

Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Shelly Black, an individual trading and doing business as Progesterone Advocates Network, File No. 072-3146

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Shelly Black, an individual trading and doing business as Progesterone Advocates Network (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves the advertising and promotion of Nature’s Precise Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. According to the FTC complaint, respondent represented that Nature’s Precise Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) does not increase the user’s risk of developing breast cancer and/or is effective in preventing or reducing the user’s risk of developing breast cancer. The complaint alleges that respondent failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user’s risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration (“FDA”) standard or under any new drug appli0800 0.d(mance, e)Tj4u3moP(tations of any test, study)Tj116.2800 0.0000 TD(, or research.)TjET1.0000

