



NDA 209112/S-007

SUPPLEMENT APPROVAL

McGuff Pharmaceuticals, Inc.
Attention: Damon P. Jones
Vice President and Director of Operations
2921 W. MacArthur Boulevard, Suite 141
Santa Ana, CA 92704

Dear Mr. Jones:

Please refer to your Supplemental New Drug Application (sNDA) dated January 12, 2022, and received January 19, 2022, and your amendment, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ascor (ascorbic acid injection).

This Prior Approval supplemental new drug application provides for labeling changes to allow ambient storage/shipping of Ascor for up to 30 days.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling and with minor editorial revisions listed below and reflected in the enclosed labeling.

The revision date listed at the end of the Highlights of Prescribing Information has been updated to "07/2022" and the grammatical error identified in the second sentence in Section 5.2 to add "deficiency".

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] in MS Word format, that includes the changes with the revisions listed above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (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

Enclosure:
Content of Labeling



Ramesh
Raghavachari

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