Planned Parenthood®
Federation of America, Inc.

June 7, 2000

Non Prescription Drugs Advisory Council
Food & Drug Administration
Washington, D.C.

To Whom It May Concern,

I have been asked by Dr Robert J Staab to comment, on behalf of the Planned Parenthood Federation of America, on the Allendale Pharmaceutical Corporation application to reintroduce the Today ® Sponge, an on over-the-counter product to the American market.

The National Medical Committee, recommended the Sponge ® for use in medical practice for the Planned Parenthood Federation of America, at its May 1983 meeting. It was recommended or dispensed until January 1995 when its manufacturer removed it from the market.

During that period of time no cases of Toxic Shock Syndrome were reported to the national office. Occasional complaints of vaginal irritation, or difficult removal were reported by affiliates.

The Sponge®, while not a perfect contraceptive, offered many women, a contraceptive that could be placed before coitus, and they controlled that. The efficacy of this method appears to be comparable to other barrier and spermicidal methods. Rates obtained for these methods, as a class, are Very highly dependent on consistent and proper use, which is of course under the control of the user and not the manufacturer. According to the manufacturer, approximately ¼ billion of these devices were purchased during their period of use with no reported "serious" complications and with a low level of consumer complaints.

The directions on the last approved labels (1995) are sufficient to inform and warn users of the potential risks associated with Toxic Shock Syndrome., irritation, and on the method and timing of insertion and removal of the device.

Though irritation and sensitivity to nonoxynol-9 has been reported whenever it has been used for contraception, there are no reported associations with transmission of HIV. Some authorities have speculated that any method of contraception associated with vaginal wall irritation could facilitate viral transmission though this has not been shown in any peer-reviewed U.S study. Investigations involving Prostitutes have been considered unsuitable for studying viral transmission.

It is the opinion of the Medical Division of the Planned Parenthood Federation of America that The Today Sponge® is safe and effective. Its reappearance on the America market will offer another Option for women to protect themselves from unwanted pregnancies.

Respectfully submitted,

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Vice President for Medical Affairs

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