

News From the Food and Drug Administration

Quality Issues Prompt Guidelines for Compounded Drug Pharmacies

Citing persistent quality issues at compounding facilities since a deadly 2012 national fungal meningitis outbreak, the FDA issued [final guidance](#) to help prevent contamination of compounded drug products.

The document identifies 55 conditions the FDA deems insanitary, including 11 that it said warrant an immediate recall of purportedly sterile products. Particularly serious problems include rodents, visible mold, or loose ceiling tiles in cleanroom areas.

The FDA suggested that facilities undergo a risk assessment, immediately evaluate how the safety issues affect products, and correct problems regardless of whether drugs pass a sterility test. In the case of a recall, facilities should notify both the FDA and regulators in states where products are shipped.

The guidance is also intended to advise state boards of pharmacy, which oversee compounding pharmacies that are not [registered with the FDA](#) and therefore not subject to the agency's routine inspections.

In 2013 [Congress amended](#) the Federal Food, Drug, and Cosmetic Act to address safety at compounding facilities, which make customized drug products, following a fungal meningitis outbreak that resulted from tainted injectable steroids produced at a Massachusetts plant. The outbreak caused [753 infections and 64 deaths](#) across 20 states.

The FDA [reported](#) in 2017 that it had inspected some 350 compounding facilities and issued more than 130 warning letters about federal violations. Investigators continue to observe problems such as dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters, the FDA said in a [statement](#).

Sesame Should Be on Food Labels to Warn Consumers With Allergy

The FDA has encouraged manufacturers to include the word "sesame" on ingredient labels whenever it's used as a food flavoring or additive to alert consumers who have a sesame allergy.

New [draft guidance](#) on the matter came 2 years after the agency invited consumers, advocacy groups, health professionals, industry groups, and others to submit data and comments about sesame allergy prevalence and how often it's contained in foods sold in the US. Although sesame isn't among the 8 major food allergens—milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans—that are required by law to be identified on food labels, the FDA noted that sesame allergy may be increasing in the US. The agency cited surveys showing that an estimated 0.2% of [adults](#) and [children](#) have a sesame allergy.



"Many Americans are allergic or sensitive to sesame, and they need the ability to quickly identify products that might contain sesame," Susan Mayne, PhD, director of the FDA's Center for Food Safety and Applied Nutrition (CFSAN), said in a [statement](#). Although most products containing sesame declare it as an ingredient, Mayne said, it doesn't have to be declared by name when it's used as a flavor or spice. She said some consumers are unaware that tahini, a paste, is made from sesame.

FDA officials said that allergic reactions to sesame can be relatively severe. Public input indicated that reactions such as hives, vomiting, wheezing, and anaphylaxis may occur. In addition to tahini, reports to the CFSAN Adverse Event Reporting System in-

dicated that hummus, halvah, and baba ghanoush were common sources of sesame allergic reactions.

Device Approved for Adults With Nightmare Disorder

A new digital device has received FDA [authorization](#) to provide adults aged 22 years or older with temporary relief from sleep disturbances caused by nightmare disorder or nightmares from [posttraumatic stress disorder \(PTSD\)](#).

Prescription-only NightWare uses an Apple Watch sensor to monitor body movement and heart rate during sleep. A proprietary algorithm creates each patient's individual sleep profile that the watch uses to detect a potential nightmare. Before the nightmare becomes severe, the watch vibrates to interrupt it without awakening the person.

NightWare is intended for use under medical supervision along with prescribed PTSD medications and other recommended therapies, FDA officials said. Patients who have been known to sleepwalk or act out violence during their nightmares should not use the device.

In a 30-day clinical trial, 70 patients were randomized to use the NightWare watch or a nonvibrating sham device. Measures of suicidality and sleepiness showed no changes in either group, according to the FDA. Although both groups had somewhat better sleep quality, those with active devices had greater improvement on the Pittsburgh Sleep Quality Index scale, a self-rated questionnaire for assessing sleep quality.

FDA officials said patients should consult a medical professional if daytime sleepiness or awakening not related to nightmares occurs, or if nightmares persist, worsen, or recur. Users should not wear the watch while reading or watching television in bed, or let the watch come in contact with their bed partner.

It was authorized through the FDA's [De Novo](#) premarket review pathway for new types of low- to moderate-risk devices. — Mary Chris Jaklevic, MSJ

Note: Source references are available through embedded hyperlinks in the article text online.