DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 27 2003

Steven W. Mosher, Executive Director
David C. Morrison, Associate Editor
Population Research Institute
7845 Airpark Road, Suite D
Gaithersburg, MD 20879

Re: Docket No. 96P-0215/CP1

Dear Messrs. Mosher and Morrison:

This responds to your citizen petition (Petition) received June 27, 1996, asking the Food and Drug Administration (FDA) to withdraw approval of the Norplant System. As you are probably aware, the Norplant System is no longer marketed in the U.S. For this reason, your petition is denied without prejudice.

The Norplant System is indicated for up to 5 years of contraceptive protection and consists of six flexible capsules containing levonorgestrel implanted beneath the skin of the upper arm. Levonorgestrel gradually diffuses through the walls of the capsules, providing the body with a continuous dose of the drug substance.

You present three reasons for the FDA to withdraw approval of the Norplant System. First, you state that adverse health conditions experienced as a result of using the Norplant System are more serious and sustained than were indicated by the Population Council and Wyeth-Ayerst at the time of FDA approval in 1990 (Petition at 1). Second, you allege that women who use the Norplant System are subject to an unquantified health risk because data were not collected on adverse health conditions after the Norplant System was introduced in several foreign countries (Petition at 1-2). Last, you claim that the Norplant System may diminish the user's natural resistance to HIV and other sexually transmitted diseases (Petition at 2).

Wyeth Pharmaceuticals (formerly Wyeth-Ayerst Laboratories) is the holder of the new drug application for the Norplant System. On July 26, 2002, Wyeth Pharmaceuticals announced that it had stopped marketing the Norplant System. Because the Norplant System has been withdrawn from the market, I do not feel it would be a productive use of Agency resources at this time to formally withdraw its approval or to address the specific concerns raised in your petition. Accordingly, the petition is denied without prejudice. If marketing of the Norplant System ever resumes, you may resubmit your petition.

Sincerely yours,

96P-0215

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

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