NDA 20-946

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

Dear Ms. Filipiak:

Please refer to your new drug application (NDA) dated November 26, 1997, received December 1, 1997, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Preven™ Emergency Contraceptive Kit (levonorgestrel and ethinyl estradiol tablets and pregnancy test).

We acknowledge receipt of your submissions dated December 5, 1997; February 9, March 10 and 25 (2), April 2, 23 and 27, May 6, 15, and 20, June 8 and 16, July 17, August 6, 11, 13, 20, 21 (telefacsimile), 25, 29 and 31 (telefacsimile) and September 1, (telefacsimile) 1998. Your submission of April 27, 1998, extended the user fee goal date for this application to September 1, 1998.

This new drug application provides for the use of Preven™ Emergency Contraceptive Kit (levonorgestrel and ethinyl estradiol tablets and pregnancy test) for prevention of pregnancy.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

From a chemistry, manufacturing and controls perspective, an 18-month expiration date for the product is acceptable based on additional stability data provided. However, you are reminded that this 18-month period is from the date of manufacture of the tablets and includes the storage time in the bulk containers.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package and patient package inserts submitted September 1, 1998, immediate container label submitted August 31, 1998 and outer carton label submitted September 1, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-946." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use

for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Christina Kish, Project Manager, at (301) 827-4260.

Sincerely,

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research