Subject: **Ascor® (Ascorbic Acid Injection, USP) PRESCRIBING CHANGE**
NDC 67157-101-50 and NDC 67157-101-51

November 13, 2025

Dear Healthcare Provider,

McGuff Pharmaceuticals, Inc. would like to inform you of important safety information regarding Ascor® Ascorbic Acid Injection, USP (500 mg/mL).

Potential Safety Issue

A recent facility recertification identified a condition that may theoretically impact sterility assurance for certain lots of Ascor® Ascorbic Acid Injection, USP. All affected lots passed sterility, endotoxin, and particulate testing, and no contamination complaints or adverse events have been reported. An independent Health Hazard Evaluation concluded that the probability of adverse health consequences is remote.

Out of an abundance of caution and in coordination with the U.S. Food and Drug Administration (FDA), McGuff Pharmaceuticals, Inc. is providing additional instructions for healthcare providers who may have Ascor® product from the distributed lots listed below.

Impacted Distributed Lots:

25B0051, 25B0061, 25B0081, 25C0011, 25C0021, 25C0031, 25C0061, 25C0071, 25C0081, 25C0091, 25D0011, 25D0021, 25D0061, 25D0081, 25D0091, 25D0101, 25D0112, 25E0021

Important Instructions for Healthcare Providers

If you have Ascor® Ascorbic Acid Injection, USP from any of the distributed lots listed below, please adhere to the following guidance:

- Prepare and administer the product only via a self-procured sterilizing filter meeting the following criteria:
  - 0.22 µm or 0.45 µm pore size
  - Adequate membrane surface area to accommodate the full administration volume
- Perform filtration immediately prior to patient administration under aseptic conditions.
- Administer only in healthcare settings where patients can be appropriately monitored.
- Monitor patients during and after administration for any signs or symptoms of infection or pyrogenic reaction (e.g., fever, chills, rigors, tachycardia, malaise, or hypotension not otherwise explained by the patient's clinical condition).
- Discontinue use immediately if contamination or sterility failure is suspected and provide supportive medical management as clinically indicated.

This additional filtration step provides an extra margin of sterility assurance for product from the lots identified below.

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WEBSITE: mcguffpharmaceuticals.com

Reporting Adverse Events and Medication Errors

Healthcare providers and patients are encouraged to report adverse events and medication errors associated with the use of Ascor® Ascorbic Acid Injection, USP to McGuff Medical at 1-800-603-4795.

Adverse events, medication errors, or quality problems may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Mail or Fax: Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a form, then complete and return to the address on the form or fax to 1-800-FDA-0178 (1-800-332-0178).

For questions regarding this information or the safe and effective use of Ascor® Ascorbic Acid Injection, USP, please contact our Medical Information department at 1-800-603-4795.

Sincerely,

Regulatory Affairs Management
McGuff Pharmaceuticals, Inc.