DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 6 2001

Bonnie Scott Jones
Simon Heller
The Center for Reproductive Law & Policy
120 Wall Street, 14th FL
New York, NY 10005

Docket No.: 01P-0075/CP1

Dear Ms. Jones and Mr. Heller,

This letter responds to your Citizen Petition (Petition) submitted on February 14, 2001 by the Center for Reproductive Law and Policy on behalf of a number of family planning and health care organizations. You request that the FDA exempt from prescription-dispensing requirements (i.e., switch to over-the-counter (OTC) status) two emergency contraceptive drugs -- Preven, marketed by Gynetics, Inc. and Plan B, marketed by Women's Capital Corporation -- as well as any new drug eligible for filing an abbreviated new drug application (ANDA) listing Preven or Plan B.

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your Citizen Petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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