FDA takes action against subpotent and methanol-contaminated hand sanitizers

Isabelle Bibet-Kalinyak, Arielle J. Lester | Wednesday, August 5, 2020

Beginning in March 2020, the U.S. Food and Drug Administration (FDA) provided temporary policies for the production of alcohol-based sanitizers to ensure access for clinical and public use during the coronavirus (COVID-19) public health emergency. Recently, the FDA has increased its monitoring due to many hand sanitizer products failing to meet the guidelines under the temporary policies and the presence of contaminants in violation of the Food Drug and Cosmetic Act (21 U.S.C. §§ 331(a)(d), 351(a-d), 352(a)(e)(j), 355(a)).

On July 2, 2020, the FDA issued its first warning to consumers against the use of hand sanitizers containing methanol. The FDA reported an increase in hand sanitizers labeled as containing ethanol, a common sanitizer ingredient, that also tested positive for varying amounts of methanol, a wood alcohol toxic to humans.

On July 27, 2020, the FDA expanded and reiterated its previous warnings to emphasize the many adverse effects that could occur to young children, adolescents, and adults if hand sanitizers containing methanol are absorbed through the skin or ingested:

- Death
- Hospitalizations
- Blindness
- Seizures

- Coma
- Adverse cardiac effects
- Adverse central nervous system effects
- Nausea
- Vomiting
- Headache

Most recently, the FDA released a statement regarding hand sanitizers which have been tested to show low levels of ethyl or isopropyl alcohol, which are essential active ingredients and necessary for effectiveness. These subpotent hand sanitizers have been added to a do-not-use list in addition to hand sanitizers that are or may also be contaminated with methanol.

As a result of the high risk for adverse effects in both children and adults, the FDA has taken several steps to prevent public harm:

1. Warning letters to certain manufacturers to cease distribution of their products
2. Recalls to remove certain hand sanitizers from stores
3. Import alert banning certain hand sanitizers from entering the market
4. Do-not-use list of dangerous subpotent and methanol-contaminated hand sanitizers
5. Q&A for consumers regarding hand sanitizers

Currently, **115 hand sanitizers are on the FDA's do-not-use dangerous product list.** To verify a sanitizer is not on the list, consumers and healthcare providers should check for several identifiers: the manufacturer's name, the product name, and the National Drug Code number. The FDA advises that if any of these identifiers match a product from the FDA's do-not-use dangerous product list, individuals should immediately stop using the hand sanitizer and dispose of it, if possible, in a hazardous waste container. If contact or ingestion occurred, the FDA urges consumers to seek immediate medical attention. Consumers and healthcare providers may also report any Adverse Events from use of suspected hand sanitizers on the FDA's website.

When purchasing or using hand sanitizer, the FDA has provided additional warning indications:

- Products with labels containing methanol as an ingredient (although generally not listed)
- **Products fraudulently marketed as "FDA-approved" (no sanitizers are FDA-approved)**
- **Products for sale with false, misleading, or unproven claims to prevent COVID-19 or prolonged protection (e.g., up to 24 hours)**
- Products with labels showing insufficient amounts of ethyl alcohol. Although The Centers for Disease Control and Prevention (CDC) recommends at least 60%, the FDA recommends 94.9% or as an alternative, USP grade isopropyl alcohol.

> Given the gravity of the FDA's warnings and the potential for harm, including, but not limited to, death and hospitalization, healthcare providers, employers, and consumers should survey their inventory of hand sanitizer and be cautious to check both the ingredient label and manufacturing information of any sanitizer products they are using, sharing, providing for professional or other use, or placing in public spaces and common areas.

Consumers, healthcare providers, or distributors who have questions for the FDA regarding hand sanitizers should email COVID-19-Hand-Sanitizers@fda.hhs.gov.

For additional information regarding this developing matter, please contact the attorneys below.

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