Exela Pharma Sciences, LLC Issues Voluntary Nationwide Recall of
Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL Vial, 20-Count Carton due to Vial Breakage

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FOR IMMEDIATE RELEASE – October 12, 2022 – Lenoir, North Carolina. Exela Pharma Sciences, LLC, (Exela) is voluntarily recalling 49 lots of Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL vial, 20-count carton, to the consumer level.

Risk Statement: The product poses a potential safety concern with vial breakage and flying glass when pressurized while preparing the product for administration. Exela has received five (5) reports of flying glass injuring skin, eye and/or other parts. There have been no reports of sterility failures.

The product is used for treatment of metabolic acidosis and is packaged in a 50 mL glass vial, 20 vials per carton. The vials are labeled with Exela brand (Carton NDC: 51754-5001-5; Vial NDC: 51754-5001-1, Figure 1) and Civica brand (Carton NDC: 72572-740-20; Vial NDC: 72572-740-1, Figure 2).

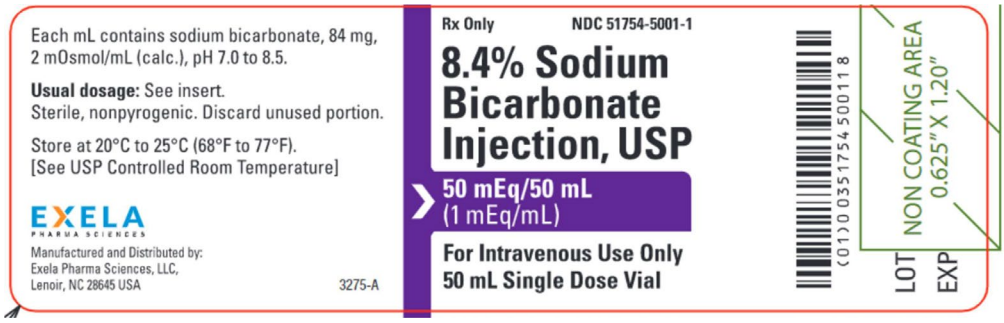

Figure 1 – Exela Vial Label

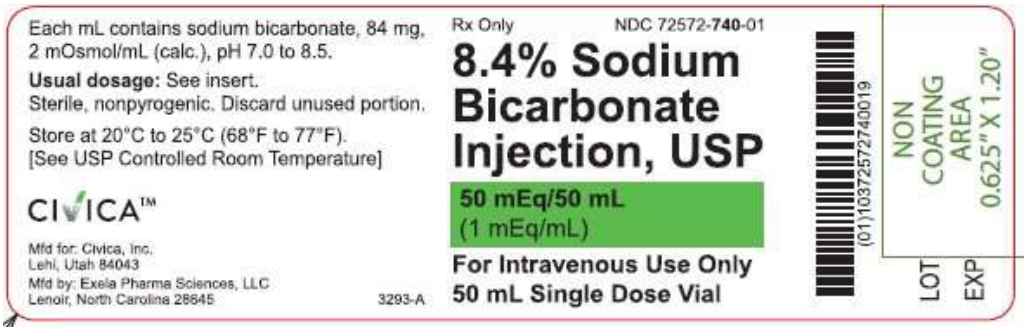

Figure 2 – Civica Vial Label

The affected Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL lots (covering both Exela and Civica brands) include the following lot numbers and expiration dates:

Brand	Lot	Expire Date
Exela	P0001370	10/2023

Brand	Lot	Expire Date
Exela	P0001371	10/2023
Exela	P0001372	10/2023
Exela	P0001433	11/2023
Exela	P0001434	11/2023
Exela	P0001443	12/2023
Exela	P0001468	12/2023
Exela	P0001469	12/2023
Exela	P0001470	12/2023
Exela	P0001495	12/2023
Exela	P0001505	12/2023
Exela	P0001506	12/2023
Exela	P0001509	12/2023
Exela	P0001510	12/2023
Exela	P0001511	12/2023
Exela	P0001512	12/2023
Exela	P0001560	01/2024
Exela	P0001561	01/2024
Exela	P0001562	01/2024
Exela	P0001564	01/2024
Exela	P0001566	01/2024

Brand	Lot	Expire Date
Exela	P0001567	01/2024
Exela	P0001568	01/2024
Exela	P0001571	02/2024
Exela	P0001572	02/2024
Exela	P0001573	02/2024
Exela	P0001574	02/2024
Exela	P0001578	02/2024
Exela	P0001579	02/2024
Exela	P0001580	02/2024
Exela	P0001583	02/2024
Exela	P0001586	02/2024
Exela	P0001587	02/2024
Exela	P0001588	02/2024
Exela	P0001593	02/2024
Exela	P0001594	02/2024
Exela	P0001610	02/2024
Exela	P0001618	02/2024
Exela	P0001619	02/2024
Exela	P0001644	03/2024
Exela	P0001645	03/2024

Brand	Lot	Expire Date
Exela	P0001646	03/2024
Exela	P0001654	02/2024
Exela	P0001662	03/2024
Exela	P0001664	03/2024
Exela	P0001730	05/2024
Civica	P0001497	12/2023
Civica	P0001600	02/2024
Civica	P0001663	03/2024

The Exela product (Carton NDC: 51754-5001-5; Vial NDC: 51754-5001-1) can be identified by the NDC numbers, and by the yellow flip-top safety cap on the 50 mL vial. The carton bears a purple stripe containing concentration information and the manufacturer name “Exela Pharma Sciences” in the lower right-hand corner. The vial label bears a purple stripe containing concentration information with the name “Exela Pharma Sciences” on the back.

The Civica Product (Carton NDC: 72572-740-20; Vial NDC: 72572-740-1) can be identified by the NDC numbers, by the yellow flip-top safety cap on the 50 mL vial, and by the carton which bears a green stripe containing concentration information and the manufacturer name “Civica” in the lower right-hand corner. The vial label bears a green stripe containing concentration information with the name “Civica” on the back.

All the above-listed lots are supplied in 20 count cartons only. This recall is not expected to cause drug shortage.

Product was distributed nationwide to wholesalers, distributors, and other customers between December 16, 2021 and August 10, 2022.

Exela is notifying its customers by e-mail and certified mail and is arranging for return and replacement of all recalled product directly to Exela. Customers that have product which is being recalled should discontinue use, segregate the recalled product, submit a recall stock response form to Exela (even if there is no product to return), and hold the product until shipment instructions are provided by Exela.

Customers with questions regarding this recall can contact Exela by phone (828-341-6118 x1017) or email (recall@exela.us) Monday through Friday, 9:00am – 5:00pm ET. Consumers should contact their physician or healthcare provider if they have experienced any problems related to the usage of this drug product.

Additionally, adverse events or quality problems experienced with the use or handling of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.