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August 29, 2000

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

**Re: Docket No. 00D-1350 "Draft Guidance for Industry on Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients"**

Dear Sir or Madam:

Reference is made to the July 10, 2000 Federal Register Notice (65 FR 42387) which announced the availability of the Draft Guidance for industry entitled "Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients." The deadline for providing written comments to this draft labeling guidance is September 8, 2000.

The purpose of this correspondence is to request a 60-day extension from the September 8, 2000 deadline. This extension is requested in order to adequately evaluate this new draft labeling guidance with respect to the existing labeling and provide the Agency with a thorough, comprehensive response to this new draft guidance.

We will follow-up with the Agency shortly to determine if this request for an extension is acceptable. Please contact Ms. Joyce Schwenk at (610) 902-3753 or the undersigned at (610) 902-3772 if there are any questions regarding this submission.

Sincerely,

WYETH-AYERST LABORATORIES



Jennifer Phillips, Pharm.D.  
Director, Women's Health  
Worldwide Regulatory Affairs

Cc: Dr. Susan Allen, Director, DRUDP  
Ms. Terri Rumble, Chief Project Management Staff, DRUDP

00D-1350

EXT 2

**This copy goes  
directly to**

**Ms. Terri Rumble**

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 Sender's Name: Joyce Schwenk Phone: (610) 902-1495  
 Company: WYETH/AYERST LABS  
 Address: 150 RADNOR-CHESTER RD BLDG F (170/2)  
 City: ST DAVIDS State: PA Zip: 19087

**2 Your Internal Billing Reference Information**

**3 To**  
 Recipient Name: Dockets Management Branch (HFA-305)  
 Company: Food and Drug Administration  
 Address: 5630 Fishers Lane, Rm. 1061  
 City: Rockville State: MD Zip: 20852

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 \*Call for delivery schedule. See back for detailed descriptions of freight products.

**5 Packaging**  FedEx Pak  FedEx Box  FedEx Tube  Other Pkg.

**6 Special Handling**  
 Does this shipment contain dangerous goods?  No  Yes (Shipper's Declaration not required)  Yes (Shipper's Declaration not required)  
 Dry Ice (Dry Ice, 9, UN 1845 III, kg 994)  CA Cargo Aircraft Only  
 (Dangerous Goods, Shipper's Declaration not required)

**7 Payment**  
 Bill to:  Sender (Account no. in bill)  Recipient  Third Party  Credit Card  Cash/Check  
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FedEx Account No. \_\_\_\_\_ Exp. Date \_\_\_\_\_  
 Credit Card No. \_\_\_\_\_

Total Packages \_\_\_\_\_ Total Weight \_\_\_\_\_ Total Charges \_\_\_\_\_

\*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.

Release Signature: Joyce Schwenk

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

Check here if package was dropped off

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