Supplements & Regulation
CWAG 2017

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USP Labs – OxyElite Pro – a crime story

USP Labs
1) Illegal ingredient(s)
2) Falsified paperwork
3) Ignored FDA regulations

Criminal Charges
• Obstruction of a FDA proceeding
• Conspiracy to commit money laundering
• Agents seized assets; investment accounts, real estate, and expensive cars
• CEO had previous criminal convictions and went to jail
Supplement Industry Welcomes Enforcement

- Industry shares the goal of stopping illegal activity that puts consumers at risk and damages the reputation of legitimate companies

- Consumer protection is a top industry priority
  - Companies that ignore laws and regulations put consumers at risk

- The supplement industry welcomes collaboration with federal, state, and local agencies to protect consumers
  - Companies that invest resources into safety and compliance are damaged by companies that ignore laws – loss of consumer trust and risk of increased regulations
Dietary Supplements are Mainstream
Used by over 170 million Americans

Nutrient Gaps
2015 Dietary Guidelines:
• Ca, Mg, and vitamins A, D, E, and C intake is below recommended levels
• Iron is under-consumed by many women
• Ca and vitamin D are “nutrients of public health concern” because low intakes associated with health concerns
• B12, protein, omega-3 fatty acids

Healthy Pregnancy
• USPSTF recommends that all women planning or capable of becoming pregnant take a daily supplement containing 400 – 800 mcg of folic acid
• Several leading medical authorities recommend that all pregnant and lactating women take a daily supplement that contains 150 mcg of iodine daily
Economic Impact of the Industry

• Study commissioned by CRN
• Examines direct, indirect & induced effects
• $122 billion; 750,000 jobs, $38 billion in wages
• Available at www.crnusa.org/economicimpact
Federal Regulations

- **Dietary supplements are extensively regulated by FDA**
  e.g., cGMP regulations/inspections, Adverse Event Reporting, “Supplement Facts” labeling, claims requirements, NDI notifications, FSMA registration, etc.

- **Advertising claims are regulated by the FTC**
  All advertising must be “truthful, not misleading and substantiated with credible and reliable scientific evidence”

- **FDA and FTC have a variety of enforcement tools available to compel compliance**
  (seizures, recalls, detentions, injunctions, civil & criminal actions)
Regulation is a Four-Legged Stool

1. Ingredient Safety
Ingredients are safe ODI, NDI, GRAS

2. Manufacturing Controls
Product is manufactured in a manner that assures quality – FDA, cGMPs

3. Claims Evaluation
Ingredients are effective; i.e., the product does what the marketer says it will do

4. Post-Market Surveillance
Monitoring the product in the marketplace – 2006 AER law
Industry Self-Regulation

1. Ingredient Safety
   Voluntary Guidelines

2. Manufacturing Controls
   Third Party Certifications

3. Claims Evaluation
   NAD Advertising Review Program

4. Post-Market Surveillance
   Industry supported 2006 Mandatory Adverse Event Reporting Law
Industry Supports Regulation and Enforcement

Mandatory Adverse Event Reporting Law - 2006

Designer Anabolic Steroid Control Act 2014

Industry Self-Regulation
The Supplement OWL™ Online Wellness Library

A single authoritative registry of dietary supplement product information where all stakeholders can find information about products, ingredients, and additional quality and safety information.

Fortune favors the OWL.

The Supplement OWL is now accepting labels.

Submit your product labels and help create a more complete picture of the marketplace.

LEARN MORE:
www.SupplementOWL.org
Example of Chewable Vitamin C on search results page

Tier 2 feature. Only visible to users that manufacturer provides access. This can be, a single person, multiple people, a company, and/or an entire persona such as retailers. Users without access would only see General Information.
### Nutritional Product Facts Per Serving

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories 10</td>
<td></td>
</tr>
<tr>
<td>Sodium (as Sodium Ascorbate) 5mg</td>
<td>1%</td>
</tr>
<tr>
<td>Total Carbohydrates 2g</td>
<td>1%</td>
</tr>
<tr>
<td>Vitamin C (as Ascorbic Acid, Calcium Ascorbate, Sodium Ascorbate, Rose Hips (Fruit), Acerola Berry Extract 4:1) 500mg</td>
<td>833%</td>
</tr>
<tr>
<td>Citrus Bioflavonoids Complex Blend (Providing: Orange Peel Powder, Lemon Bioflavonoids (Peel), Turmeric Extract (Rhizome), Grape Seed Extract (Seed), Orange Bioflavonoids (Peel), Grapefruit Bioflavonoids (Peel), Rutin (from Sophora Japonica Linnae) (Flower), Hesperidin (from Orange, Lemon, Grapefruit) (Péel) 20mg</td>
<td></td>
</tr>
</tbody>
</table>

The information presented here was acquired by UL from the producer of the material. UL makes substantial efforts to assure the accuracy of this data. However, UL assumes no responsibility for the data values and strongly encourages that upon final material selection data points are validated with the material supplier.
Summary

• The supplement industry shares concerns about illegal activity that puts consumers at risk and damages the reputation of responsible industry
  • Responsible industry supports full enforcement of laws and regulations
• Industry invests in self-regulatory programs to increase compliance, improve transparency and to protect consumers
• Responsible industry welcomes further dialogue and collaboration with states to protect consumers from non-compliant companies and products
Thank You!

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