

# Supplement manufacturers often ignore FDA warning letters

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A considerable proportion of products remain available for purchase

after issuance of U.S. Food and Drug Administration warning letters targeting specific supplement products, according to a research letter published in the July 26 issue of the *Journal of the American Medical Association*.

Pieter A. Cohen, M.D., from Cambridge Health Alliance in Somerville, Massachusetts, and colleagues examined the frequency of drug recalls and presence of FDA-prohibited drugs in supplements after FDA warning letters. Dietary supplement [products](#) that had previously been the subject of an FDA warning letter regarding the presence of the amphetamine analog  $\beta$ -methylphenethylamine, the ephedrine analog methylsynephrine, or the dimethylamylamine analog octodrine were included.

The FDA issued warning letters regarding 31 supplement products. The researchers found that one of these 31 products was recalled by the manufacturer. At a mean of six years following the issue of warning letters, nine of the products (29 percent) remained available for purchase online. Four of these nine products (44 percent) listed the presence of at least one prohibited ingredient on the label: One label declared the prohibited ingredient included in the FDA warning letter and three listed other FDA-prohibited ingredients. Five of the nine products were found to contain at least one FDA-prohibited ingredient after [chemical analysis](#) : Four products contained one prohibited ingredient and one product contained three. Two products contained the ingredient for which the FDA issued the [warning letter](#).

"The FDA should consider ways to ensure that prohibited drugs are removed from [supplements](#), perhaps by testing products sold after warning letters and mandating recalls whenever products remain adulterated," the authors write.

One author disclosed being the subject of a civil suit brought by Hi-Tech

Pharmaceuticals, a supplement company.

**More information:** [Abstract/Full Text \(subscription or payment may be required\)](#)

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