Drugs and Distilleries

A practical approach to compliance
Making and Selling Hand Sanitizers

Janet Winter Blaschke, CEO
ICRS, LLC
Practical Approach

• Formulator of products
• Current with FDA’s real priorities
• Veteran of dozens of FDA inspections, US and overseas
• Simplification from an Operations point of view
Things you do know......

• Hand Sanitizers are OTC Drugs
• Regulated by FDA just like other OTCs (Advil, Robitussin)
• Temporary allowance for production and sale of WHO formula
• FDA registration is required, even for temporary production
What you may not know.......
You used an OTC drug this morning

- Fluoride toothpaste
- Anti-perspirant
- Any SPF product
- Acne product
FDA is not necessarily FDA

• FDA has a number of divisions, all independent
  • CFSAN- food, cosmetics, and colors
  • CDRH- Radiologic devices
  • CBER- Biologics
  • CVM- Veterinary products
  • CTP- Tobacco
  • CDER- Drugs

• And of course others:
  • CPSC, FTC, OSHA, etc.
Registration can be ridiculous

• Origin is outside of OTCs
• Not intuitive
• Currently evolving
• Far too much effort for its purpose
The famous WHO formula

• No fragrance additions
• No botanical additions (Aloe vera, etc.)
• Potential to change proven formula effectiveness
• Changes possible, but need additional requirements
  • Stability 3-6 month testing
• Chances of “minor” changes enforcement
• WHO doesn’t address FDA requirements
Product donation vs. Product sale

• Good news in current times
• OTCs not offered for sale still need compliance
• Careful understanding what is exempt and what is not.
<table>
<thead>
<tr>
<th>What does FDA expect?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formula (WHO only)</strong></td>
</tr>
<tr>
<td><strong>Labeling (WHO only)</strong></td>
</tr>
<tr>
<td><strong>Good Manufacturing Practices</strong></td>
</tr>
<tr>
<td><strong>Facility and Product registration</strong></td>
</tr>
<tr>
<td><strong>Raw Material quality requirements</strong></td>
</tr>
</tbody>
</table>
Good Manufacturing Practices

• Code of Federal Regulations 21 CFR part 211
• Product Safety- and Effectiveness-focused
• Not prescriptive
• Templates are more work than needed
• Work with existing processes and documents, then augment
• Shelf life of product
Manufacturing Relationships

• Contract Manufacturer/Third Party Manufacturers’ obligations
• Both manufacturer and brand owner have responsibilities
• Partnership must be made clear to FDA in audit
• Alcohol suppliers must be registered
• Supplier Quality Agreement is an important new focus
Small or large company?

• ALL companies have the same obligations for OTCs
• Equally predominant on FDA list for audit
• Facility license allows Drug production, inspected as such.
• Typical FDA OTC inspection is five days
Quick in, quick out is not an exemption

- Expected product life is in distribution, on the shelf, and in the hands of the consumer
- FDA ultimately decides enforceability
- Enforcement already happening
- Considered a producer in the future
Consequences can be unexpected

- First infraction is not a “pass”
- FDA currently phone auditing documents - open door
- 48 hour response to FDA if cited
- Emergency injunction
- Facility registration is visibility with FDA
FDA looks in unexpected places for enforcement

- Websites/Internet
- Instagram/Twitter
- Press Releases
- Label compliance
- Shelf checks
- Consumers “Report a Website”
One audit doesn’t avoid another

• An inspection of another Agency (e.g., TTB) will not fulfill an OTC inspection
• A State inspections can also be performed for OTCs
• One audit can trigger another of a different kind
Enforcement and What’s ahead

• Current enforcement
  • “Failure to immediately correct the violations cited...may result in legal action, including, without limitation, seizure and injunction.”
  • Labeling
  • Claims, ingredients: What is an “Unapproved New Drug”

• Deadline extension?
  • Moving target
  • Likely dependent upon events
It’s not really unsurmountable

• Not difficult to do with practical knowledge and approach
• Longer term- expanding claims- % effectiveness
• Cheaper and easier to commit to GMPs at the onset
• Start now, don’t worry later.
Thank you

Janet Winter
ICRS, LLC
Manhattan Beach, CA / London / Dublin
www.icrsregulatory.com
310.545.3223