

Aidaccess.org 3/8/19



TO: Aidaccess.org

FROM: The United States Food and Drug Administration

RE: Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce

DATE: March 8, 2019

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your website, <http://www.aidaccess.org>, and determined that you cause the introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 331(a), 331(d), and 355(a)).

The sale of misbranded and unapproved new drugs poses an inherent risk to consumers who purchase those products. Unapproved new drugs do not have the same assurance 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.

FDA requests that you immediately cease causing the introduction of these violative drugs into U.S. commerce.

Unapproved New Drug

Aidaccess.org states on its website, "Aid Access supports women who are not able to access local services. If you are healthy and less than 9 weeks pregnant, you can do the online consultation. The abortion pills mifepristone and misoprostol will be delivered to you by mail." By facilitating the sale of unapproved mifepristone and misoprostol to consumers in the U.S., Aidaccess.org causes the introduction of unapproved new drugs into U.S. commerce in violation of the FD&C Act. These products 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 use. 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)).

Aidaccess.org facilitates the sale to U.S. consumers of unapproved mifepristone in a regimen with unapproved misoprostol labeled for the termination of pregnancy, including "(b)(4), (b)(6)," a combination pack that includes both mifepristone and misoprostol tablets. The "(b)(4), (b)(6)" product is labeled as a "Combipack of Mifepristone Tablets IP & Misoprostol Tablets IP" and is manufactured by (b)(4), (b)(6). The patient insert accompanying the product states that "(b)(4), (b)(6)" is "indicated for early medical abortion for up to 9 weeks." The product labeling states that "(b)(4), (b)(6)" is "Marketed by: (b)(4), (b)(6)."

No approved applications pursuant to section 505 of the FD&C Act are in effect for this product. Accordingly, its introduction or delivery for introduction into interstate commerce violates sections 301(d) (21 U.S.C. § 331(d)) and 505(a) (21 U.S.C. § 355(a)) of the FD&C Act.

There is an FDA-approved prescription mifepristone drug product that is marketed in the U.S. under the brand name "Mifeprex" and indicated in a regimen with FDA-approved misoprostol, for the termination of early pregnancy (10 weeks or less since last menstrual period began). However, there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "(b)(4), (b)(6)" product manufactured by (b)(4), (b)(6), caused to be introduced into U.S. commerce via Aidaccess.org.

The substitution of unapproved drugs for FDA-approved prescription drugs poses significant health risks to U.S. consumers. For example, in this case, use of the unapproved drug would not be subject to the same protections as use of the FDA approved product. Mifeprex labeling bears a boxed warning indicating that the drug carries a risk of serious or even life-threatening adverse effects, including serious and sometimes fatal infections and prolonged heavy bleeding, which may be a sign of incomplete abortion or other complications. As further noted in the Mifeprex labeling, Mifeprex is only available in the U.S. through a Risk Evaluation and Mitigation Strategy (REMS) program. The REMS program is intended to mitigate the risk of serious complications associated with Mifeprex by: requiring healthcare providers who prescribe Mifeprex to be certified in the Mifeprex REMS program; ensuring that Mifeprex is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber; and informing patients about the risk of serious complications associated with Mifeprex. Consistent with the REMS, Mifeprex is not sold through retail pharmacies or over the internet. Use of the unapproved "(b)(4), (b)(6)" product would not be subject to these FDA-approved REMS provisions.

Misbranded Drug

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 "(b)(4), (b)(6)" product contains prescription drugs 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 its intended use. Consequently, the labeling for "(b)(4), (b)(6)" fails to bear adequate directions for its intended use, causing it to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because "(b)(4), (b)(6)" 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.

The "(b)(4), (b)(6)" product is also misbranded under section 502(f)(2) of the FD&C Act (21 U.S.C. § 352(f)(2)) because it fails to bear "adequate warnings against use ... where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application" This is particularly concerning because FDA-approved mifepristone indicated for medical termination of early pregnancy is subject to a REMS program. The REMS program for Mifeprex restricts dispensing to certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

Healthcare providers who prescribe Mifeprex must be certified in the Mifeprex REMS program. In order to be certified, the prescriber must have the ability to: assess the duration of the pregnancy accurately, diagnose ectopic pregnancies, and provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made arrangements for others to provide such care. Healthcare providers must be able to ensure that women have access to medical facilities for emergency care, and must agree to other responsibilities, including reviewing and signing the Patient Agreement Form with the patient and providing each patient with a copy of the signed Patient Agreement Form and the Medication Guide. In addition, the REMS program contains specific requirements for distributors including, but not limited to, following processes and procedures for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of Mifeprex. By facilitating the sale of the unapproved and misbranded "(b)(4), (b)(6)" product, Aidaccess.org is causing important safety measures that are put in place for FDA-approved mifepristone for medical termination of early pregnancy to be bypassed.

By facilitating the sale of "(b)(4), (b)(6)" to U.S. consumers, Aidaccess.org 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)).

FDA is taking this action against Aidaccess.org because of the risks posed by its conduct in causing the introduction of a misbranded and unapproved new drug into U.S. commerce. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Sourcing drugs from outside of the legitimate U.S. drug supply chain can pose serious risks to patients who may receive medications that are adulterated and are not shipped and/or stored properly.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the sale of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act. 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 15 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 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. If you believe that this product is 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 FDALInternetPharmacyTaskForce-CDER@fda.hhs.gov (<mailto:FDALInternetPharmacyTaskForce-CDER@fda.hhs.gov>).

Sincerely,

/S/

Thomas Christi
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc:
Dr. Rebecca Gomperts
(b)(4), (b)(6)

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