

Forty eight members of Congress write FDA about the delay in the consideration of the application for over-the-counter status for the emergency contraception drug Plan B.

February 26, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. McClellan:

Recently, the Food and Drug Administration announced a delay in its consideration of Barr Laboratories' application for over-the-counter status for the emergency contraception drug Plan B.

The scientific standards for approval of an OTC application are straightforward. When a firm submits an application for OTC status, the FDA must determine whether the standards for approval are met. In the case of Plan B, an overwhelming majority of the experts found that the standards for approval were met.

1. Does the actual use study demonstrate that consumers used the product as recommended? **27 Yes; 1 No**

2. Is the actual use study generalizable to the overall population of potential non-Rx users? **27 Yes; 1 No**

3. Based on the actual use study and literature review, is there evidence that non-Rx availability is necessary? **9 Yes; 28 No**

4. Does the data demonstrate that Plan B is safe for use in the nonprescription setting? **28 Yes; 0 No**

5. Are the plans for introduction of Plan B into the nonprescription setting adequate with respect to consumer education? **22 Yes; 5 No; 1 Abstain**

6. Do you recommend Plan B be switched from Rx to non-Rx status?
23 Yes, 4 No

Despite the strong vote in support of making the drug available

without a prescription, FDA has

According to press accounts, this delay follows pressure from

conservative Members of Congress

There is increasing concern among the scientific community that

the Bush Administration is

As you review the data on Plan B and decide whether to make this

crucial drug available to millions

Sincerely,

(Signed by forty eight members of Congress. See pdf letter below

for full list of signatories)

Documents and Links

- [Letter to FDA](#)