

WARNING LETTER

**VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED**

May 20, 2021

Fertility Nutraceuticals LLC
Norbert Gleicher
21 E 69th St
New York, NY 10021

RE: [605595](#)

- “Fertinatal Fertility DHEA has been show in multiple studies to . . . reduce miscarriage risk.”

On the website www.fertilitysupplementstore.com:

On the “Supplement Guide” page:

- “FERTINATAL® DHEA For Women is recommended for: . . . Women . . . receiving fertility treatment . . .”
- “CONFLAM

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug 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 C.F.R. § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your “CONFLAM Forte™” product is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, your “CONFLAM Forte™” product fails to bear adequate directions for its intended use and, therefore, this product is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of this misbranded drug violates section 301(a) of the Act [21 U.S.C. § 331(a)].

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 r4 (x)8 (nt)-7.7 (r)-24.A(a)15.47 (ith)8 (a)23.)8 (n)8 (Yt)]TJ 0 Tc 0 Tw15.4864 0 Td ()

whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See Daniel Chapter One, WL 5160000 at *17-19.

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by

