U.S. FOOD & DRUG ADMINISTRATION

For updated information refer to: https://www.fda.gov/medical-devices/safety-communications/fda-warns-against-use-energy-based-devices-perform-vaginal-rejuvenation-or-vaginal-cosmetic

August 01, 2018

Yoni Iger
Venus Concept, Ltd.
Hayetsira Street, Bld. 2
Yokneam Illit, Israel 2066728

Document Number: CPT1800784

Dear Mr. Iger:

It has come to our attention that you may be marketing the Venus Fiore System, which meets the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act (FD&C Act), in a manner that potentially violates the FD&C Act.

Specifically, we have conducted a review of our files and have been unable to identify Food and Drug Administration (FDA) clearance or approval for the Venus Fiore System as marketed on the website (as of 7/24/18), https://www.venusconcept.com/en-gl/venus-fiore.htm, for internal vaginal health restoration, labia skin tightening, and mons pubis reduction.

We request that you provide us with the following information:

- FDA clearance or approval number for the Venus Fiore System.
- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the Venus Fiore System.

We appreciate that you have already contacted us to begin modifications to your website.

In addition, we request that a written response be submitted within 30 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Document Number, listed above, and should be submitted to:

Complaints Program Manager, WO66-3684
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, you may contact CDR Cesar Perez at 301-796-5770, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely,

Cesar A. Perez -S

Digitally signed by Cesar A. Perez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Cesar A. Perez -S, 0.9.2342.19200300.100.1.1=2000613874
Date: 2018.08.01 17:39:41 -04'00'

CDR Cesar A. Perez, PhD
Chief
Surveillance and Enforcement Branch I
Division of Premarket and Labeling Compliance
Office of Compliance
Center for Devices and Radiological Health

Cc.

Horacio Gaspar
U.S. Agent
Venus Concept USA Inc.
1880 N. Commerce Parkway, Suite 2
Weston, FL 33326