



News from GCM

Dear Colleagues,

Many questions have been asked about the next steps in verifying the results of the [CAPRISA 004](#) trial and—if the product is confirmed safe and effective for preventing HIV and HSV-2 infections—ensuring its accessibility by the women who need it most.

The United States Food and Drug Administration (FDA) met on 20 October to determine its requirements for the submission of a new drug application (NDA) for the product. The FDA and CONRAD, a partner in the CAPRISA 004 trial, announced on 25 October that the agency would grant fast track approval of the NDA for 1% tenofovir gel for vaginal use if the results of the [VOICE](#) trial provide that confirmation. The VOICE trial, managed by the Microbicides Trial Network, is evaluating the safety and effectiveness of the daily vaginal use of tenofovir gel. (The study is also examining oral use of tenofovir and Truvada). The trial began in 2009, and results are expected in early 2013. About 5,000 women from four African countries are expected to take part in the VOICE trial.

GCM hails this decision regarding the possible US licensure of tenofovir. We believe it will have a strong impact on future trials, action by other country regulators, and GCM's own advocacy. Most importantly, it offers hope for millions of women.

We are committed to work to advance this and future HIV-prevention candidates.

- Read our [statement](#)
- Read more about the [CONRAD announcement](#)
- Read more about the [CAPRISA 004](#) trial

Onward,

Global Campaign for Microbicides

The [Global Campaign for Microbicides](#) is a civil society organization working to ensure the ethical and accelerated development of, and widespread access to, new and existing HIV-prevention options—especially for women. Contact: [info@global-campaign.org](mailto:info@global-campaign.org)

For more information on microbicides please email [info@global-campaign.org](mailto:info@global-campaign.org)



[www.global-campaign.org](http://www.global-campaign.org)