WARNING LETTER

Smart Women's Choice

MARCS-CMS 614359 — MAY 19, 2021

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Francoise Farron

CEO

Smart Women's Choice

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Issuing Office:

Center for Drug Evaluation and Research

United States

WARNING LETTER

May 19, 2021

RE: 614359

Dear Dr. Farron:

This letter is to advise you that the United States Food and Drug Administration (FDA) has reviewed your product labeling, including your website at https://www.smartwomenschoice.com/, from February to April 2021 and has determined that you take orders there for "Smart Women's Choice." We have also reviewed your social media websites at https://www.facebook.com/SmartWomensChoiceInc/ and https://www.instagram.com/smartwomenschoice/; these social media websites direct consumers to your website https://www.smartwomenschoice.com/ to purchase products. The claims on your website and social media websites establish that your Smart Women's Choice product is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). As explained further below, introducing or delivering this product for introduction into interstate commerce violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov. (//www.fda.gov.) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Unapproved New Drug Product

Based on our review of your websites, "Smart Women's Choice" is a drug under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body.

Some examples of claims observed on your website and social media websites that establish the intended use of your product as a drug include, but may not limited to, the following:

From your website at https://www.smartwomenschoice.com/:
• “One hundred percent hormone-free, completely safe, natural birth control that cannot fail when used as directed and causes no harmful side effects.”
• “Our patented vaginal contraceptive cream is the ONLY healthy alternative to prevailing medical options. Say goodbye to hormone-based pills, patches and mechanical devices, whose dangerous side effects include: sleeping disorders, fatigue, depression, reduced libido, personality changes, blood clots, increased risk of breast or cervical cancer, stroke and more!”

From your website at https://www.smartwomenschoice.com/science-behind-swc:
• “HOW SMART WOMEN’S CHOICE WORKS TO PREVENT FERTILIZATION”.
• “IF THEY CAN’T SWIM . . . THEY CAN’T GET IN”
• “SWC works by an entirely different mechanism than other birth controls: it immobilizes the sperm in the vagina; therefore the sperm cannot make the journey from the vagina, where it is deposited during intercourse, to the Fallopian tubes, the only place where an egg can get fertilized. Without fertilization taking place, it is impossible to get pregnant.”
• “SMART WOMEN’S CHOICE birth control cannot fail when used as directed!”
• “CONTRACEPTIVE”
• “Natural, safe, effective patented birth control”

From your website at https://www.smartwomenschoice.com/about-swc:
• “It was only when a friend lost her beautiful young daughter caused by blood clots that formed due to her use of a hormone-containing birth control device, that Francoise felt a moral imperative to share her discovery with other women as an alternative to the dangerous hormone-based contraceptives.”

From your website at https://www.smartwomenschoice.com/order:
• “I really appreciate this product. It has made my sexual health much better. I was tired of feeling sick all of the time or being worried that other non-hormonal birth controls would fail.”

From the “About” sidebar on your Facebook page https://www.facebook.com/SmartWomensChoiceInc/:
• “Smart Women’s Choice is the only non-hormonal birth control that is 99.8% effective with no side effects, as an alternative to hormonal contraceptives.”

From a February 4, 2021 post on your Facebook page at https://www.facebook.com/SmartWomensChoiceInc/ and a February 6, 2021 post on your Instagram page at https://www.instagram.com/smartwomenschoice/:
• “Smart Women’s Choice is a great option for Natural Family Planning . . . is a safe and effective alternative to hormonal birth control that gives you peace of mind while allowing you to start a family in your own time.”

From January 31, 2021 posts on your Facebook and Instagram pages at
https://www.facebook.com/SmartWomensChoiceInc/ and
https://www.instagram.com/smartwomenschoice/:
• “SMART WOMEN’S CHOICE . . . No Unwanted Pregnancies”

From January 30, 2021 posts on your Facebook and Instagram pages at
https://www.facebook.com/SmartWomensChoiceInc/ and
https://www.instagram.com/smartwomenschoice/:
• “I STOPPED TAKING THE PILL A FEW WEEKS AGO AND I DIDN’T REALIZE HOW MUCH IT AFFECTED ME AND MY EMOTIONS THANKS FOR CREATING A SAFE ALTERNATIVE TO HORMONAL BIRTH CONTROL.”

Your “Smart Women’s Choice” is not generally recognized as safe and effective for its above referenced uses and, therefore it is a “new drug” under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect for your product.

Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and/or injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within fifteen working days, state the reason for the delay and the time within which you will do so. 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 should be sent to U.S. Food and Drug Administration, Center for Drug Evaluation and Research/Office of Compliance/Office of Unapproved Drugs and Labeling Compliance by e-mail to FDAADVISORY@fda.hhs.gov.

Sincerely,
/S/

Carolyn E. Becker
Director
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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