

January 25, 2012

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Request for Priority Review- Supplemental NDA submission by Gilead Sciences, Inc. requesting approval of a labeling change to include HIV prevention indication use for emtricitabine; tenofovir disoproxil fumarate fixed dose combination

Dear Commissioner Hamburg:

We write as a coalition of 25 leading HIV/AIDS and health organizations to request that FDA grant priority review of a supplemental New Drug Application¹ (sNDA) for the approval of emtricitabine/tenofovir disoproxil fumarate (Truvada®) fixed dose combination for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV infection among adults as part of a comprehensive prevention package including risk reduction counseling and condoms. The rigorous priority review process applicable to efficacy supplements is the best means to promote public health by recognizing the potential of PrEP to offer a major advance in HIV prevention and deserving this priority “where no adequate alternate therapy exists or as a significant improvement compared to marketed products ... including *nondrug* products or therapies.”²

Our organizations understand that granting priority review is not tantamount to a final approval. Nevertheless, we are hopeful that the full dossier of data on emtricitabine/tenofovir disoproxil fumarate fixed dose combination of PrEP from multiple clinical trials in different populations can lead to a responsible regulatory and marketing plan that allows safe use in the populations that may benefit from this innovative development.

The need for significantly improved safe and effective HIV prevention tools is clear. Despite many years of efforts to reduce HIV incidence using available counseling methods, some 50,000 new infections occur annually. Disparities persist so that incidence continues to concentrate among African Americans and Latinos, men who have sex with men (including transgender individuals), and the poor. These grim and stubborn facts led to the creation of the White House-directed National HIV/AIDS Strategy for the United States (NHAS), which lists enhanced prevention efforts as a primary objective.³ If emtricitabine/tenofovir disoproxil fumarate for PrEP satisfies FDA approval criteria, health programs and individuals will have improved choices to address a domestic priority and save lives.

The PrEP sNDA for Truvada® meets criteria set out in FDA’s Manual of Policies and Procedures for priority review. As organizations committed to ending the AIDS epidemic, we appreciate how the history of FDA’s regulatory tools for fast track approval or for accelerated

¹ http://www.gilead.com/pr_1640306 The submittal of the sNDA was announced December 15, 2011.

² FDA Manual of Policy and Procedures Review Classification Policy: Priority (P) and Standards (S) -MAPP 6020.3
<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm082000.pdf>

³ <http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf>

and priority review⁴ introduced the current suite of HIV therapeutic drugs to treat active infection. In the present case, there is a clear unmet need for new effective methods for preventing HIV infection, a need that is as urgent today as was the need for HIV therapeutics over the past two and more decades.

HIV advocacy organizations made it possible to launch such regulatory procedures for the benefit of all patient disease groups when those tools were not yet available. We are not aware of any legitimate reason to thwart the faster introduction of medicines FDA determines to be safe and effective to stop HIV, nor should anyone turn back the pages of history and act against the interests of patients to do so now. Unfortunately, recent actions by the AIDS Healthcare Foundation regarding PrEP would introduce unwarranted roadblocks in the FDA process of making responsible decisions about potentially useful medicines and public health. Those actions also foster misunderstandings of the careful balancing of risk and benefits that informs a mature marketing permission based on all available data. Those actions would also set an unhelpful precedent as PrEP research evolves in the future and the FDA is asked to review non-tenofovir-based regimens (e.g. maraviroc), microbicide gels, and intermittent PrEP. We urge that FDA continue its public health promotion goals now in the service of the critical need to prevent, as well as treat, HIV and grant this priority review.

We would be happy to discuss the priority review process as applied to HIV prevention further at your convenience. Mitchell Warren, Executive Director of AVAC, acts as the contact person for the organizations signing this letter (tel: 1-212-796-6423 or email: Mitchell@avac.org).

Sincerely,

AIDS Foundation of Chicago
AIDS Legal Referral Panel
AIDS Resource Center Ohio
AIDS Research Consortium of Atlanta
AIDS United
amfAR, The Foundation for AIDS Research
Asian & Pacific Islander Wellness Center
AVAC: Global Advocacy for HIV Prevention
Black AIDS Institute
Caracole, Inc.
Chicago Black Gay Men's Caucus
Fenway Health
HIV Prevention Justice Alliance
International Rectal Microbicide Advocates
Justice Resource Institute

LA Gay and Lesbian Center
Multicultural AIDS Coalition
National Alliance of State and Territorial AIDS Directors
National Black Gay Men's Advocacy Coalition
National Latino AIDS Action Network
National Minority AIDS Council
Ohio AIDS Coalition
Project Inform
San Francisco AIDS Foundation
SisterLove, Inc.
TACTS – The Association of Clinical Trial Services
Ursuline Sisters of Youngstown HIV/AIDS Ministry
Us Helping Us

⁴ CRS Report for Congress. FDA Fast Track and Priority Review Programs February 21, 2008
<http://www.nationalaglawcenter.org/assets/crs/RS22814.pdf>