
| 5. PORT<br>2720   | 6. SINGLE TRANS. BOND<br>X458       | 7. BROKER/IMPORTER FILE NUMBER<br>S8-07975       |                                  |
|   | 8. CONSIGNEE NUMBER<br>60-020570700 |  | 9. IMPORTER NUMBER<br>SAME       |
| 10. ULTIMATE CONSIGNEE NAME<br>SHOKING EVERYWHERE LLC<br>4500 N RAYING RD<br>SUNRISE, FL 33351-7984 |                                     | 11. IMPORTER OF RECORD NAME<br>SAME              |                                  |
| 12. CARRIER CODE<br>CX  | 13. VOYAGE/FLIGHT/TRIP<br>084       | 14. LOCATION OF GOODS-CODE(S)/NAME(S)<br>(b) (4) |                                  |
| 15. VESSEL CODE/NAME  |                                     |  |                                  |
| 16. U.S. PORT OF UNLADING<br>2720   | 17. MANIFEST NUMBER                 | 18. G.O. NUMBER                                  | 19. TOTAL VALUE<br>(b) (4)       |
| 20. DESCRIPTION OF MERCHANDISE<br>ATOMIZER DEVICE   |                                     |  |                                  |
| 21. IT/BL/AWB CODE<br>H   | 22. IT/BL/AWB NO.<br>(b) (4)        | 23. MANIFEST QUANTITY<br>(b) (4)                 | 24. H.S. NUMBER<br>(b) (4)       |
|   |                                     |  |                                  |
|   |                                     |  |                                  |
|   |                                     |  |                                  |
|   |                                     |  |                                  |

**27. CERTIFICATION**

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

**SIGNATURE OF APPLICANT**X  
(b) (4)PHONE NO  
(b) (4)DATE  
10/16/200829. BROKER OR OTHER GOVT. AGENCY USE  
EXAM SITE: 2428 E LINE: 2428

MAILING FACILITY \*\*\*\*\*

**28. CBP USE ONLY** OTHER AGENCY ACTION REQUIRED, NAMELY: CBP EXAMINATION REQUIRED. ENTRY REJECTED, BECAUSE:

|                      |           |      |
|----------------------|-----------|------|
| DELIVERY AUTHORIZED: | SIGNATURE | DATE |
|----------------------|-----------|------|

DET 000121

Paperwork Reduction Act Notice: This information is to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary. The estimated average burden associated with this collection of information is 15 minutes per respondent depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to Bureau of Customs and Border Protection, Information Services Branch, Washington, DC 20229, and to the Office of Management and Budget, Paperwork Reduction Project (1651-0024), Washington, DC 20503.

## ENTRY/IMMEDIATE DELIVERY

(b) (4)

FOIA

CST # 744

19 CFR 142.3, 142.16, 142.22, 142.24 \*\*\* ABI CERTIFIED \*\*\*

|   |                                     |  |                                  |
|---|-------------------------------------|--|----------------------------------|
| 1. ARRIVAL DATE<br>092808   | 2. ELECTED ENTRY DATE<br>101608     | 3. ENTRY TYPE CODE/NAME<br>01                    | 4. ENTRY NUMBER<br>D07-1112224-5 |
| 5. PORT<br>2720   | 6. SINGLE TRANS. BOND<br>3458       | 7. BROKER/IMPORTER FILE NUMBER<br>S8-07975       |                                  |
|   | 8. CONSIGNEE NUMBER<br>80-020570700 |  | 9. IMPORTER NUMBER<br>SAME       |
| 10. ULTIMATE CONSIGNEE NAME<br>SMOKING EVERYWHERE LLC<br>4500 N RIBAUT RD<br>SUNRISE, FL 33351-7984 |                                     | 11. IMPORTER OF RECORD NAME<br>SAME              |                                  |
| 12. CARRIER CODE<br>CE  | 13. VOYAGE/FLIGHT/TRIP<br>884       | 14. LOCATION OF GOODS-CODE(S)/NAME(S)<br>(b) (4) |                                  |
| 15. VESSEL CODE/NAME  |                                     |  |                                  |
| 16. U.S. PORT OF UNLADING<br>2720   | 17. MANIFEST NUMBER                 | 18. G.O. NUMBER                                  | 19. TOTAL VALUE<br>(b) (4)       |
| 20. DESCRIPTION OF MERCHANDISE<br>ATOMIZER DEVICE   |                                     |  |                                  |
| 21. ITIS/AWB CODE<br>H  | 22. IT/BL/AWB NO.<br>(b) (4)        | 23. MANIFEST QUANTITY<br>(b) (4)                 | 24. H.S. NUMBER<br>(b) (4)       |
|   |                                     |  | 25. MANUFACTURER<br>(b) (4)      |
|   |                                     |  | 26. MANUFACTURER NO.<br>(b) (4)  |
|   |                                     |  |                                  |
|   |                                     |  |                                  |
|   |                                     |  |                                  |

## 27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT

**X**  
(b) (4)PHONE NO.  
(b) (4)

DATE

10/16/2008

29. BROKER OR OTHER GOVT. AGENCY USE  
EXAM SITE: 12428 E LRNS: 2428

## 28. CBP USE ONLY

 OTHER AGENCY ACTION REQUIRED, NAMELY: CBP EXAMINATION REQUIRED. ENTRY REJECTED, BECAUSE:

|                      |           |      |
|----------------------|-----------|------|
| DELIVERY AUTHORIZED: | SIGNATURE | DATE |
|----------------------|-----------|------|

DET 000122

FEBRUARY 177

U.S. DEPARTMENT OF HOMELAND SECURITY  
Bureau of Customs and Border ProtectionForm Approved  
OMB No. 1651-0024**ENTRY/IMMEDIATE DELIVERY**

(b) (4)

FDA

CST # 744

19 CFR 142.3, 142.16, 142.22, 142.24 \*\*\* ABI CERTIFIED \*\*\*

|  |                                     |  |                                  |
|--|-------------------------------------|--|----------------------------------|
| 1. ARRIVAL DATE<br>092808  | 2. ELECTED ENTRY DATE<br>101608     | 3. ENTRY TYPE CODE/NAME<br>01                    | 4. ENTRY NUMBER<br>D07-1112224-5 |
| 5. PORT<br>2720  | 6. SINGLE TRANS. BOND<br>X 458      | 7. BROKER/IMPORTER FILE NUMBER<br>S8-07975       |                                  |
|  | 8. CONSIGNEE NUMBER<br>89-020570700 |  | 9. IMPORTER NUMBER<br>SAME       |
| 10. ULTIMATE CONSIGNEE NAME<br>SMOKING EVERYWHERE LLC<br>4500 N RIBATIS RD<br>SUNRISE, FL 33351-3984 |                                     | 11. IMPORTER OF RECORD NAME<br>SAME              |                                  |
| 12. CARRIER CODE<br>CX   | 13. VOYAGE/FLIGHT/TRIP<br>884       | 14. LOCATION OF GOODS-CODE(S)/NAME(S)<br>(b) (4) |                                  |
| 15. VESSEL CODE/NAME   |                                     |  |                                  |
| 16. U.S. PORT OF UNLADING<br>2720  | 17. MANIFEST NUMBER                 | 18. G.O. NUMBER                                  | 19. TOTAL VALUE<br>(b) (4)       |
| 20. DESCRIPTION OF MERCHANDISE<br>ATOMIZER DEVICE  |                                     |  |                                  |
| 21. IT/BL/AWB CODE<br>H  | 22. IT/BL/AWB NO.<br>(b) (4)        | 23. MANIFEST QUANTITY<br>(b) (4)                 | 24. H.S. NUMBER<br>(b) (4)       |
|  |                                     |  |                                  |
|  |                                     |  |                                  |
|  |                                     |  |                                  |
|  |                                     |  |                                  |

**27. CERTIFICATION**

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT

X (b) (4)

PHONE NO.

(b) (4)

DATE

10/16/2008

29. BROKER OR OTHER GOVT. AGENCY USE

EXAM SITE: 2420 E LIMS: 2420

**28. CBP USE ONLY** OTHER AGENCY ACTION REQUIRED, NAMELY: CBP EXAMINATION REQUIRED. ENTRY REJECTED, BECAUSE:

|                      |           |      |
|----------------------|-----------|------|
| DELIVERY AUTHORIZED: | SIGNATURE | DATE |
|----------------------|-----------|------|

DET 000123

Paperwork Reduction Act Notice: This information is to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary. The estimated average burden associated with this collection of information is 15 minutes per respondent depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to Bureau of Customs and Border Protection, Information Services Branch, Washington, DC 20229, and to the Office of Management and Budget, Paperwork Reduction Project (1651-0024), Washington, DC 20503.

# **Smoking Everywhere, LLC**

**4500 North Hiatus Road, Suite 215**

**Sunrise, FL 33351**

**954-675-8400**

---

To whom it may concern,

Here is a brief description on atomizer device:

The Atomizer device is driven by modern microelectronic technology, a small rechargeable battery and a unique, safe replaceable cartridge containing water, propylene glycol, nicotine or non-nicotine (depending on cartridges), a scent and other flavorings.

Any questions, please feel free to contact me anytime.

Regards,  
Encko Taieb  
Smoking Everywhere, LLC

*Fax P*

(b) (6)



DET 000124

**Manufacturer****Original**

(b) (4)

**INVOICE** NO1166374 IN date september 26 2008

| Consignee |   |
|-----------|---|
| Attn      | Contact Name: Mr elicko taieb<br>Company: Smoking Everywhere, LLC.<br>Address: 4500 North Hiatus Road, Suite 215, Sunrise, Florida, 33351 USA<br>Country/Region: United States<br>Business Email: elicko@yahoo.com<br>Telephone: 954-675-8400 |

Terms of Delivery: FOB Shenzhen

Means of Transportation: By Air

Shipping time :4-5days

Payment Term : TT

Shipping cost : prepaid

Per FDA  
 9018.90.8000  
 FDA# 80 M-SN

| Order detail         |  |                         |               |            |     |
|----------------------|--|-------------------------|---------------|------------|-----|
| Quantity<br>Unit No. | Description                                  | Country<br>of<br>Origin | Unit<br>Value | Sub. Value |     |
| (b) (4)              | Atomizer device for 808<br>HTS# 8419.89.0500 | CHINA                   | (b) (4)       | (b) (4)    | B✓  |
|                      | Shipping cost                                |                         |               | (b) (4)    | NDC |
| Totally              |  |                         | (USD)         | (b) (4)    | IN  |

Go EN  
 HKHON Bro 610 HON

DET 000125

(b) (4)

DET 000126

(b) (4)

## Full Manifest

MAWB: 12086317094

(Total for Master)

Origin: HKG

Flight: CX084

Date: 02/28/2008

Total Houses: 3

Total Value: 12,516.44

Total MBags: 3

Total Boxes: 18

Total Weight: 738.00

(Totals by Entity Type)

Entity Type: 0) Formal

Total Houses: (b) (4)

Total Pieces:

INBOUND MANIFEST FINAL

Total Value: (b) (4)

Total MBags: (b) (4)

Total Weight: 738.00

HAWB: 027732145

PCS: (b) (4)

WGT: 62.000

VALUE: (b) (4)

DESC: BEDS

HTS:

BAG #: D7359697

FILE #: LS0804817

SH. ORIG: CNJ

SHIPPER: (b) (4)

CN. DEST:BQ4

CONSIGNEE: (b) (4)

(b) (4)

HAWB: 467496450

PCS: (b) (4)

WGT: 291.000

VALUE: (b) (4)

DESC: ATOMIZER DERICE

HTS:

BAG #: W1799733

FILE #: LS0804818

SH. ORIG: CXO

SHIPPER: (b) (4)

CN. DEST:MIA

CONSIGNEE:SMOKING EVERYWHERE LLC

4500 NORTH HIATYS RD SUITE 215

SUNRISE, FL 33304

(b) (4)

HAWB: 655634018

PCS: (b) (4)

WGT: 385.000

VALUE: (b) (4)

DESC: PLASTIC TOY SAMPLES

HTS:

BAG #: D7246663

FILE #: LS0804816

SH. ORIG: HKG

SHIPPER: (b) (4)

CN. DEST:LAX

CONSIGNEE: (b) (4)

(b) (4)

FDA OASIS v5.6.01 Web Application . Production - WebUtil - Microsoft Internet Explorer

Window Line Details

**Line Information**

Entry No: DO7-111224-S Importer of Record: Smoking Everywhere Lic, 4500 N Hiatus Rd Ste 215, Fort Lauderdale, FL  
Doc-Line#: [REDACTED] Suffix: [REDACTED] HTS: 2018906000

**Date Available Information**

Expected: 09-28-2008 Actual: [REDACTED] Storage status: [REDACTED]

**Product Information**

Product Code: 80 [REDACTED] M [REDACTED] SN Country of Origin: China  
Product Code Desc: Cigarettes (containing Tobacco)  
Importer Desc: ATOMIZER DEVICE  
Corrected Desc: Electronic Cigarette E-Cigarette Kit  
Brand Name: SMOKING EVERYWHERE E-Cigarette Package/ Can Codes: www.SmokingEverywhere.com  
Quantity: (b) (4) [REDACTED]  
Value of Goods: (b) (4) A of C [REDACTED]

**Firm Information**

Manufacturer: (b) (4) [REDACTED] SA  
Shipper: [REDACTED] SB  
Consignee: 3007162091 Smoking Everywhere Lic, 4500 N Hiatus Rd Ste 215, Fort Lauderdale, FL SC

Trans\Cont Id's: [REDACTED]  
Location of Goods: (b) (4) [REDACTED]

View Update Cancel

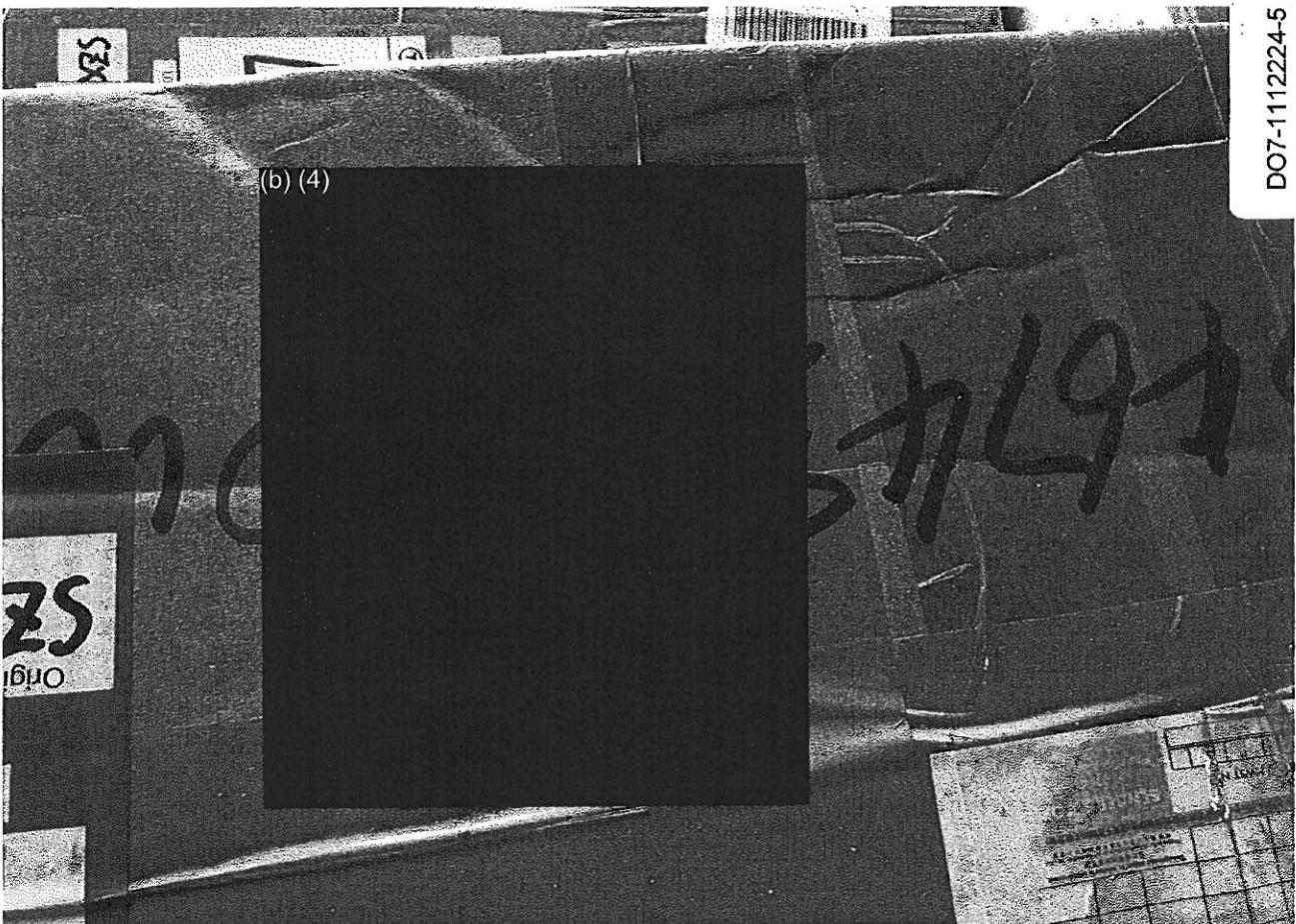
Print  
Help  
Entry Details

Start... | Inbox - Microsoft Out... | 3 Internet Explorer | 1 G-General.doc - Microsoft Word | 3:20 PM



DO7-1112224-5 JM 10/21/08

Top: View of Master Cartons  
Bottom: Master AWB Label

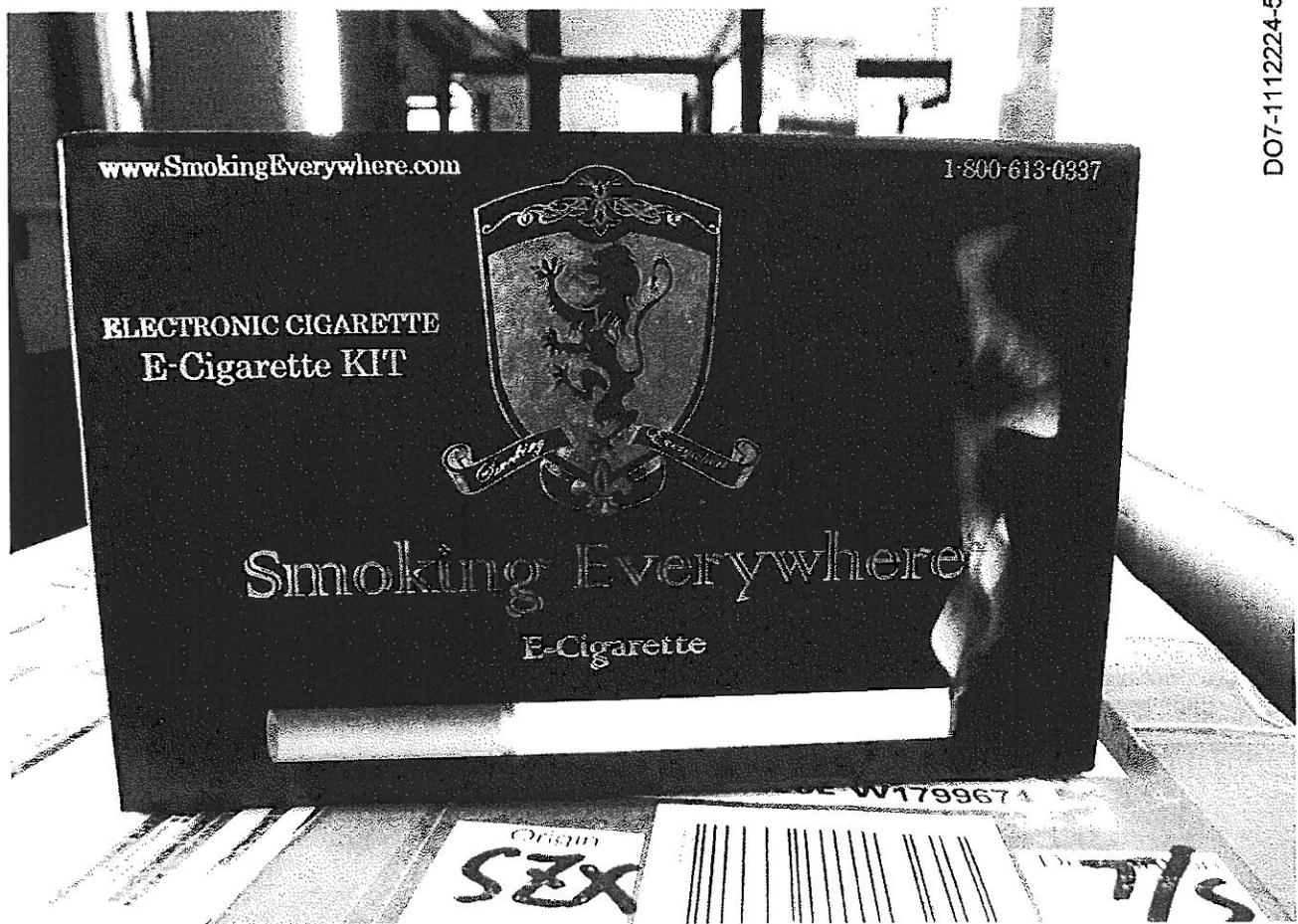


DET 000129



DO7-1112224-5 JM 10/21/08

Top - View of open carton  
Bottom - View of top of Kit



DET 000130

[www.SmokingEverywhere.com](http://www.SmokingEverywhere.com)

1-800-613-0337



Smoking Everywhere™  
E-Cigarette

E-Cigarette Kit Includes:  
Electronic Cigarette  
2 Rechargeable Batteries  
Main Charger  
Power Lead (US Plug)  
5 Cartridges



DOT-1112224-5 JM 10/21/08

Top - View of bottom of Kit  
Bottom - View of sides of Kit



DET 000131



DO7-111224-5 JM 10/21/08

Top - Open view of Kit  
Bottom - Contents of Kit



DET 000132



DO7-112224-5 JM 10/21/08



Top - Cartridges  
Bottom - Charger

DET000133



DET-1112224-5 JM 10/21/08

Top - Power cord.

DET 000134