Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

February 1, 2017

Re: FDA's Proposed Order: Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom

Dear Division of Dockets Management,

The undersigned organizations respectfully submit these comments in response to the U.S. Food and Drug Administration's (USFDA) proposed order Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom (Federal Register Docket No FDA-2017-N-6538).

As organizations working to improve the sexual and reproductive health and rights of individuals both in the United States and globally, we agree with the FDA's proposed order to:

- reclassify the female condom from a Class III to a Class II medical device;
- de-gender the device through renaming it the "single-use internal condom"; and
- expand the indication to include using the device for protection during anal sex.

Down-classification will enable new products to enter the U.S. market.[1] Expanding the number of receptive-partner initiated options that offer dual protection is critical to meeting the HIV, STI, and contraceptive needs of diverse populations. The current Class III designation of female condoms is an artifact of what was known about this prevention tool more than 20 years ago and does not reflect the body of evidence available today. It also serves as a barrier to other safe and effective products from entering the U.S. market. The latest scientific data demonstrate that female condoms are safe, effective, perform well, and needed by women and men in the U.S. and around the globe.

- **Safety:** More than two decades of use data show a strong safety record for the FC1/FC2 female condoms. Newer female condoms have shown to be non-inferior to FC2.[2] A study of 600 women using four different female condom products indicated non-inferiority for performance for each product.[3] The *WHO Medical Eligibility Guidelines for Contraceptive Use* lists female condoms as a Category One, a product that can be used by any client.[4] The 2010 Centers for Disease Control and Prevention (CDC) *Medical Eligibility Criteria for Contraceptive Use,* adapted from the WHO Guideline, concurs with this recommendation. The *Family Planning: Global Handbook for Providers*, written by the U.S. Agency for International Development (USAID), WHO, and Johns Hopkins University, states that there are no adverse side effects and no known health risks associated with using female condoms. Additionally, a December 2017 search of FDA's

Manufacturer and User Facility Device Experience (MAUDE) database from January 1, 1994 through November 30, 2017 resulted in only one report of an adverse event related to the FC1 and none for the FC2.

- **Performance:** Millions of women and men have used female condoms receiving FDA approval in 1993. Clinical data show that female condoms have low failure rates.[5] Qualitative data indicate that women are better able to negotiate safer sex practices when female condoms are available.[6] Such ability is of critical importance to women's health, particularly in contexts where male condom use is not possible or acceptable. Female condoms offer women a unique and important prevention option. Studies also demonstrate the total number of protected sex acts increases when female condoms are made available to couples alongside male condoms.[7-10]
- **Effectiveness:** Three studies examining protection offered against pregnancy by the female condom indicate it is an effective contraceptive.[11-13] Together these trials indicate that perfect use of female condoms offer between .08% and 9.5% probability of pregnancy. Data from these studies indicate that typical use of female condoms results in 3.2% to 22.2% probability of pregnancy. Research also demonstrates that female condoms offer effectiveness for reducing women's risk of STIs comparable to that of male condoms. [14-16]

New name and new indication affirms its use by diverse populations with diverse needs.
Renaming the "female condom" the "single use internal condom" removes a significant barrier to use among people who do not identify as women, yet would benefit from it. De-gendering the product name will reduce the perception that it is only intended and appropriate for use by women. Sexual health educators and providers who serve gay and bisexual men as well as transwomen, transmen, and genderqueer people have long used the term "internal condom" to refer to the female condom. Officially changing the name will align with many public health providers' practices and the decades-long request by providers and people who use the condom to change the name to one that does not imply use by just women. It could also encourage more people to consider, purchase, and use the product to reduce acquisition of HIV and STIs.

Expanding the indication to include use during anal sex acknowledges the prevention tool's utility as a necessary risk reduction option for people who engage in anal sex. Since the internal condom came on the market more than 20 years ago, people of all genders have used it both vaginally and anally to reduce transmission of HIV and STIs. Several studies have documented that a significant proportion of gay and bisexual men use the female condom for anal intercourse, with prevalence estimates ranging from 13% to 21%.[17-20]

While there are no published studies on female condom use among transgender women, the female condom could also be an important option for transwomen.[21] According to the 2015 Sexual Exploration in America Study, nearly 12% of sexually active U.S. women engaged in anal

sex in the last year.[22] Additionally, researchers estimate that women engaging in receptive anal sex usually do so without a condom. [23] This exposure to risk can be reduced by clearly labeling the female condom as a product designed for anal, as well as vaginal, use.

STI and HIV infection rates underscore the imperative for more preventative options.
HIV and STI rates in the U.S. illustrate the need for a wider array of tools for people of all gender identities and sexual orientations. The Centers for Disease Control and Prevention (CDC) data on HIV and STIs demonstrate the significant need in the U.S. for increased access to prevention methods. According to the CDC, there were more than 37,000 new HIV infections in 2014. HIV continues to disproportionately impact gay and bisexual men of all races and ethnicities, and Black cisgender and transwomen. The CDC also reports that approximately 20 million other new STIs occur each year.

For each of these reasons, we support the USFDA's proposals to reclassify the female condom from a Class III to a Class II medical device; rename it the "single-use internal condom"; and expand the indication to include using the device for anal sex. Please direct any questions regarding these comments or requests for additional information to National Female Condom Coalition secretariat Sara Semelka at ssemelka@aidschicago.org.

Sincerely,
(List in formation.)

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