PHARMACEUTICALS, INC.

URGENT DRUG RECALL
Expansion of Previous Recall Notification
FCA-2018-05-02.2

Friday, September 7th, 2018

Dear Wholesaler,

On 05/04/2018, Noven initiated recall notification (FCA-2018-05-02) to the retail level via its direct consignees of 4 (four) Minivelle® lots: 81638 (0.1 mg/day), lot 82264 (0.0375 mg/day), lot 81896 (0.0375 mg/day) and 81391 (0.1 mg/day).

Today September 7th 2018, the recall is being expanded to also include the following Minivelle® lots:

Minivelle® (estradiol transdermal system)

Lot Number	Strength	NDC#	Manufactured Date	Expiration Date	Quantity (Boxes)
81637	0.1 mg/day	68968-6610-8	11/07/2016	Oct-18	31,340
82139	0.05 mg/day	68968-6650-8	11/04/2016	Oct-18	51,043
82199	0.025 mg/day	68968-6625-8	01/26/2017	Dec-18	16,233
82200	0.1 mg/day	68968-6610-8	02/10/2017	Jan-19	34,658
82292	0.05 mg/day	68968-6650-8	03/07/2017	Feb-19	64,733
82293	0.1 mg/day	68968-6610-8	03/08/2017	Feb-19	30,562
82598	0.05 mg/day	68968-6650-8	05/10/2017	Apr-19	49,664
82599	0.075 mg/day	68968-6675-8	06/01/2017	May-19	40,556
82600	0.1 mg/day	68968-6610-8	05/11/2017	Apr-19	33,765
82660	0.075 mg/day	68968-6675-8	04/03/2017	Mar-19	16,941
83025	0.025 mg/day	68968-6625-8	06/06/2017	May-19	9,984
83027	0.1 mg/day	68968-6610-8	05/31/2017	Apr-19	34,703
83173	0.1 mg/day	68968-6610-8	07/25/2017	Jun-19	29,412
83395	0.075 mg/day	68968-6675-8	10/17/2017	Sep-19	17,411
83396	0.1 mg/day	68968-6610-8	10/04/2017	Sep-19	35,201
81391*	0.1 mg/day	68968-6610-8	11/08/2016	Oct-18	28,898
81638*	0.1 mg/day	68968-6610-8	11/09/2016	Oct-18	33,062
81896*	0.0375 mg/day	68968-6637-8	4/03/2017	Mar-19	32,579
82264*	0.0375 mg/day	68968-6637-8	1/26/2017	Dec-18	38,291

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PHARMACEUTICALS, INC.

URGENT DRUG RECALL
Expansion of Previous Recall Notification
FCA-2018-05-02.2

This Expanded Recall has been initiated because MINIVELLE® patches in lot 81637 no longer met the specification for shear, an attribute related to the adhesive properties of the Minivelle transdermal patches. Noven also included fourteen (14) additional Minivelle lots that currently meet specifications; however, they were manufactured with the same raw material and may no longer meet the specification for shear prior to expiry.

Patients could experience patches that do not stick well to skin. This issue could lead to the following risks:

- User inconvenience
- Decreased or lack of drug effect with return of menopausal symptoms
- Accidental secondary drug exposure

There is also a low risk of ingestion and/or choking in small children, if patches that fall off go unnoticed. The potential for serious injury is low and Noven Pharmaceuticals is not aware of any serious health consequences related to this issue.

This Expanded Recall is being extended to the **Retail Level**. Noven is notifying all of its direct customers (Wholesalers).

IF YOU HAVE FURTHER DISTRIBUTED THIS PRODUCT FOR COMMERCIAL SALE, YOU ARE REQUESTED TO NOTIFY YOUR CUSTOMERS TO THE *RETAIL LEVEL*.

Your immediate action is required per The Food and Drug Administration's (FDA) Code of Federal Regulations (CFR), Title 21, Part 7.49(2)(d) to prevent potential patient harm. Please review the attached, updated Expanded Urgent Drug Recall Information and complete all of the required actions without delay.

If you have further distributed this product for commercial sale, you are requested to notify your customers to the RETAIL LEVEL by forwarding the attached Expanded Recall Notification and Expanded Recall Acknowledgement Form to your direct customers

If you have any questions, please contact NOVEN PHARMACEUTICALS @ **1-800-455-8070, Option 1 or via email to fca@noven.com.**

Best regards,

Mark Jackson
Vice President - Quality & Operations
NOVEN PHARMACEUTICALS

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URGENT DRUG RECALL

FCA-2018-05-02.2

EXPANDED RECALL NOTIFICATION

MINIVELLE® (estradiol transdermal system)

	Lot Number	Strength	NDC#	Manuf. Date	Expiration Date	Quantity (Patches)
Expanded to include	81637	0.1 mg/day	68968-6610-8	11/07/2016	Oct-18	250,720
Expanded to include	82139	0.05 mg/day	68968-6650-8	11/04/2016	Oct-18	408,344
Expanded to include	82199	0.025 mg/day	68968-6625-8	01/26/2017	Dec-18	129,864
Expanded to include	82200	0.1 mg/day	68968-6610-8	02/10/2017	Jan-19	181,702
Expanded to include	82292	0.05 mg/day	68968-6650-8	03/07/2017	Feb-19	423,010
Expanded to include	82293	0.1 mg/day	68968-6610-8	03/08/2017	Feb-19	244,496
Expanded to include	82598	0.05 mg/day	68968-6650-8	05/10/2017	Apr-19	397,312
Expanded to include	82599	0.075 mg/day	68968-6675-8	06/01/2017	May-19	324,448
Expanded to include	82600	0.1 mg/day	68968-6610-8	05/11/2017	Apr-19	270,120
Expanded to include	82660	0.075 mg/day	68968-6675-8	04/03/2017	Mar-19	135,528
Expanded to include	83025	0.025 mg/day	68968-6625-8	06/06/2017	May-19	79,872
Expanded to include	83027	0.1 mg/day	68968-6610-8	05/31/2017	Apr-19	277,624
Expanded to include	83173	0.1 mg/day	68968-6610-8	07/25/2017	Jun-19	235,296
Expanded to include	83395	0.075 mg/day	68968-6675-8	10/17/2017	Sep-19	139,288
Expanded to include	83396	0.1 mg/day	68968-6610-8	10/04/2017	Sep-19	281,608
Previously Reported	81391	0.1mg/day	68968-6610-8	11/08/2016	Oct-18	231,184
Previously Reported	81638	0.1 mg/day	68968-6610-8	11/09/2016	Oct-18	264,496
Previously Reported	81896	0.0375 mg/day	68968-6637-8	4/03/2017	Mar-19	260,632
Previously Reported	82264	0.0375 mg/day	68968-6637-8	1/26/2017	Dec-18	306,328

MANUFACTURED BY

NOVEN PHARMACEUTICALS, INC.

REASON FOR RECALL

This Expanded Recall has been initiated because MINIVELLE® patches in lot 81637 no longer met the

For any questions or concerns, ***please contact your Corporate Headquarters, Wholesaler***, or ***NOVEN PHARMACEUTICALS*** at: **1-800-455-8070, Option 1**

specification for shear, an attribute related to the adhesive properties of the Minivelle transdermal patches. Noven also included fourteen (14) additional Minivelle lots that currently meet specifications; however, they were manufactured with the same raw material and may no longer meet the specification for shear prior to expiry. As a result, patients may experience patches that do not stick well to skin.

This Expanded recall applies ONLY to the lots indicated in this notification*

POTENTIAL RISKS ASSOCIATED WITH THIS ISSUE

The potential for serious injury is low and NOVEN PHARMACEUTICALS is not aware of any serious health consequences related to this issue. Users may experience:

1. User inconvenience
2. Decreased or lack of drug effect with return of menopausal symptoms
3. Accidental secondary drug exposure

There is also a low risk of ingestion and/or choking in small children, if patches that fall off go unnoticed.

ACTIONS TO BE TAKEN

1. ***IMMEDIATELY STOP DISPENSING OR DISTRIBUTING*** the above specified lots of **MINIVELLE®**.
2. ***IDENTIFY, REMOVE, QUARANTINE AND COUNT*** your affected inventory of the above specified lots of MINIVELLE®.
3. ***COMPLETE THE ATTACHED "EXPANDED RECALL ACKNOWLEDGEMENT FORM"*** included with this letter and return to Cardinal SPS:

   Email: GMB-SPS-ReturnRequests@cordlogistics.com

   Fax: 614-652-0271

   a. ***If you do not have the impacted product lots,*** you must still complete the included "Expanded Recall Acknowledgement Form" and return it via email to Cardinal SPS:

   Email: GMB-SPS-ReturnRequests@cordlogistics.com,

   Fax: 614-652-0271

   b. ***If you do have the impacted product lots,*** upon receipt of your completed "Expanded Recall Acknowledgement Form", you will be sent a Product Return Package, including:

   - Return Authorization Number
   - Packing Slip and
   - a prepaid Return Shipping label

   c. ***DO NOT Return any recalled product to NOVEN PHARMACEUTICALS.*** For shipping assistance or questions about the recall process, please contact your ***Corporate Headquarters, Wholesaler, or Cardinal SPS*** via email to **GMB-SPS-ReturnRequests@cordlogistics.com**

4. ***IMMEDIATELY NOTIFY ANY DIRECT CUSTOMERS.*** If you have further distributed this product for ***RETAIL SALE***, you are requested to notify your customers to the ***RETAIL LEVEL by forwarding this***

Expanded Recall Notification and the Expanded Recall Acknowledgement Form to your direct customers, via your established recall procedure(s).

5. ***ONCE YOU RECEIVE THE PRODUCT RETURN PACKAGE:***
   - **a.** Complete the accompanying Packing Slip.
   - **b.** Enclose the completed Packing Slip along with the returned product.
   - **c.** Attach the prepaid Return Service shipping label to the outside of the return carton and
   - **d.** Return to: **Cardinal SPS, ATTN: FCA-2018-05-02.2**

OTHER INFORMATION

It is not necessary to notify any patients who might have received the MINIVELLE® lots indicated in this correspondence. In the event a patient requests information about MINIVELLE® and/or this recall please, direct them to contact the:

NOVEN MINIVELLE® INFORMATION LINE
1-800-455-8070, Option 1

A credit for the total number of MINIVELLE® boxes returned will be issued to each pharmacy through the Wholesaler or Corporate Headquarters. In order for credit to be issued for returned product, it is critical that the pharmacy location obtain the Debit Memo number from the Corporate Headquarters or Wholesaler and include this number on the Recall Acknowledgement Form, along with Wholesaler Name and Wholesaler Account number.

NOVEN PHARMACEUTICALS, INC.

FCA-2018-05-02.2
EXPANDED RECALL ACKNOWLEDGEMENT FORM

Complete this Expanded Recall Acknowledgement Form within 5 days of receipt by completing all fields.
Return this completed form via: **Email** to **GMB-SPS-ReturnRequests@cordlogistics.com**, *or* **Fax** to **614-652-0271.**

Customer† Account Name: _____ **Account Contact Name:** _____

Customer Address: _____ **Customer City/State:** _____

Customer Phone #: _____ **Customer Fax #:** _____

Customer DEA #: | | | | | | | | | |

Wholesaler Name: _____ **Wholesaler City/State:** _____

Wholesaler DEA #: | | | | | | | | | |

Debit Memo #: _____

†Note: "Customer" is defined as any secondary wholesaler, distributor, or retail pharmacy.

1. **Check *ALL* that apply:**

☐ ***I ACKNOWLEDGE THAT I HAVE RECEIVED*** and reviewed MINIVELLE® Expanded Recall Notification and that ***I UNDERSTAND ALL ACTIONS*** that I am required to take.

2. **I have:**

☐ ***NO EXPANDED RECALL EXPANDED AFFECTED PRODUCT on hand.*** No product will be returned and no reimbursement is required.

☐ ***THE FOLLOWING EXPANDED AFFECTED PRODUCT on hand AND*** will return it in accordance with the MINIVELLE® Recall Notification.

☐ ***THE FOLLOWING EXPANDED AFFECTED PRODUCT on hand BUT*** will return it in accordance with the pharmacy chain's own formal recall process:

3. **I have:**

☐ ***Further distributed the* Expanded *Recall Affected Product to another company for Further Distribution*** and will notify my direct customers as required.

☐ ***NOT further distributed the* Expanded *Recall Affected Product to another company for Further Distribution*** and I am not required to notify any customers. ***If you are a pharmacy that only sold to patients/caregivers, please check this box.***

For any questions or concerns, ***please contact your Corporate Headquarters, Wholesaler***, or ***NOVEN PHARMACEUTICALS*** at: **1-800-455-8070, Option 1**

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EXPANDED RECALL ACKNOWLEDGEMENT FORM

4. Please provide the quantity of Expanded Recalled Product that will be returned:

Brand Name	Lot Number	Strength	NDC#	Total QTY of Recalled Product to be Returned (Boxes)
MINIVELLE®	82199	0.025 mg/day	68968-6625-8	
MINIVELLE®	83025	0.025 mg/day	68968-6625-8	
MINIVELLE®	82139	0.05 mg/day	68968-6650-8	
MINIVELLE®	82292	0.05 mg/day	68968-6650-8	
MINIVELLE®	82598	0.05 mg/day	68968-6650-8	
MINIVELLE®	82660	0.075 mg/day	68968-6675-8	
MINIVELLE®	82599	0.075 mg/day	68968-6675-8	
MINIVELLE®	83395	0.075 mg/day	68968-6675-8	
MINIVELLE®	81637	0.1 mg/day	68968-6610-8	
MINIVELLE®	82200	0.1 mg/day	68968-6610-8	
MINIVELLE®	82293	0.1 mg/day	68968-6610-8	
MINIVELLE®	82600	0.1 mg/day	68968-6610-8	
MINIVELLE®	83027	0.1 mg/day	68968-6610-8	
MINIVELLE®	83173	0.1 mg/day	68968-6610-8	
MINIVELLE®	83396	0.1 mg/day	68968-6610-8	

Complete this Expanded Recall Acknowledgement Form within 5 days of receipt via:
Email to: **GMB-SPS-ReturnRequests@cordlogistics.com**, or
Fax to: **614-652-0271**

For any questions or concerns, ***please contact your Corporate Headquarters, Wholesaler***, or
NOVEN PHARMACEUTICALS at: **1-800-455-8070, Option 1**