CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

209112Orig1s008

Trade Name:	**ASCOR**
Generic or Proper Name:	(ascorbic acid)
Sponsor:	MCGUFF PHARMACEUTICALS, INC.
Approval Date:	April 23, 2023

Indication:

ASCOR is vitamin C indicated for the term (up to 1 week) treatment of scurvy in adult and pediatric patients age 5 months and older for whom oral administration is not possible, insufficient or contraindicated.

Limitations of Use

ASCOR is not indicated for treatment of vitamin C deficiency that is not associated with signs and symptoms of scurvy.

CENTER FOR DRUG EVALUATION AND RESEARCH

209112Orig1s008

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 209112/S-008

APPROVAL LETTER

McGuff Pharmaceuticals, Inc.
Attention: Jacqueline McKay
Regulatory Affairs Manager
2921 West MacArthur Blvd., Suite 141
Santa Ana, CA 92704

Dear Ms. McKay:

Please refer to your Supplemental New Drug Application (sNDA) dated December 6, 2022, and received December 7, 2022, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ascor (ascorbic acid injection).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of McGuff Pharmaceuticals, Inc (FEI: 2022073) as an additional site (b) (4) (b) (4) of the drug product.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christopher LaFleur, Regulatory Business Process Manager, at (240) 402 - 4724.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch 1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209112Orig1s008

PRODUCT QUALITY REVIEW(S)

Office of Lifecycle Drug Products
Division of Post-Marketing Activities I
Review of Chemistry, Manufacturing, and Controls

1. **NDA Supplement Number:** NDA-209112-SUPPL-008
   sNDA Recommendation: Approval
   sNDA Managed by: OPQ

2. **Submission(s) Being Reviewed**:

Submission	Type	Submission Date	CDER Stamp Date	Assigned Date	PDUFA Goal Date	Review Date
Original Supplement	CBE-30	12/06/2022	12/07/2022	12/08/2022	06/07/2023	04/20/2023

3. **Provides For:**

   - Addition of McGuff Pharmaceuticals, Inc (FEI: 2022073) as an additional site (b) (4) (b) (4) of ASCOR®.

4. **Review #**: 01

5. **Clinical Review Division**: OCHEN/DGE

6. **Name and Address of Applicant**:
   McGuff Pharmaceuticals, Inc.
   29211 W. MacArthur Boulevard, Suite 141
   Santa Ana, CA, USA, 92704

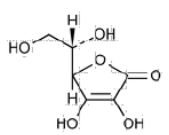
   Contact: Damon Jones
   Phone: 714-918-7277 x 300
   Email: djones@mcguff.com

7. **Drug Product**:

Drug Name	Dosage Form	Strength	Route of Administration	Rx or OTC	Special Product	Orphan Designation
ASCOR (ascorbic acid injection)	Solution for injection	25,000 mg /50 mL*	Intravenous	Rx	Yes	07-2437

*** (500 mg/mL) only supplied as a pharmacy bulk package**

8. **Chemical Name and Structure of Drug Substance**:

	**USAN:** Ascorbic Acid, USP **Chemical Name:** (2R)-2-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxy-2H-furan-5-one **Molecular Formula:** $C_6H_8O_6$ **MW**: 176.12 g/mol

9. **Indication**: ASCOR® is indicated for the short term (up to 1 week) treatment of scurvy in adult and pediatric patients, age 5 months and older, for whom oral administration is not possible, insufficient or contraindicated.

10. **Supporting/Related Documents**: None

11. **Disciplines/Consults**: None

12. **Executive Summary**:

ASCOR (ascorbic acid injection) 25,000 mg /50 mL (500 mg/mL) pharmacy bulk packages are indicated in the treatment of scurvy. ASCOR is currently manufactured, tested, packaged and stored at McGuff Pharmaceuticals, Inc (FEI: 2022073, 2921 W MacArthur Blvd, Santa Ana, CA). The drug product, supplied in a pharmacy bulk package (PBP), is dispensed as a single dose to multiple patients in a pharmacy admixture program within 4 hours of puncture. Currently, the drug product is stored in a refrigerator at 2° to 8°C (36° to 46°F) with an expiry of 24 months. Supplement 007 was approved to update the package insert instructions to add the following text, "Excursions to ambient conditions for up to 30 days during storage or shipping are acceptable."

Supplement 008 proposes the addition of McGuff Pharmaceuticals, Inc (FEI: 2022073, (b) (4) as an additional site (b) (4) of ASCOR®. The proposed McGuff facility is currently used for (b) (4) of the drug product. The firm has provided (b) (4) to be used at the proposed site. There is no proposed change to (b) (4) as a result of the proposed change. Since the proposed facility (b) (4) of the final drug product there is no OPMA/Facility evaluation needed.

The proposed change is recommended for approval.

13. **Conclusions & Recommendations**:

This supplement is recommended for approval.

14. **Comments/Deficiencies to be Conveyed to Applicant**: None

15. **Primary Reviewer**:
Sarah C. Zimmermann, Ph.D., CMC reviewer, Branch 1, DPMAI, OLDP, OPQ

16. **Secondary Reviewer**:
Ramesh Raghavachari, Ph.D., Branch Chief, Branch 1, DPMAI, OLDP, OPQ

Sarah Zimmermann

Digitally signed by Sarah Zimmermann
Date: 4/20/2023 03:44:52PM
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Ramesh Raghavachari

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