

UNDERSTAND BETTER: Making and Selling Hand Sanitizers For The U.S. Market

How NSF International's Health Sciences Team Can Help



U.S. FDA facility registrations and product listings



Facility audits to ensure compliance with drug GMPs and quality systems

Consulting services* that include:

Filling in and remediating audit gaps so your facility is in FDA compliance

Preparing and training staff on how to best manage the FDA inspection process

Advising on formulations and drug GMPs

Certifying your facility to the OTC drug standard NSF/ANSI 455

Acting as your U.S. agent (if you are a non-U.S. company)



To make and sell hand sanitizers in the U.S., your products must:

- Follow OTC drug monographs and other temporary policies put in place by the FDA (items of interest to the FDA include formulations and active ingredients)
- Use United States Pharmacopeia (USP)-grade materials
- Meet purity requirements for ingredients (confirmed by analytical testing)
- Follow FDA drug fact paneling requirements for OTC drug labels
- Be listed with the FDA and have a National Drug Code (NDC) number

Alcohol-based hand sanitizers are considered over-the-counter (OTC) drugs by the U.S. FDA.

In Addition

- Your establishment must be registered as a drug facility with the FDA.
- Your facility needs to comply with Good Manufacturing Practices (GMPs) for drugs and other applicable quality systems.
- Non-U.S. companies must be represented by a U.S. agent.



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How NSF International's Nonfood Compounds Team Can Help



Third-party verification that your product is suitable for use in food handling facilities



Ingredients validation to applicable FDA guidelines



Almost any non-consulting work related to food safety

Benefits include:

Tracing products via literature reviews and supplier source

Increased regulatory and end user acceptance in global food markets

Greater product exposure around the world

Use of the instantly recognized NSF registration mark

An online public listing in the NSF White Book™

*Use of NSF consulting services does not provide an advantage, nor is it linked in any way to the granting of certification.