FDA takes action against marketer of unapproved products claiming to treat addiction, chronic pain and other serious conditions

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Release

The U.S. Food and Drug Administration today posted a warning letter to Nutra Pharma Corp. for illegally marketing unapproved products labeled as homeopathic with claims about their ability to treat addiction and chronic pain, including pain associated with cancer, diabetes, shingles, fibromyalgia and other serious conditions.

“One of our most important obligations is to protect consumers from those who would prey on them with bogus claims and fraudulent products. We’ve dedicated new resources to our enforcement work and I consider these activities the cornerstone of our consumer protection mission and one of our most significant institutional obligations. We’re especially focused on those who would exploit Americans harmed by the opioid crisis with the false promise of products that can treat pain or addiction, but that offer no such benefit,” said FDA Commissioner Scott Gottlieb, M.D. “Today, we posted a warning letter to a company preying on patients who may be seeking alternative treatments for chronic pain, cancers, arthritis and autoimmune and neurological disorders. Health fraud scams like these are inexcusable. These patients deserve proven treatments not false promises that can deter them from seeking otherwise effective care, and that can also contain ingredients or contaminations that can threaten their health. We have great concern for the millions of Americans who live with chronic pain or cancer, and for whom traditional treatment options have been exhausted, as well as those battling opioid addiction. They deserve new advances in care that can address pain without the risk of addiction, not the deception of bogus products that offer no proven benefit. We’ll continue our efforts to protect consumers from such false claims, while also working to advance the development of new treatment options, including non-addictive products for pain management and innovative products for the treatment of opioid use disorder.”

The FDA issued a warning letter to Nutra Pharma for their products: “Nyloxin Oral Spray,” “Nyloxin Topical Gel,” “Nyloxin Topical Roll-On,” “Nyloxin Topical Roll-On ES,” “Nyloxin Professional Size Pump Topical Gel” and “Regular Strength Sample Pack.” These products also may confuse consumers because its name is similar to FDA-approved drugs.

Examples of claims made include:

- "Nyloxin . . . treats conditions that cause chronic pain."
- "[C]obra venom saw its primary use in the treatment of cancer and arthritis. Reportedly the venom was used to treat liver cancer, lung cancer, esophageal cancer, skin cancer, and leukemia."
- "Today, cobra venom is being studied for treating various forms of pain, cancers, autoimmune and neurological disorders."
- "Researchers in China are examining the possibility that cobra venom can be used to treat drug addiction."
- "Treatment of the Cobrotoxin in 90 cases with heroin dependence."

Health fraud scams like these can pose serious health risks. These products have not been demonstrated to be safe or effective and may keep some patients from seeking appropriate, FDA-approved therapies. Selling these unapproved products with claims that they can treat chronic pain is a violation of the Federal Food, Drug, and Cosmetic Act.

In addition to supporting the development of alternatives to opioid analgesics for chronic pain, reducing the number of Americans who are addicted to opioids and cutting the rate of new addiction is one of the Administration's highest priorities. This work includes promoting more widespread innovation and access to medication-assisted treatment (MAT) for the more than 2 million of Americans with an opioid use disorder (OUD). The FDA is taking steps to make safe and effective MAT available to those who suffer from OUD and to reduce the stigma that is sometimes associated with use of these therapies. Using products with unsubstantiated claims may prevent those addicted to opioids from seeking approved treatments that have been demonstrated to be safe and effective, delay their path to recovery and put them at greater risk of death. In fact, patients receiving FDA-approved medication-assisted treatment cut their risk of death from all causes in half, according to the Substance Abuse and Mental Health Services Administration.

The FDA has requested responses from Nutra Pharma within 15 working days. The warning letter also states that failure to correct violations may result in legal action without further notice, including, without limitation, seizure and injunction.

In December 2017 the FDA proposed a risk-based enforcement approach that prioritizes enforcement and regulatory actions involving drug products labeled as homeopathic that have the greatest potential to cause risk to patients. Given the concerns about the proliferation of potentially ineffective and harmful products labeled as homeopathic, the FDA previously stated it would consider taking additional enforcement and/or regulatory actions, consistent with its current compliance policies, in the interest of protecting the public. Homeopathic products have not been approved by the FDA for any use and may not meet modern standards for safety, effectiveness and quality.

Health care professionals and consumers are encouraged to report any adverse events related to these products to the FDA's MedWatch Adverse Event Reporting program. To file a report, use the MedWatch Online Voluntary Reporting Form. The completed form can be submitted online or via fax to 800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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