



THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

South African Generic Drug Eligible for Use in Emergency Plan

January 25, 2005

The Office of the U.S. Global AIDS Coordinator recognizes tentative approval of HIV/AIDS medication by the U.S. Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) as demonstrating quality, safety and efficacy of antiretroviral drug products for purchase under President Bush's Emergency Plan for AIDS Relief, consistent with international laws and agreements.

HHS/FDA today reported that it has granted tentative approval to Aspen Pharmacare (South Africa) for a generic co-packaged antiretroviral drug product - known as a "blister pack" – through an expedited review process established for certain antiretroviral drugs. The 3 drug combination contained in the blister pack (the fixed dose combination of zidovudine/ lamivudine and the single drug nevirapine) is one of the most commonly used regimens in resource-limited settings and provides patients with an easy-to-use package of two tablets twice per day.

The U.S. Global AIDS Coordinator, Ambassador Randall Tobias, commented, "President Bush's Emergency Plan for AIDS Relief is moving aggressively to support national strategies to expand treatment for HIV/AIDS. Today's tentative approval of a generic co-packaged antiretroviral drug product made in South Africa is another step in ensuring that families throughout the world receive the same quality of drugs that we provide to our own families in the U.S."

HHS/FDA reported that this decision was made only two weeks after Aspen submitted a completed application for review under the expedited review process for HIV/AIDS drugs announced in May 2004. This is the second product to receive tentative approval; in December, Barr Laboratories (USA) received tentative approval for generic didanosine, commonly used in second-line regimens.

The President's Emergency Plan supports national strategies to provide the full spectrum of services required for quality treatment, which includes not only drugs but also:

- Trained clinical and laboratory personnel
- Counselors for treatment regimen adherence, prevention and healthy living
- Physical infrastructure including laboratory equipment
- Distribution, logistics and management systems for drugs and other commodities

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