FDA Warns Companies over Unapproved Fertility Claims

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On May 26, FDA published a constituent update informing the public that it has issued warning letters to five companies for marketing dietary supplements that claim to cure, treat, mitigate, or prevent infertility and other reproductive health conditions. The warning letters were sent to LeRoche Benicoeur dba ConceiveEasy, EU Natural Inc., Fertility Nutraceuticals LLC, SAL NATURE LLC/FertilHerb, and NS Products, Inc. In the update, FDA noted that consumers seeking safe and effective therapies who rely on these products’ claims could potentially suffer harm and may not receive appropriate treatment.

According to the Federal Food, Drug, and Cosmetic Act (FD&C Act), products intended to cure, treat, mitigate, or prevent infertility are considered drugs that must undergo appropriate FDA drug approval. In such a review, FDA evaluates issues including safety, effectiveness, drug interactions, and dosage. Examples of claims noted in the warning letter are statements on the supplements’ ability to treat luteal phase defects and ovarian cysts, prevent miscarriages, and enhance in vitro fertilization treatment. The companies also published testimonials alleging that use of the products resulted in pregnancy.

The companies have been given 15 working days to provide a response to the FDA. FDA notes that those who do not comply risk legal action in the form of product seizure and/or injunction.