



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 13 2005

The Honorable Michael Enzi
Chairman, Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Enzi:

Per your request, this letter is to follow up on concerns that the Food and Drug Administration (FDA) has not acted on the application of East Laboratories to shift the product known as "Plan B" to over-the-counter for women 18 years of age and older, and prescription-only for younger age groups.

As you know, this decision rests solely with the FDA and must be made according to the scientific evidence and FDA's authority. Accordingly, I am not a part of this decision-making process.

However, I have spoken to the FDA, and, based on the feedback I have received, the FDA will act on this application by September 1, 2005.

I hope this is responsive to your request.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael O. Leavitt", with a long horizontal flourish extending to the right.

Michael O. Leavitt

Cc: The Honorable Edward M. Kennedy, Ranking Member