# FDA & FTC Issue Joint Warning Letters to Companies Marketing Products to Overcome Opioid Addiction and Withdrawal

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The FDA & FTC today posted warning letters to 11 marketers and distributors of opioid cessation products, alleging that such products were unapproved new drugs that violated the Federal Food, Drug and Cosmetic Act (FDCA) and that made unsubstantiated, deceptive claims in violation of the FTC Act. In addition to the 11 joint warning letters issued to named marketers and distributors, the FTC issued four additional warning letters to unidentified marketers of similar products. It is not clear why these four marketers were not identified by name or targeted by FDA, although it is possible that they used less egregious claims than those targeted in the 11 joint warning letters.

As to issues under the FDCA, the warning letters allege that the identified products are unapproved new drugs because they are intended to diagnose, cure, mitigate, treat, or prevent disease. The warning letters identify representative claims that render the products "drugs" under the FDCA, including:

- "For temporary relief of cravings, irritability, and inability to concentrate related to the use and over-use of. . . alcohol and narcotics";
- "Support withdrawal relief, effective detox, and lasting recovery from addiction"; and
- "Opiate withdrawal aid supplement."

Because the products are not generally recognized as safe and effective for these marketed "drug" uses, the products constitute unapproved new drugs that violate the FDCA, according to the warning letters. The warning letters further provide that the products are marketed for treatments that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner, and thus would be prescription drugs even if they were recognized as a safe and effective treatment for opiate withdrawal.

Two warning letters targeted products labeled as "homeopathic" under FDA enforcement policies set

forth in FDA's Compliance Policy Guide (CPG), "Conditions Under Which Homeopathic Drugs May be Marketed." While that policy suggests that FDA will exercise enforcement discretion as to certain drug products labeled as "homeopathic" and marketed without FDA approval, the letters state that the CPG acknowledges that special circumstances may apply that supersede that policy. According to the warning letters, the nationwide public health emergency relating to opioid addiction is one such circumstance and thus the enforcement policy does not apply to drugs marketed for opiate addiction. In December 2017, FDA released a draft guidance that proposed a new risk-based enforcement approach to homeopathic drug products marketed without FDA approval that would prioritize regulation and enforcement for products that pose the greatest risk to patients.


As to the FTC Act violations, the warning letters note that health-related claims must be supported by competent and reliable scientific evidence at the time the claims are made. The warning letters point to previous FTC enforcement actions challenging unsupported claims for the treatment of opiate addiction and withdrawal symptoms as evidence that such claims are likely unsubstantiated under the FTC Act.

The warning letters request unique responses to both FTC and FDA within 15 working days and direct the marketers and distributors to explain the steps they are taking to address both FDA and FTC-related concerns.