WARNING LETTER

rxshopmd.com

MARCS-CMS 615753 — FEBRUARY 15, 2022

Product:

Drugs

Recipient:

rxshopmd.com

Cyprus

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

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: February 15, 2022

WARNING LETTER

This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.rxshopmd.com on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] and a variety of other diseases such as HIV. Based on our review, these products are unapproved new drugs introduced into interstate commerce 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), 301(d), and 301(k) of the FD&C Act [21 U.S.C. § 331(a), 331(d), and 331(k)].

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been

named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus 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, there was a Presidential declaration of 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, FDA has observed that your website offers drug products for sale in the U.S. that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.

There are inherent risks to consumers who purchase unapproved new drugs and misbranded 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 cease the sale of any unapproved and misbranded products, whether for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, or any other disease for which the drugs you are selling are not approved by FDA for distribution in the U.S.

Unapproved New Drugs:

Certain products offered for sale by www.rxshopmd.com 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. With certain exceptions not applicable here, 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.rxshopmd.com offers lopinavir + ritonavir marketed as “Hivus-LR (Lopinavir + Ritonavir 200/50 mg)” manufactured by Aurobindo Pharma Ltd. In the description of “Hivus-LR (Lopinavir + Ritonavir 200/50 mg),” your website states, “The medication known mostly as Kaletra is based on Lopinavir + Ritonavir. It is a HIV medication that is used in a combination therapy. In 2020, it have[sic] been also tested and included in the protocols of treatment of the novel coronavirus COVID-19.” Additionally, under the “Generic Hivus-LR (Lopinavir + Ritonavir 200/50 mg) guide” heading, www.rxshopmd.com states, “The medication sold under the brand name Kaletra is used as a part of a complex therapy of HIV and AIDS. Since March 2020, it is also approved for the treatment of the novel coronavirus, COVID-19…” While there are FDA-approved versions of lopinavir + ritonavir, including “Kaletra,” 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 “Hivus-LR (Lopinavir + Ritonavir 200/50 mg)” manufactured by Aurobindo Pharma Ltd. and offered by www.rxshopmd.com. FDA-approved lopinavir + ritonavir is an HIV-1 protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and is only available by prescription. In addition, the combination of lopinavir and ritonavir has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19.

Misbranded Drugs:

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if its labeling fails to bear adequate directions for use. “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (see 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 be used safely only at the direction, and under the supervision, of a licensed practitioner.

Because the aforementioned drug is a prescription drug intended for a condition 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 the intended use. Consequently, the labeling for this drug fails to bear adequate directions for use, causing it to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because the drug is not approved in the U.S., it is also not exempt under 21 CFR 201.115(a) from the requirements of section 502(f)(1) of the FD&C Act. By offering this drug for sale to U.S. consumers, www.rxshopmd.com is causing the introduction of a misbranded drug into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

Furthermore, under U.S. law, prescription drugs can be dispensed only pursuant to a prescription from a healthcare practitioner licensed by law to administer prescription drugs. By offering the aforementioned drugs without requiring a prescription, www.rxshopmd.com jeopardizes patient safety and misbrands the drugs under section 503(b)(1) of the FD&C Act. Dispensing a prescription drug without a prescription is an act which results in the drug being misbranded while held for sale, in violation of section 301(k) of the FD&C Act [21 U.S.C. § 331(k)].

FDA is sending this Warning Letter to www.rxshopmd.com 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 products or operations might be in violation of the law. It is your 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 address any violations of the FD&C Act (which may include the offer for sale of similarly misbranded and/or unapproved new drugs other than the drugs noted above). 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 use for which they have not been approved by FDA and that you are not distributing misbranded products in violation of the FD&C Act.

Within 48 hours, please send an email to FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address any violations and to prevent their recurrence. Include an explanation of each step being taken to remedy and prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately address this matter may result in legal action, including, without limitation, seizure and injunction, without further notice. 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. This letter notifies you of our concerns and provides you with an opportunity to address them. 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 within 48 hours.

If you are not located in the U.S., please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission. We may advise the appropriate regulatory officials in the country from which you operate that your products referenced above appear to be unapproved and misbranded products that cannot be legally sold to consumers in the U.S.

Please direct any inquiries to FDA at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and 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, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

3 President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020, 85 FR 15337, available at https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak.

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WARNING LETTER

Extrapharmacy.ru

MARCS-CMS 615132 — FEBRUARY 15, 2022

Product:

Drugs

Recipient:

Mikhail Kazankov

Extrapharmacy.ru

Russia

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

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: February 15, 2022

WARNING LETTER

This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.extrapharmacy.ru on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] and a variety of other diseases such as systemic lupus erythematosus, rheumatoid arthritis, and malaria. Based on our review, these products are unapproved new drugs introduced into interstate commerce 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 301(d) of the FD&C Act [21 U.S.C. § 331(a) and 331(d)].

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus 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, there was a Presidential declaration of 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, FDA has observed that your website offers drug products for sale in the U.S. that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.

There are inherent risks to consumers who purchase unapproved new drugs and misbranded 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 cease the sale of any unapproved and misbranded products, whether for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, or any other disease for which the drugs you are selling are not approved by FDA for distribution in the U.S.

Unapproved New Drugs:

Certain products offered for sale by www.extrapharmacy.ru 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. With certain exceptions not applicable here, 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, among other drugs offered on your website under the category of Coronavirus/COVID-19, www.extrapharmacy.ru offers hydroxychloroquine marketed as "Plaquenil (Hydroxychloroquine)" manufactured by Sanofi. Your website states, "Plaquenil is an effective remedy for malaria, systemic lupus erythematosus, rheumatoid arthritis." While there are FDA-approved versions of hydroxychloroquine, including "Plaquenil," 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 "Plaquenil (Hydroxychloroquine)" manufactured by Sanofi and offered by www.extrapharmacy.ru. FDA-approved hydroxychloroquine is labeled for the treatment of uncomplicated malaria, discoid and systemic lupus erythematosus, and acute and chronic rheumatoid arthritis and is only available by prescription. In addition, hydroxychloroquine has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19.[4]

Your website also offers a product marketed as "Areplivir (Favipiravir)" manufactured by Promomed. Your website states, "Favipiravir inhibits SARS-CoV-2 Virus Causing COVID-19," and provides a dosing regimen "[f]or the treatment of COVID-19." There are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Areplivir (Favipiravir)" manufactured by Promomed and offered by www.extrapharmacy.ru.

Misbranded Drugs:

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if its labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (see 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 be used safely only 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 use, 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(a) from the requirements of section 502(f)(1) of the FD&C Act. By offering these drugs for sale to U.S. consumers, www.extrapharmacy.ru 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 sending this Warning Letter to www.extrapharmacy.ru 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 products or operations might be in violation of the law. It is your 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 address any violations of the FD&C Act (which may include the offer for sale of similarly misbranded and/or unapproved new drugs other than the drugs noted above). 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 use for which they have not been approved by FDA and that you are not distributing misbranded products in violation of the FD&C Act.

Within 48 hours, please send an email to FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address any violations and to prevent their recurrence. Include an explanation of each step being taken to remedy and prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately address this matter may result in legal action, including, without limitation, seizure and injunction, without further notice. 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. This letter notifies you of our concerns and provides you with an opportunity to address them. 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 within 48 hours.

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Please direct any inquiries to FDA at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and 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, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

3 President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020, 85 FR 15337, available at https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak.

4 On March 28, 2020, FDA issued an Emergency Use Authorization (EUA), pursuant to section 564 of the FD&C Act [21 U.S.C. § 360bbb-3], to permit the emergency use of hydroxychloroquine sulfate and chloroquine phosphate supplied from the Strategic National Stockpile to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible. On April 24, 2020, FDA issued a Drug Safety Communication cautioning against the use of hydroxychloroquine or chloroquine for COVID-19 outside of either: (1) use in a hospital setting pursuant to FDA's EUA; or (2) participation in a clinical trial investigating use of chloroquine or hydroxychloroquine for treatment of COVID-19. FDA issued that Drug Safety Communication to remind patients and health care professionals of the known risk of serious heart rhythm problems associated with chloroquine and hydroxychloroquine. FDA revoked this EUA on June 15, 2020, based on FDA's continuing review of available scientific evidence, including clinical trial results, that led FDA to determine that the statutory criteria for EUA as outlined in Section 564(c)(2) of the FD&C Act were no longer met. Specifically, FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses under the EUA and that the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the formerly authorized uses. Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability, 85 Fed. Reg. 56231 (Sept. 11, 2020) (accessible at https://www.federalregister.gov/documents/2020/09/11/2020-20041/authorizations-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability).

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