March 2, 2020

Dear Sir or Madam,

This letter is to inform you that Noven Pharmaceuticals is initiating an URGENT DRUG RECALL involving:

![Figure 1. Product Labels](image)

<table>
<thead>
<tr>
<th>Lot Number</th>
<th>Strength (mg)</th>
<th>NDC#</th>
<th>Expiry Date</th>
<th>Manuf. Date</th>
<th>Date First Shipped</th>
<th>Quantity (Patches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>86280</td>
<td>10mg</td>
<td>68968-5552-3</td>
<td>06/2020</td>
<td>02/2019</td>
<td>05/2019</td>
<td>285,390</td>
</tr>
<tr>
<td>85942</td>
<td>15mg</td>
<td>68968-5553-3</td>
<td>03/2020</td>
<td>11/2018</td>
<td>04/2019</td>
<td>197,400</td>
</tr>
<tr>
<td>86281</td>
<td>15mg</td>
<td>68968-5553-3</td>
<td>06/2020</td>
<td>02/2019</td>
<td>06/2019</td>
<td>215,430</td>
</tr>
<tr>
<td>86081</td>
<td>20mg</td>
<td>68968-5554-3</td>
<td>04/2020</td>
<td>12/2018</td>
<td>05/2019</td>
<td>162,960</td>
</tr>
</tbody>
</table>
URGENT DRUG RECALL

<table>
<thead>
<tr>
<th>Lot Number</th>
<th>Strength</th>
<th>Batch Number</th>
<th>Expiration Date 1</th>
<th>Expiration Date 2</th>
<th>Expiration Date 3</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>86196</td>
<td>20mg</td>
<td>68968-5554-3</td>
<td>06/2020</td>
<td>02/2019</td>
<td>07/2019</td>
<td>169,830</td>
</tr>
<tr>
<td>86083</td>
<td>30mg</td>
<td>68968-5555-3</td>
<td>05/2020</td>
<td>01/2019</td>
<td>04/2019</td>
<td>115,740</td>
</tr>
<tr>
<td>86282</td>
<td>30mg</td>
<td>68968-5555-3</td>
<td>06/2020</td>
<td>02/2019</td>
<td>05/2019</td>
<td>108,330</td>
</tr>
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</table>

Please review the attached Recall Notification and follow the instructions.

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, 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 Recall Notification and NOVEN Recall Acknowledgement Form to your direct customers.

If you have any questions, please contact NOVEN PHARMACEUTICALS at 1-800-455-8070, Option 3, or via email to fca@noven.com

This recall is being initiated with the knowledge of the Food and Drug Administration.

Best regards,

Mark Jackson
Vice President - Quality & Operations
NOVEN PHARMACEUTICALS
# URGENT DRUG RECALL

**FCA-2020-02-01**

DAYTRANA® (methylphenidate transdermal system)

<table>
<thead>
<tr>
<th>Lot</th>
<th>Strength</th>
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**Figure 1. Product Labels**

[Image of product labels]
URGENT DRUG RECALL
FCA-2020-02-01

MANUFACTURED BY
NOVEN PHARMACEUTICALS, INC.

REASON FOR RECALL
This recall has been initiated because DAYTRANA® patches in lot 86081 and 86083 were found to be out of specification (OOS) for mechanical peel and DAYTRANA® patches in lot 86280 and 85942 were found to be out of specification (OOS) for shear. The investigation of these events led to conclude that there is a multifactor root cause involving specific acrylic and silicone raw material lots. All Daytrana lots using this combination of acrylic and silicone raw materials are included within the scope of this recall; therefore, Daytrana 15mg lot 86281, Daytrana 20mg lot 86196, and Daytrana 30mg lot 86282 were also included along with lots which produced OOS peel and shear results.

As a result, patients and caregivers could potentially experience one or more of the following:
1. Transfer of adhesive from the patch to the liner when removing the liner.
2. Difficulty removing the patch from the liner.
3. Tearing of the patch while attempting to remove from the liner.
4. Patches do not stick well to skin when applied (won’t stick or falls off).

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

POTENTIAL RISKS ASSOCIATED WITH THIS ISSUE
1. User annoyance.
2. Decreased or lack of drug effect.
3. Accidental drug exposure to caregivers or others.

Of note: The potential for serious injury is very low and Noven Pharmaceuticals is not aware of any serious health consequences related to this issue.

ACTIONS TO BE TAKEN
1. IMMEDIATELY STOP DISPENSING OR DISTRIBUTING the above specified lots of DAYTRANA®.

2. IDENTIFY, REMOVE, QUARANTINE AND COUNT your affected inventory of the above specified DAYTRANA® lots.

3. COMPLETE THE ATTACHED “NOVEN RECALL ACKNOWLEDGEMENT FORM” included with this letter and return via email to: GMB-SPS-ReturnRequests@cordlogistics.com, or Fax to 614-652-0271.

   a. If you do not have the impacted product lot, you must still complete the included “NOVEN Recall Acknowledgement Form” and return to Cardinal SPS:

      Email - GMB-SPS-ReturnRequests@cordlogistics.com, or
      Fax - 614-652-0271

   b. If you do have the impacted product lot, upon receipt of your completed “NOVEN Recall Acknowledgement Form”, you will be sent a Product Return Package, including:
      • Return Authorization Number
      • a DEA Form 222,
      • Packing Slip and
URGENT DRUG RECALL
FCA-2020-02-01

- a prepaid return service shipping label to return recalled product to:
  Cardinal SPS
  Attn: FCA-2020-02-01

c. **DO NOT return any recalled product directly 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
d. **Please note that return of product via Genco and/or Inmar (third-party processors) will not be accepted by Cardinal SPS.** Genco and Inmar must destroy the product and provide Proof of Destruction (POD) to via email to: GMB-SPS-ReturnRequests@cordlogistics.com in order for you to receive credit.

4. **IMMEDIATELY NOTIFY ANY DIRECT CUSTOMERS.** If you have further distributed this product for commercial sale, you are requested to notify your customers **TO THE RETAIL LEVEL** by forwarding this Recall Notification and the NOVEN 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 & DEA Form 222†.
   b. Enclose the completed Packing Slip and DEA Form 222, 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-2020-02-01

†Please note, a completed DEA Form 222 is required to process your return.

**OTHER INFORMATION**

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

   NOVEN MEDICAL INFORMATION
   1-800-455-8070, Option 3

2. A credit for the total number of DAYTRANA® 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 your Wholesaler and include this number on Recall the Acknowledgement Form, along with Wholesaler Name and Wholesaler Account number.
Complete this 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 City/State: ______________________________ Customer Phone #: ________________________________

Customer DEA #: __________________________________________________________

Wholesaler Name: ___________________________ Wholesaler City/State: ________________________________

Wholesaler DEA #: __________________________________________________________

Debit Memo #: __________________________________________________________

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

Check **ALL** that apply:

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

2. I have:

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

  ☐ THE FOLLOWING RECALL AFFECTED PRODUCT on hand AND will return it in accordance with the DAYTRANA® Recall Extended Notification.

  ☐ THE FOLLOWING RECALL AFFECTED PRODUCT on hand BUT will return it in accordance with the pharmacy chain’s own formal recall process. **Please note that return of controlled product via Genco and/or Inmar (returns processors) will not be accepted by Cardinal SPS. Genco and Inmar must destroy the product and provide Proof of Destruction (POD) to via email to: GMB-SPS-ReturnRequests@cordlogistics.com**

3. I HAVE:

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

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

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

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Lot Number</th>
<th>Strength</th>
<th>NDC#</th>
<th>Total QTY of Recalled Product to be Returned (Boxes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAYTRANA®</td>
<td>86280</td>
<td>10mg</td>
<td>68968-5552-3</td>
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For any questions or concerns, please contact your Corporate Headquarters, Wholesaler, or NOVEN PHARMACEUTICALS at: 1-800-455-8070, Option 3
**FCA-2020-02-01**  
**RECALL ACKNOWLEDGEMENT FORM**

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*Complete this 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 3