THE CENTER FOR REPRODUCTIVE LAW AND

120 WALL STREET NEW YORK NEW YORK 10005

917/637-3600 917/637-3666 fax

1146:49TH STREET, NW WASHINGTON, DC 20036

> 202/530-2975 202/530-2976 fax

HTTP://www.crlp.org

February 13, 2002

Dockets Management Branch Food and Drug Administration Department of Health and Human Services Room 10-61 5630 Fishers Lane Rockville MD 20857

Docket No. 001P-0075/CP 1

To Whom It May Concern:

One year ago today, the Center for Reproductive Law & Policy submitted a petition on behalf of seventy-six organizations to request that the Food and Drug Administration ("FDA") switch two FDA-approved emergency contraceptive drugs ("EC") and any equivalent new drugs from prescription to over-the-counter ("OTC") status. To date, the FDA has not issued any decision on our petition, and the prescription limitation on EC continues to harm the public health. Accordingly, I write to request that you inform me of the current status of our petition, as well as the expected date for its resolution.

I also write, pursuant to 21 C.F.R. 10.30(g), to supplement the above-cited petition with the accompanying documentation of the fact that four countries -- Finland, Israel, Norway and Sweden -- have already granted OTC status to EC. These four OTC countries are in addition to the numerous countries where EC is available without a prescription from a pharmacist.

Thank you very much for your attention to this matter.

Staff Attorney

\*admitted only in Massachusetts

01P-0075

Supa