DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 23, 2003

FILE COPY

André Ulmann, MD, Ph.D.
Chief Executive Officer
HRA Pharma
19,rue Frédérick Lemaître
75020 Paris
FRANCE

Dear Dr Ulmann:

Your petition requesting the Food and Drug Administration to permit the filing of an ANDA for a drug product (1.5 mg levonorgestrel tablet) which is not identical to the reference listed drug (Plan B 0.75 mg levonorgestrel tablet) in strength, was received by this office on 05/08/03. It was assigned docket number 2003P-0216/CP 1 and it was filed on 05/08/03. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

2003P-0216

ACK 1