

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Apotex Corp. is recalling eighteen (18) lots of Paroxetine Tablets, USP as identified below to the Retail/Pharmacy level. This recall is being initiated due to six (6) lots (RV2375, RV2376, RV2377, RV2384, RV2385 and RV2254) in which the specification limit of not more than 0.33% for Amadori Glucose adduct of Paroxetine (PR RC5) has been exceeded at 36-month timepoint. There have been no reports of relevant adverse event or complaints received for any of these six (6) lots between 08/09/2020 and 10/24/2023. Out of an abundance of caution, the company extends the recall to include twelve (12) additional lots as identified below. The details for the lots being recalled are listed below.

| <b>Product</b>                     | <b>Strength</b> | <b>Pack Size</b>         | <b>NDC</b>               | <b>UPC Code</b>     | <b>Lot Number</b> | <b>Expiry Date (mm/yyyy)</b> | <b>First Date of Sale<br/>(mm/dd/yyyy)</b> | <b>Last Date of Sale<br/>(mm/dd/yyyy)</b> |
|------------------------------------|-----------------|--------------------------|--------------------------|---------------------|-------------------|------------------------------|--|---|
| <b>Paroxetine<br/>Tablets, USP</b> | <b>10 mg</b>    | <b>100's<br/>Bottle</b>  | <b>60505-<br/>0097-2</b> | <b>360505009725</b> | <b>RV2376</b>     |                              | <b>10/01/2021</b>                          | <b>05/02/2022</b>                         |
|                                    |                 |                          |                          |                     | <b>RV2377</b>     |                              | <b>11/05/2021</b>                          | <b>10/25/2022</b>                         |
|                                    |                 | <b>1000's<br/>Bottle</b> | <b>60505-<br/>0097-4</b> | <b>360505009749</b> | <b>RV2379</b>     |                              | <b>08/10/2021</b>                          | <b>03/30/2022</b>                         |
|                                    |                 |                          |                          |                     | <b>RV2380</b>     |                              | <b>04/26/2022</b>                          | <b>08/29/2022</b>                         |
|                                    |                 | <b>30's<br/>Bottle</b>   | <b>60505-<br/>0097-1</b> | <b>360505009718</b> | <b>RV2375</b>     |                              | <b>07/26/2021</b>                          | <b>04/05/2022</b>                         |
|                                    | <b>20 mg</b>    | <b>100's<br/>Bottle</b>  | <b>60505-<br/>0083-2</b> | <b>360505008322</b> | <b>RV2384</b>     | <b>08/2024</b>               | <b>10/17/2020</b>                          | <b>08/03/2021</b>                         |
|                                    |                 |                          |                          |                     | <b>RV2385</b>     |                              | <b>08/04/2021</b>                          | <b>09/28/2021</b>                         |
|                                    |                 | <b>1000's<br/>Bottle</b> | <b>60505-<br/>0083-4</b> | <b>360505008346</b> | <b>RV2396</b>     |                              | <b>01/21/2021</b>                          | <b>08/20/2021</b>                         |
|                                    |                 |                          |                          |                     | <b>RV2397</b>     |                              | <b>01/22/2021</b>                          | <b>08/09/2021</b>                         |
|                                    | <b>30 mg</b>    | <b>100's<br/>Bottle</b>  | <b>60505-<br/>0084-2</b> | <b>360505008421</b> | <b>RV8686</b>     |                              | <b>04/27/2021</b>                          | <b>08/13/2021</b>                         |
|                                    |                 | <b>1000's<br/>Bottle</b> | <b>60505-<br/>0084-4</b> | <b>360505008445</b> | <b>RX0119</b>     |                              | <b>02/12/2021</b>                          | <b>09/28/2021</b>                         |
|                                    |                 |                          | <b>RX0120</b>            |                     |                   | <b>09/28/2021</b>            | <b>08/01/2022</b>                          |   |

|              |                          |                          |                            |                   |                   |
|--------------|--------------------------|--------------------------|----------------------------|-------------------|-------------------|
|              | <b>30's<br/>Bottle</b>   | <b>60505-<br/>0084-1</b> | <b>360505008414 RV2254</b> | <b>01/15/2021</b> | <b>04/01/2021</b> |
|              |                          |                          | <b>RV0131</b>              | <b>10/29/2020</b> | <b>04/14/2021</b> |
|              |                          |                          | <b>RV2387</b>              | <b>04/19/2021</b> | <b>07/22/2021</b> |
| <b>40 mg</b> | <b>1000's<br/>Bottle</b> | <b>60505-<br/>0101-4</b> | <b>360505010141 RV2389</b> | <b>10/29/2021</b> | <b>02/09/2022</b> |
|              |                          |                          | <b>RW3296</b>              | <b>02/09/2022</b> | <b>05/11/2022</b> |
|              |                          |                          | <b>RV2388</b>              | <b>07/22/2021</b> | <b>10/29/2021</b> |