FAMILY PLANNING COUNCIL

Promoting Reproductive Health in Southeastern Pennsylvania

February 12, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: "COMBINED ORAL CONTRACEPTIVES—LABELING FOR HEALTHCARE PROVIDERS AND PATIENTS" (DOCKET NO. 00D-1350)

Dear Sir or Madam:

The Family Planning Council (Council) appreciates the opportunity to provide comments on the FDA's Draft Guidance for Industry on Oral Contraceptives (*65 Fed Register 132, 42387*) with regard to Section III of that Guidance. The Council requests that the attached Patient Package Insert replace the text of Section III: "Instructions for Patients."

The Council has received permission from the Division of Reproductive, Urologic and Drug Products to submit our comments and recommendations regarding the OC labeling guidance at this time. The comments include a simplified version of the full Patient Package Insert (PPI) for oral contraceptives, to replace Section III in the Guidance document. The complete text of the proposed PPI is attached as *Appendix 1*, with additional comments in *Appendix 2*. We believe that this PPI is in compliance with Requirements for Prescription Drug Products Labeling, *65 Federal Register 247*, published on December 22, 2000.

These comments and recommendations are the result of a Family Planning Council project to prepare a PPI that would provide the essential information for safe and effective use of oral contraceptives in a way that makes specific points easy to find, easy understand, and easy to use. Funding for these efforts were provided by Wyeth-Ayerst Laboratories, Ortho-McNeil Pharmaceutical, Inc. and DHHS, OPHS, Region III. This revised PPI is written in lay language and below a 6th grade reading level as is recommended for all health education materials. *Appendix 3* contains a summary description of the project, which included testing iterative versions of this PPI in one-on-one interviews with 94 women, and its review by more than 40 experts on oral contraception and health education materials. *Appendix 4* is the list of the expert reviewers.

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The Family Planning Council is a private, nonprofit organization whose mission is to ensure the availability of high quality, comprehensive reproductive health care services. The Council oversees family planning services for almost 109,000 women yearly attending 24 agencies in the five-county Philadelphia region. The primary author of these comments on the Guidance for Industry, Dr. Linda Potter, was also the primary author of the first draft of the guidance document as submitted to the FDA in February 1997. In addition, she was primary author of two previous proposals to the FDA for changes in oral contraceptive labeling: 1). draft instructions for-oral contraceptive use, submitted to the FDA in February 1991 and now in all packs of combined OCs; and 2). professional and patient labeling for progestin-only oral contraceptives, submitted in February 1995, and now in all packs of progestin-only Pills.

We will be in contact within two weeks to check, on the receipt of these materials. Please contact Kay Armstrong at (215) 985-2623, email: **kay@familyplanning.org**; or Linda Potter at (609) 716-6365, email: **lspotter@att.net** if you have any questions regarding the content of this submission.

Sincerely yours,

Linda S. Potter

Linda Potter, Dr. P.H.

Kay Armstrong

Kay Armstrong, M.S.
Director of Research

cc: Dorothy Mann, Executive Director, Family Planning Council
Dr. Susan Allen, Director, DRUDP
Terri Rumble, DRUDP
Diane Harrison, MD, Wyeth-Ayerst Laboratories
Thomas Schwend, R.Ph.Ortho-McNeil Pharmaceutical, Inc.
Louis Belmonte, Region III, DHHS, OPHS

Att: Disk of PPI Word Text