

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.

SCA Pharmaceuticals (SCA) is expanding a recall previously initiated on June 16, 2020, based upon the results of our investigation.

SCA had previously recalled one lot of compounded product due to an out-of-specification stability test result at the 30-day stability test timepoint. This out-of-specification stability test result indicated that acceptable potency would not be maintained through the currently labelled shelf life for the lot in question. Our investigation has now concluded that the out-of-specification stability test failure is applicable to all lots currently within expiry for this specific NDC.

This recall is being carried out at the hospital level with the knowledge of the Food and Drug Administration.

Product details of the original recall are as follows:

| Product Name | NDC Number | Lot Number | Beyond Use Date | Quantity Shipped | Dates Distributed |
|---|-------------------|------------|-----------------|------------------|--------------------------|
| Heparin Sodium 5,000 units in 0.9% Sodium Chloride 1000mL Bag (5 units/mL) | 70004-0650- 46 | 1220017764 | 6/24/2020 | 333 | 4/27/2020 – 4/30/2020 |

Product details of the expanded recall are as follows:

| Product Description | NDC Number | Lot Number | Beyond Use Date | Quantity Shipped | Dates Distributed |
|---------------------|------------|------------|-----------------|------------------|--------------------------|
| | | 1220018755 | 7/30/2020 | 277 | 6/2/2020 – 6/16/2020 |
| | | 1220018861 | 8/4/2020 | 368 | 6/3/2020 – 6/16/2020 |
| | | 1220018850 | 8/4/2020 | 366 | 6/11/2020 – 6/16/2020 |

| Product Description | NDC Number | Lot Number | Beyond Use Date | Quantity Shipped | Dates Distributed |
|----------------------------|-------------------|-------------------|------------------------|-------------------------|--------------------------|
| Heparin Sodium | | 1220018899 | 8/5/2020 | 372 | 6/9/2020 – 6/18/2020 |
| 5,000 units in | | 1220019027 | 8/11/2020 | 371 | 6/18/2020 – 6/30/2020 |
| 0.9% Sodium Chloride | 70004-0650-46 | | | | |
| 1000mL Bag | | 1220019075 | 8/12/2020 | 368 | 6/17/2020 – 6/30/2020 |
| (5 units/mL) | | 1220019243 | 8/20/2020 | 342 | 6/24/2020 – 6/30/2020 |
| | | 1220019439 | 8/24/2020 | 375 | 6/24/2020 – 7/8/2020 |
| | | 1220019279 | 8/24/2020 | 369 | 6/30/2020 – 7/7/2020 |
| | | 1220019392 | 8/24/2020 | 369 | 6/30/2020 – 7/7/2020 |
| | | 1220019488 | 8/26/2020 | 355 | 6/26/2020 – 7/8/2020 |