



THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

2997 00 AUG 25 22 2000

RE: DOCKET NO. 00D-1350

Comment to Draft Guidance

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madame:

Reference is made to the draft guidance entitled "Combined Oral Contraceptives-Labeling for Healthcare Providers and Patients". The R.W. Johnson Pharmaceutical Research Institute (RWJPRI), an affiliate of the Johnson & Johnson family of companies, would like to request a 30-day extension for submitting comments to this draft guidance document. RWJPRI and Johnson & Johnson sponsor many women's health care products and we have been working diligently to provide our comments to this important guidance document. We hope that you can grant us this extension to the September 8, 2000 deadline.

If you have any questions or require any additional information, please contact me directly at (908) 704-4812, Terri Williams at (908) 429-1896, or at our phone number designated for FDA use (908) 704-4600.

Sincerely,

Ramon Polo, PhD
Director
Regulatory Affairs

00D-1350

EXT /

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