TeraPharm 10/9/18

10903 New Hampshire Avenue
Silver Spring, MD 20993

TO: TeraPharm

FROM: The United States Food and Drug Administration

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

DATE: October 9, 2018

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) has determined that TeraPharm 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, misbranded and unapproved new drugs, including, but not limited to cancer 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)].

In addition, the sale of unapproved and misbranded drugs poses an inherent risk to consumers who purchase those products, especially to those who suffer from serious conditions such as cancer. Unapproved new drugs do not have the same assurance of safety and effectiveness as those drugs subject to FDA oversight, and drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

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 TeraPharm 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, TeraPharm offers letrozole, marketed as “Fempro” and described as being used “to treat breast cancer in women who are post-menopausal.” While there are FDA-approved versions of letrozole 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 “Fempro” product offered by TeraPharm. FDA-approved letrozole is associated with risks including increased incidence of bone fractures and osteoporosis. Furthermore, dosage modifications are required in patients with severe liver impairment.

Another example of an unapproved new drug offered by TeraPharm is acyclovir, marketed as “Aciclovir” and described as “an antiviral drug” that “slows the growth and spread of the herpes virus so that the body can fight off the infection.” While there are FDA-approved versions of acyclovir 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 “Aciclovir” product offered by TeraPharm. FDA-approved acyclovir is associated with kidney failure, which in some cases has resulted in death. Furthermore, dosage modifications are required in patients with impaired kidney function.

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) [21 U.S.C. § 353(b)(1)] of the FD&C Act 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 drugs are prescription drugs intended for conditions that are not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the products safely for their intended uses. Consequently, the labeling for these drugs fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because these drugs are not approved in the U.S., they are also not exempt under 21 CFR 201.115 from the requirements of section 502(f)(1) of the FD&C Act. By offering these drugs for sale to U.S. consumers, TeraPharm is causing the introduction of misbranded drugs into 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 TeraPharm because of the inherent risk to consumers who purchase misbranded and unapproved new drugs. 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 TeraPharm’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 drugs 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 (/ICECI/EnforcementActions/WarningLetters/default.htm)**.

Table of Websites:

Connecting URL
http://www.canadameds24h.com
http://www.infoaboutpills.com
http://www.cheamedspbuy.com
http://www.bestonlinepharmshop.com
http://www.noprescriptiontabs.com
http://www.fastxpills.com
http://www.medsatdiscountprices.com
http://www.new-qualitypharm.com
http://www.edhelp24.com
http://www.24pills.org
http://www.about-drugs.net
http://www.mypersonalpharmacy247.com
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http://www.bestonlinepharmshop.net
http://www.cheapmeds24.net
http://www.druggstorre.org
http://www.healmepills.net
http://www.online-pharmacy-market.net
http://www.secure-meds24.nethttp://www.discountmeds.su
http://www.cheapmeds24.biz
http://www.hellpinmeds24x7.net
http://www.meds-365.net
http://www.europharmapills.com
http://www.goodhealf.com
http://www.mdexpress.men
http://www.rxonline-top.net

Sincerely,
/S/
Donald D. Ashley
Director
Office of Compliance

Center for Drug Evaluation and Research
Food and Drug Administration

More in Warning Letters (/ICECI/EnforcementActions/WarningLetters/default.htm)