WARNING LETTER

Unitedpharmacies.md

MARCS-CMS 605686 — MARCH 30, 2020

Product:

Drugs

Recipient:

Unitedpharmacies.md

United States

inquiry@unitedpharmacies.md

Issuing Office:

Center for Drug Evaluation and Research | CDER

10903 New Hampshire Avenue

Silver Spring, MD 20993

United States

WARNING LETTER

Date: March 30, 2020

RE: Notice of Unlawful Sale of Unapproved and Misbranded Drugs Related to Coronavirus Disease 2019 (COVID-19) to United States Consumers Over the Internet

This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address www.unitedpharmacies.md on March 12, 2020. The FDA has determined that your website offers drug products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. FDA has determined that these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently an outbreak of respiratory disease caused by a novel coronavirus that has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell unapproved drug products products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.

There are inherent risks 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. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

As labeled, certain products offered for sale by www.unitedpharmacies.md 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, www.unitedpharmacies.md offers lopinavir + ritonavir marketed as "Lopimune" and

"Hivus-LR." Your website states that "Lopinavir + Ritonavir have recently been receiving a lot of media coverage as Chinese health officials are using this combination to combat the recent outbreak of the 2019-nCov coronavirus. Lopimune . . . is a combination product for HIV treatment containing the active ingredients Lopinavir (200mg) and Ritonavir (50mg)." Your website further states, "Lopinavir + Ritonavir (Hivus-LR) is a HIV treatment that has been central to most treatment plans for COVID-19 (2019-nCov coronavirus)." While there are FDA-approved versions of Lopinavir + Ritonavir 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 "Lopimune" or "Hivus-LR" products offered by www.unitedpharmacies.md.

Your website, www.unitedpharmacies.md also offers ribavirin marketed as "Ribasure." Your website states that "Ribasure (Ribavirin) is a nucleoside analogue. . . . Ribavirin has been recommended to treat COVID-19 (coronavirus) by some experts due to its effect on MERS (Middle East Respiratory Syndrome)." While there are FDA-approved versions of Ribavirin 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 "Ribasure" product offered by www.unitedpharmacies.md.

You should take immediate action to correct the violations cited in this letter. The violations cited in this letter are not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to** COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure and injunction.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. 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.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs are subject to detention and refusal of admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov.

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

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1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).
2 Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).
3 President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at https://www.whitehouse.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

Content current as of:

04/15/2020

Regulated Product(s)

Drugs

More Warning Letters

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