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Organon Inc.

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CONFIDENTIAL

January 29, 2001

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

Dear Sir or Madam:

Reference is made to the Notice, "Electronic Filing of Drug Registration and Listing Information: Notice of Pilot Project," [Docket No. 00N-1669]. Please accept this written request to include Organon Inc. as a participant in the referenced pilot project. Please notify of acceptance of our request, and send all communications regarding the pilot to the undersigned at:

Organon Inc.
Regulatory Affairs Department
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Sincerely,

Edward A. Saltus
Regulatory Associate II
Regulatory Affairs Department

Phone: (973) 325-4728
Fax: (973) 669-6289

EAS/cjw

via Federal Express Airbill No. 8244-4434-1339

cc: A. DePasquale, A. Mayo, T.Pituk

00N-1669



Organon Inc.
375 Mt. Pleasant Avenue
West Orange
New Jersey 07052
USA
Tel.: (973) 325-4500
Fax: (973)-325-4589

LET 12



Organon Inc.

January 30, 2001

FAX# (301) 827-6870
Attn: Frances Turner
Dockets Management Branch (HFA-305)
Food and Drug Administration

Dear Ms. Turner:

Reference is made to the Notice, "Electronic Filing of Drug Registration and Listing Information: Notice of Pilot Project," [Docket No. 00N-1669]. Please note that the letter dated January 29, 2001 regarding the aforementioned pilot project is considered open to the public.

Sincerely,

Edward A. Saltus
Regulatory Associate II
Organon Inc.
475 Mt. Pleasant Ave.
West Orange, NJ 07052
Phone: (973) 325-4728
Fax: (973) 669-6289
Email: e.saltus@organoninc.com

cc: T.Pituk



Organon Inc.
475 Mt. Pleasant Avenue
West Orange
New Jersey 07052
USA
Tel.: (973) 325-4500
Fax: (973) 625 4509

TOTAL P.01

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1 From This portion can be removed for Recipient's records.

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Sender's Name **Edward A. Saltus** Phone **973 325-4728**

Company **ORGANON INC**

Address **375 MOUNT PLEASANT AVE** **Regulatory Affairs**

City **WEST ORANGE** State **NJ** ZIP **07052**

2 Your Internal Billing Reference

10500-86506

3 To

Recipient's Name **Dockets Management Branch** Phone

Company **Food and Drug Administration (HFA-305)**

Address **5630 Fishers Lane, Room 1061**

To "HOLD" at FedEx location, print FedEx address.

We cannot deliver to P.O. boxes or P.O. ZIP codes.

City **Rockville** State **MD** ZIP **20852**



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4a Express Package Service

FedEx Priority Overnight Next business morning
 FedEx Standard Overnight Next business afternoon
 FedEx First Overnight Earliest next business morning delivery to select locations
 FedEx 2Day* Second business day
 FedEx Express Saver* Third business day

Packages up to 150 lbs.
Delivery commitment may be later in some areas.

* FedEx Envelope/Letter Rate not available. Minimum charge: One-pound rate.

4b Express Freight Service

FedEx 1Day Freight* Next business day
 FedEx 2Day Freight Second business day
 FedEx 3Day Freight Third business day

Packages over 150 lbs.
Delivery commitment may be later in some areas.

* Call for Confirmation.

5 Packaging

FedEx Envelope/Letter*
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 Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.

* Declared value limit \$500

6 Special Handling

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
 SUNDAY Delivery Available only for FedEx Priority Overnight to select ZIP codes
 HOLD Weekday at FedEx Location Not available with FedEx First Overnight
 HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Include FedEx address in Section 3.

Does this shipment contain dangerous goods?

No One box must be checked.
 Yes As per attached Shipper's Declaration
 Yes Shipper's Declaration not required
 Dry Ice Dry Ice, 3 UN 1845 x kg
 Cargo Aircraft Only

7 Payment Bill to:

Enter FedEx Acct. No. or Credit Card No. below.
 Sender Acct. No. in Section 1 will be billed.
 Recipient
 Third Party
 Credit Card
 Cash/Check

Obtain Recip. Acct. No.

Total Packages

Total Weight

Total Charges

*Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature

Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Visit our Web site at www.fedex.com or call 1-800-Go-FedEx® (800)463-3339.

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