



URGENT: DRUG SUB-RECALL **June 03, 2009**

PRODUCT INFORMATION

Product: **Nicotine Transdermal System, 14 mg/day**
Manufactured by, and Recall initiated by: **AVEVA**

<u>Manufacturer/ Initiator</u>	<u>Label</u>	<u>NDC #</u>	<u>Size</u>	<u>Lot Number</u>	<u>Expiration Date</u>
Aveva	Equaline	41163-895-88	Cartons of 14 patches	37050	06/2011
Aveva	Premier Value	68016-895-88	Cartons of 14 patches	37050	06/2011
Aveva	Rugby	0536-5895-88	Cartons of 14 patches	37050	06/2011
Aveva	Meijer	41250-895-88	Cartons of 14 patches	37050	06/2011

RECALL INFORMATION

Level: **Wholesale**
Reason: Failure of some units to meet specification for two impurities, β -Nicotyrine and Myosmine, during long term room temperature stability testing at the nine month test point. The potency of the Nicotine patches remains within specification.

Health Hazard: There is no known potential for public health risk.

-The Food and Drug Administration has been notified of this recall -

ACTIONS REQUIRED

- **Immediately examine your inventory and discontinue distribution of the specified lot.** Our records indicate that we shipped this lot to you between 10/31/08 and 5/11/09.
- Promptly complete the attached business reply card, even if you have none of the referenced lot, and return it within five (5) business days.
- To facilitate the return of the subject lot, we are providing you with the enclosed packing slip and UPS RS label, which will allow you to return the product at no cost to you. Please return your inventory of the lot being recalled, including the completed packing slip to:

Stericycle
2670 Executive Drive
Suite A
Indianapolis, IN 46241

CREDIT

Credit will be issued **ONLY** for the recalled lot and any associated shipping costs.
Please do not return lot numbers or products that are not subject to this recall.

QUESTIONS?

If you have any questions, please contact (888) 345-5359. We appreciate your cooperation in this product recall, and regret any inconvenience that this may have caused.