DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services

Food and Drug Administration
Rockville, MD 20857

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January 21, 2004

George C. Benjamin, M.D.
Executive Director
American Public Health Association
800 I Street NW
Washington, DC 20001-3710

Dear Dr. Benjamin:

This is in response to your January 8, 2004, letter on behalf of the American Public Health Association (APHA) to Dr. Mark McClellan, Commissioner, Food and Drug Administration (FDA) regarding the switch of Plan B (levonorgestrel) from prescription to over-the-counter (OTC) status. Your letter was forwarded to my office in the Center for Drug Evaluation and Research (CDER) for response.

Thank you for writing and expressing the APHA's thoughts and concerns regarding this important issue. As you may know, FDA has created a public docket for the purpose of receiving comments regarding the switching of Plan B to OTC status. This docket will be open for public comment until November 25, 2004. I have taken the liberty of forwarding your letter to the Division of Dockets Management so that it can be recorded and considered as an official comment.

If you would like to make additional comments, electronic comments can be submitted to http://www.fda.gov/dockets/ecomments. Select docket "2001P-0075 - Switch Status of Emergency Contraceptives from Rx to OTC" and follow the prompts to submit your statement. Written comments can be submitted to Dockets Management Branch, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Again thank you for making your thoughts and concerns known to the Agency.

Sincerely,

Donald Dobbs
Division of Drug Information (HFD-240)
Office of Training and Communications
Center for Drug Evaluation and Research
Food and Drug Administration

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