PharmaMedics 8/16/18

10903 New Hampshire Avenue
Silver Spring, MD 20993

TO: PharmaMedics

FROM: The United States Food and Drug Administration

RE: Notice of Unlawful Sale of Unapproved and Misbranded Opioids to United States Consumers Over the Internet

DATE: August 16, 2018

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) has determined that PharmaMedics offers products for sale in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). More specifically, your network introduces into interstate commerce, opioids that are misbranded and unapproved new drugs, in violation of sections 301(a), 301(d), 503(b), and 505(a) of the FD&C Act [21 U.S.C. §§ 331(a), 331(d), 353(b), and 355(a)].

Offering unapproved opioids for sale is particularly concerning given their potential for abuse and dependency, especially amid the growing opioid epidemic in the U.S. On average, 115 Americans die every day from an opioid overdose.***1*** In 2016, opioids killed more than 42,000 people ***2***, surpassing even the number of deaths resulting from traffic accidents in the U.S.***3***

FDA requests that you immediately cease offering violative drugs for sale to U.S. consumers.

Unapproved New Drugs

As labeled, certain products offered for sale by PharmaMedics are drugs within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These drugs are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled uses. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No approved applications pursuant to section 505 of the FD&C Act are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) [21 U.S.C. § 331(d)] and 505(a) of the FD&C Act.

For example, PharmaMedics offers tramadol marketed as “RECDOL,” manufactured by “Hab Pharmaceuticals & Research Ltd,” to treat “moderate to severe pain.” While there are FDA-approved versions of tramadol on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the ”RECDOL” offered by PharmaMedics. FDA-approved tramadol bears a boxed warning, commonly referred to as a “black box warning,” which is the strongest warning FDA requires, indicating that the drug carries a significant risk of serious or even life-threatening adverse effects. The boxed warning addresses risks including addiction, abuse, misuse, life-threatening respiratory depression (breathing problems), and neonatal opioid withdrawal syndrome (withdrawal symptoms in newborn baby). In addition, when taken in conjunction with other central nervous system depressants, including alcohol, use may result in coma or death.

Misbranded Drugs

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if it fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)] include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Because the aforementioned drug is a prescription drug intended for a condition(s) that is not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the product safely for its intended use(s). Consequently, the labeling for this drug fails to bear adequate directions for its intended use(s), causing it to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because this drug is not approved in the U.S., it is also not exempt under 21 CFR 201.115 from the requirements of section 502(f)(1) of the FD&C Act. By offering this drug for sale to U.S. consumers, PharmaMedics is causing the introduction of a misbranded drug into U.S. interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

* * *

FDA is taking this action against PharmaMedics because of the inherent risk to consumers who purchase misbranded and unapproved new drugs. Unapproved new drugs do not carry the same assurances of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

This letter is not intended to identify all the ways in which your activities might be in violation of law. Furthermore, included below is a list of websites identified as part of your network (this is not intended to be all inclusive). It is PharmaMedics’s responsibility to ensure that all products you offer for sale are in compliance with the FD&C Act and its implementing regulations. You should take prompt action to correct the violations noted above as well as any other violations of the FD&C Act (which would include the offer for sale of all misbranded and/or unapproved new drugs, not just the drug noted above). Failure to correct these violations may result in FDA regulatory action, including seizure or injunction, without further notice.

Please notify this office in writing within 10 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence.

If the corrective action(s) cannot be completed within 10 working days, state the reason for the delay and the time within which the correction(s) will be completed. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. Your response and any other inquiries concerning this letter should be sent to FDA's Internet Pharmacy Task Force at **FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov (mailto:FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov)**.

Table of Website(s):

Connecting URL
http://www.medstore-online.co
http://www.medstore-online.global

Sincerely,
/s/
Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc: .CO Internet S.A.S.
Dot Global Domain Registry Limited
1API GmbH
TLD Registrar Solutions Ltd.

---

1 Centers for Disease Control and Prevention, Understanding the Epidemic (August 30, 2017), **https://www.cdc.gov/drugoverdose/epidemic/index.html (https://www.cdc.gov/drugoverdose/epidemic/index.html)** [last visited August 1, 2018]
2 Centers for Disease Control and Prevention, Opioid Overdose (October 23, 2017), **https://www.cdc.gov/drugoverdose/index.html (https://www.cdc.gov/drugoverdose/index.html)** [last visited August 1, 2018]
3 U.S. Department of Transportation, USDOT Releases 2016 Fatal Traffic Crashes Data (October 6, 2017), **https://www.nhtsa.gov/press-releases/usdot-releases-2016-fatal-traffic-crash-data (https://www.nhtsa.gov/press-releases/usdot-releases-2016-fatal-traffic-crash-data)** [last visited August 1, 2018]

More in Warning Letters

(/ICECI/EnforcementActions/WarningLetters/default.htm)