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**Contact:** Ariel C. Herr  
Susie Lomelino  
214-521-8596  
Michael A. Burns & Assoc.  
[acherr@mbapr.com](mailto:acherr@mbapr.com)  
[slomelino@mbapr.com](mailto:slomelino@mbapr.com)

**Instead Submits FDA Application for Softcup as OTC Fertility Aid**

***Women's Health Company Files 510(k) Device Clearance  
To Include Marketing Product for Fertility***

**La Jolla, CA (January 24, 2006)** – Women's health company Instead Inc. filed a 510(k) application with the U.S. Food and Drug Administration (FDA) this week to obtain clearance to market its Instead Softcup product as an over-the-counter (OTC) fertility aid. A decision from the FDA is expected within 90 days.

The move to seek new claims on the Softcup, currently marketed as a feminine hygiene product, was stimulated by an underground movement of Softcup users. These women were employing the product as an internal device to hold semen close to the cervix. Instead vice president and general manager, Teri Hirschfeld, said the trend was first discovered in letters from users and on the company's online message boards at [www.softcup.com](http://www.softcup.com).

"These users, who represent a portion of the one in ten people of reproductive age affected by infertility, were seeking a simple and affordable option before going to more extreme measures," Hirschfeld said. "They had learned, either from each other or online, that the Softcup could be inserted immediately after intercourse to promote conception, and had the amazing success stories to prove it."

Potentially an OTC device for those trying to conceive (TTC), the Softcup is used as a reservoir to keep sperm close to the cervix. It may aid conception by helping maintain the maximum concentration of semen in the vicinity of the cervical opening. The Softcup must be inserted after sex while semen is still present near the cervix, or with sperm directly deposited in the cup itself, to promote conception.

“Beyond those experiencing infertility, we believe many of the more than three million women in the U.S. deciding to have babies every year will be interested in using the Softcup as an easily affordable and readily available way to potentially help advance the conception process.”

Following the anticipated FDA clearance, Hirschfeld said the Instead Softcup will be sold with the new indication for fertility on the package at its current points of sale.

“The fertility claim represents an exciting expansion in the innovative applications of the disposable Instead Softcup, which has been on the market as a feminine hygiene product since 1997, and is the only menstrual protection product that can be worn during a woman’s period for clean sex,” Hirschfeld added.

Instead Softcups are currently sold at retail outlets nationwide, including Target, Walgreens, CVS, Wal-Mart, Rite-Aid, Kroger and Fred Meyer, and online at [www.drugstore.com](http://www.drugstore.com). A package of six retails for a suggested \$3.49, a package of 14 for \$7.49 and a package of 24 for \$10.49.

Instead also recently announced that its candidate microbicide Amphora™, which was cleared as a personal lubricant by the FDA in late 2004, will be used in a forthcoming clinical trial. A microbicide is a substance a woman can insert vaginally prior to intercourse to protect herself from infection by sexually transmitted diseases. Amphora was selected by the U.S. Centers for Disease Control and Prevention, the United States Agency for International Development, Contraceptive Research and Development, and the University of North Carolina at Chapel Hill for a formative research study in Madagascar to test its acceptance by urban women at high risk for sexually transmitted infections.

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**About Instead, Inc.**

Instead, Inc. provides women with new and different choices for greater freedom and control of their reproductive and sexual health. The San Diego-based company is dedicated to offering women better options in health care segments where their needs are underserved with products that are thoroughly tested for safety and efficacy. Instead has focused research and development efforts on period protection and feminine hygiene, contraception, prevention of sexually transmitted infections including HIV/AIDS, and other conditions where vaginal therapy can be an effective preventative or treatment. More information about Instead and its products is online at [www.softcup.com](http://www.softcup.com) or [www.amphoragel.com](http://www.amphoragel.com).