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# Ensuring Quality Hand Sanitizer Production During COVID-19 Seminar

## Labeling: Ensuring Quality During Hand Sanitizer's Journey

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# Labels are Essential for Product Identification



“Labels are fundamental to material identification... Labels applied, even to small containers, should be clear, indelible, unambiguous, and permanently fixed in the format established by the manufacturer, packager, or repackager.”

General Chapter <1079> *Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products*



# Labeling - Definitions



## Labeling

“The term ‘labeling’ includes all labels and other written, printed, or graphic matter on an article’s immediate container or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container.”

General Chapter <7> *Labeling*

## Label

“The term ‘label’ is that part of the labeling on the immediate container.”

General Chapter <7> *Labeling*

# Labeling



<1079> Table 2. Mitigation Strategies Used by Organization within Supply Chain

Applicable Mitigation Strategies	Role of Organization within Supply Chain					
	Manufacturer	Wholesaler and Distributor	Pharmacy or Compounding Pharmacy	Hospital and Healthcare Provider	Broker	Logistics Service Provider (LSP)
<b>Documentation (Manuals, Procedures, Protocols, Records)</b>						
Quality manual	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	Yes	Yes	Yes	No	Yes
Procurement	Yes	Yes	Yes	Yes	Yes	Yes
Receiving	Yes	Yes	Yes	Yes	No	Yes

# Labeling - Receiving Hand Sanitizer Ingredients



- ▶ Labels of hand sanitizer ingredients should align with current FDA requirements detailed in FDA guidances

<b>Manufacturing</b>	<b>Compounding</b>
<i>Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry</i>	<i>Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry</i>
<i><u>Alcohol labels:</u> Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)</i>	

- ▶ Specific details such as concentration and grade (e.g., USP, FCC) clearly stated on label and should be confirmed upon receipt

## Receiving Hand Sanitizer Ingredients

- ▶ USP designation indicates that the product meets a specific *USP-NF* monograph
  1. specific monograph name on label and
  2. any additional labeling requirements described in the specific monograph.

Example: **ISOPROPYL ALCOHOL (IPA) 99%, USP**

# Labeling - Compounding Hand Sanitizer



- ▶ “...expectation is that compounders follow USP General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations*, including:
  - The preparation to be appropriately labeled”<sup>1</sup>
- ▶ Follow specific labeling requirements according to the formulation

Formulation 1:	Formulations 2 and 3:
For external use only	For external use only
Percentage/concentration of ethanol	Percentage/concentration of isopropyl alcohol
Beyond-Use Date	Beyond-Use Date

**Principal display panel and drug facts label examples**  
located in the Appendices of FDA Guidance document\*

- **Appendix A.** Labeling for Ethyl Alcohol Formulation Consumer Use
- **Appendix B.** Labeling for Isopropyl Alcohol Formulation Consumer Use
- **Appendix C.** Labeling for Ethyl Alcohol Formulation Health Care Personnel Hand Rub Use
- **Appendix D.** Labeling for Isopropyl Alcohol Formulation Health Care Personnel Hand Rub Use

*\*Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry*



# Labeling - Shipping of Hand Sanitizer



## Outer Shipping Container

- ▶ Product identification
- ▶ Lot number
- ▶ Wording or icons to emphasize:
  - Storage and transportation conditions
  - Handling requirements
  - Hazards



# Labeling



**Ensure labeling documentation** according to the organization's role in preparation of hand sanitizers.

<1079> Table 2. Mitigation Strategies Used by Organization within Supply Chain

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	Manufacturer	Wholesaler and Distributor	Pharmacy or Compounding Pharmacy	Hospital and Healthcare Provider	Broker	Logistics Service Provider (LSP)
	<b>Documentation (Manuals, Procedures, Protocols, Records)</b>					
Quality manual	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	Yes	Yes	Yes	No	Yes

# Thank You



**Empowering a healthy tomorrow**