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Drugs and Distilleries

A practical approach to compliance

Making and Selling Hand Sanitizers

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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

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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

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What you may not know…….

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You used an OTC drug this morning

- Fluoride toothpaste
- Anti-perspirant
- Any SPF product
- Acne product

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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.

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Registration can be ridiculous

- Origin is outside of OTCs
- Not intuitive
- Currently evolving
- Far too much effort for its purpose

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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

World Health Organization

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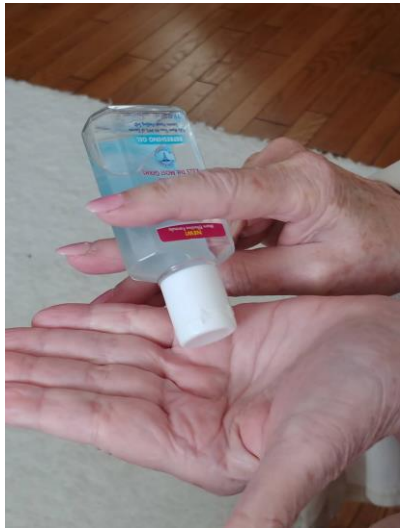
Product donation vs. Product sale

- Good news in current times
- OTCs not offered for sale still need compliance
- Careful understanding what is exempt and what is not.



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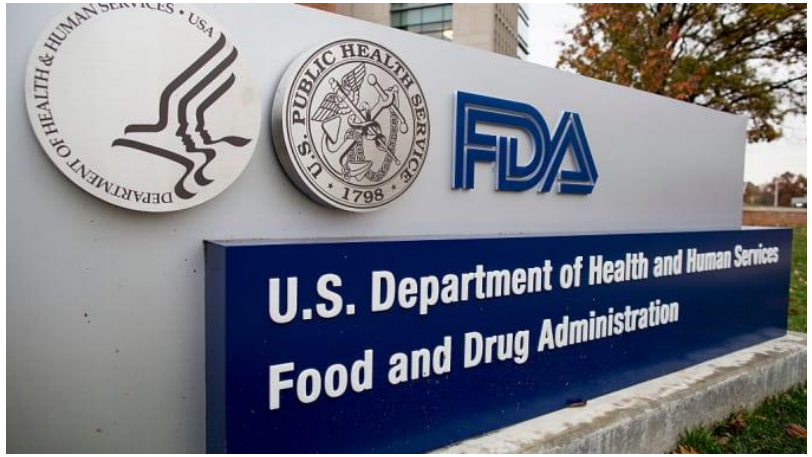
What does FDA expect?

Formula (WHO only)	Exempt from stability testing
Labeling (WHO only)	Exempt
Good Manufacturing Practices	Not covered by exemption, 21 CFR 211
Facility and Product registration	Not exempt
Raw Material quality requirements	Not exempt



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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

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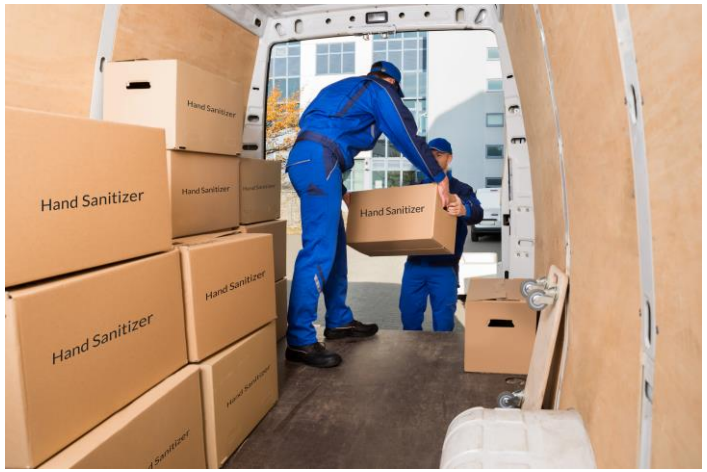
Manufacturing Relationships

- 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



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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

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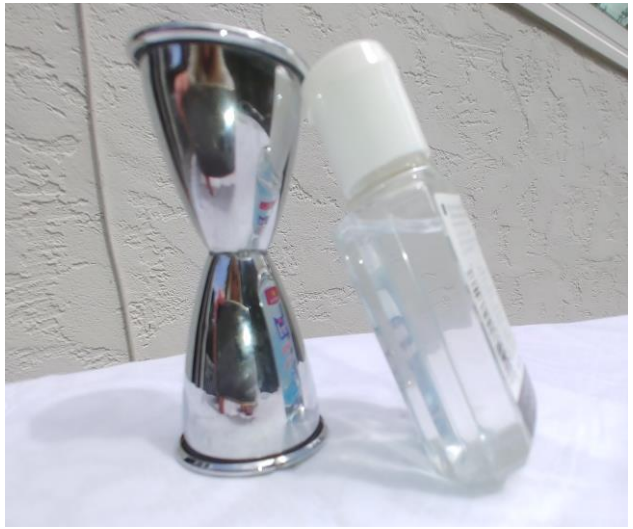
Quick in, quick out is not an exemption

- 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



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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

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FDA looks in unexpected places for enforcement

- Websites/Internet
- Instagram/Twitter
- Press Releases
- Label compliance
- Shelf checks
- Consumers“Report a Website”

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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

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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

FDA
CDRH
CDER Enforcement
CBER

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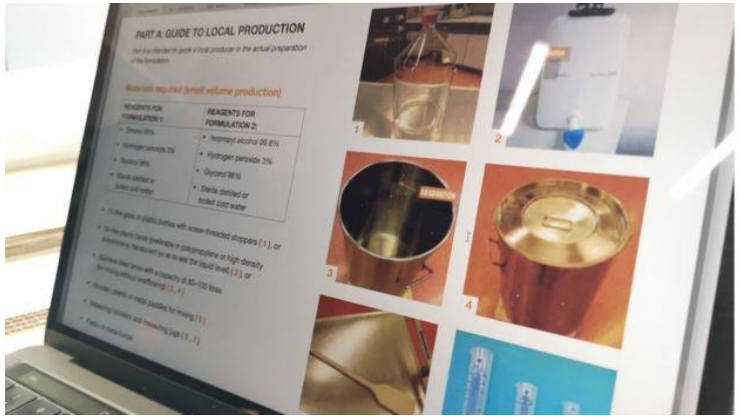
It’s not really unsurmountable

- 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.



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Thank you

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