DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 2 1 1999

TRANSMITTED VIA FACSIMILE

Margaret P. Filipiak
Regulatory Manager
Gynetics Inc.
56 Locust Lane
Princeton, NJ 08540

RE: **NDA#** 20-946
Preven Emergency Contraceptive Kit (levonorgestrel and ethinyl estradiol tablets and pregnancy test)
MACMIS ID# 7476

Dear Ms. Filipiak:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Preven, that were submitted by Gynetics on Form FDA 2253, that are considered to be false or misleading, and in violation of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder. These materials include a sales aid (ID# 0891010), direct-to consumer (DTC) journal ads (ID#s 0891002A, 0891002B), a patient brochure (ID# 0891011), a convention panel (ID# 0891046B), letters (ID#s 0891070, 1891070B, 0891070C), and pharmacy self sheets (ID#s 0891039A, 0891044).

Specifically, DDMAC has the following objections:

1. Materials that state or imply that Preven is an alternative to regular contraceptive use are misleading. For example, the sales aid directs the physician to prescribe Preven for patients who "practice birth control infrequently or not at all." Also, the DTC journal ad presentation "Your contraceptive may have let you down. Now there's help to prevent a pregnancy...," implies that Preven may be used as a regular form of contraception.

2. Materials that claim that "about 2% of women might become pregnant" when Preven is used as directed are misleading because they imply that 98% of women might become pregnant after an act of sexual intercourse without the use of Preven. In fact, women have

only an 8% chance of becoming pregnant after an act of sexual intercourse in a month without contraceptive protection. Thus, out of context, this claim exaggerates the efficacy of Preven.

3. The preface to the risk information in DTC ads, stating that "many women do not experience side effects," is misleading because it minimizes the fact that there are adverse events that occur with the use of Preven.

4. The patient brochure is misleading and lacking fair balance for many of the reasons discussed above. For example, page 3 has the misleading claim that "only 2% of women may become pregnant from an act of sex in a month." Further, the first paragraph on page 5 implies that an optional use of Preven is when a patient has sex without birth control. Also, the risk information on page 7 is prefaced by the misleading statement that "many women do not experience side effects."

5. Letters that do not carry the risk information in the body of the letter are lacking fair balance because the risk information is not given prominence and readability comparable to the information regarding effectiveness.

6. The pharmacy sell sheet number 0891-039A is lacking in fair balance because no risk information is presented with the information regarding effectiveness and use of the product. The pharmacy sheet number 0891-044 is lacking in fair balance because "serious as well as minor side effects have been reported" is not adequate disclosure of the risk information for this product.

DDMAC requests that Gynetics immediately discontinue these and any other promotional materials that have the same or similar messages. Gynetics should respond, in writing, with its intent to comply with DDMAC's request by February 4,1999. This response should include a list of all violative materials that will be discontinued and a description of Gynetics' plan for addressing this issue.

If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

Margaret Filipiak
Gynetics
NDA 20-946 (MACMIS 7476)

In all future correspondence regarding this matter, please refer to the MACMIS ID # 7476 in addition to the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
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