

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-881

CORRESPONDENCE

February 14, 2001

Mr. Gary Buehler
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

MINOR DRUG AMENDMENT
Am

RE: Levocarnitine Injection, USP
ANDA 75-881

MINOR AMENDMENT

Dear Mr. Buehler,

Reference is made to Gensia Sicor's ANDA 75-881 for Levocarnitine Injection, USP, 200 mg/mL, which was submitted to the Agency on May 22, 2000. Reference is also made to our amendment dated December 22, 2000. Further reference is made to the Agency's facsimile dated February 6, 2001.

In accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby amend our application to provide the additional **chemistry** information requested

We trust you will find the information in this amendment satisfactory for your review and approval. If you have any questions or require additional information, please contact me at (949) 455-4724. I can also be reached by facsimile at (949) 583-7351.

Sincerely,

Elvia O. Gustavson

Elvia O. Gustavson
Director, Regulatory Affairs

H:\DATA\IRGL\Levocarnitine75881\Amends\Amend4.doc

cc: Mr. Alonza Cruse
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612



ACW
2-15-01

January 19, 2001

Mr. Gary Buehler
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

ANDA 75-881 AMENDMENT
AS

RE: Levocarnitine Injection, USP
ANDA 75-881

**AMENDMENT
RESPONSE TO MICROBIOLOGY DEFICIENCIES**

Dear Mr. Buehler,

Reference is made to Gensia Sicor's ANDA 75-881 for Levocarnitine Injection, USP, 200 mg/mL, which was submitted to the Agency on May 22, 2000. Reference is also made to our amendment dated December 22, 2000. Further reference is made to the Agency's facsimile dated January 19, 2001.

In accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby amend our application to provide the additional **microbiology** information requested

We trust you will find the information in this amendment satisfactory for your review and approval. If you have any questions or require additional information, please contact me at (949) 455-4724. I can also be reached by facsimile at (949) 583-7351.

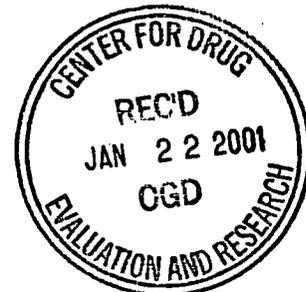
Sincerely,

Rosalie A. Lowe

for Elvia O. Gustavson
Director, Regulatory Affairs

H:\DATA\URG\Levocarnitine75881\Amends\Amend3.doc

cc: Mr. Alonza Cruse
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612



ORIG AMENDMENT

N/AM

December 22, 2000

Mr. Gary Buehler
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: Levocarnitine Injection, USP
ANDA 75-881

MINOR AMENDMENT

Dear Mr. Buehler,

Reference is made to Gensia Sicor's ANDA 75-881 for Levocarnitine Injection, USP, 200 mg/mL, which was submitted to the Agency on May 22, 2000. Reference is also made to the Agency's letter dated November 24, 2000.

In accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby amend our application to provide the additional **chemistry and labeling** information requested

We trust you will find the information in this amendment satisfactory for your review and approval. If you have any questions or require additional information, please contact me at (949) 455-4724. I can also be reached by facsimile at (949) 583-7351.

Sincerely,

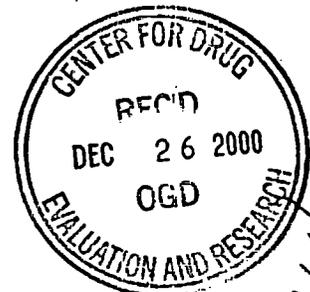
Elvia O. Gustavson

Elvia O. Gustavson
Director, Regulatory Affairs

S:\Levocarnitine\Amends\Amend1.doc

cc: Mr. Alonza Cruse
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

000003



00-822-21
ML



July 14, 2000

Mr. Gary Buehler
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: Levocarnitine Injection, USP
ANDA No. To Be Assigned

TELEPHONE AMENDMENT

Dear Mr. Buehler,

Reference is made to Gensia Sicor's ANDA (number to be determined) for Levocarnitine Injection, USP, 200 mg/mL, which was submitted to the Agency on May 22, 2000. Reference is also made to the telephone conversations between Lt. Greg Davis and myself. Further reference is made to the request from Lt. Greg Davis to revise the following:

- Form 356h to include the correct name of the Reference Listed Drug.
- Provide a copy of the Filter Validation Study Report, inadvertently omitted from the Validation of the Sterility Assurance Processes, Attachment 11.
- Provide revised batch record documentation (i.e., Bill of Material) to delineate the proposed maximum fill-off volume for each strength. Specifically, the maximum batch size designated for the 1 g/5 mL size and for the 2.5 g/12.5 mL size. We commit to scale-up proportionately in accordance with the guidance entitled "Post Approval Changes to an Approved NDA/ANDA".

The corrected Form 356h is provided in **Attachment 1**, Filter Validation Study Report is provided in **Attachment 2**, and the revised Bill of Materials (BOMs) for the 1 g/5 mL and 2.5 g/12.5 mL vial configurations are provided in **Attachment 3**

Mr. Gary Buehler
July 14, 2000
Page 2

We trust that the information provided is in accordance with the request from the agency. Should you have any additional questions regarding our application, please feel free to contact me at (949) 455-4724 or by facsimile at (949) 583-7351.

Sincerely,

Elvia O. Gustavson
Elvia O. Gustavson
Associate Director, Regulatory Affairs

S:\lvocam\lrm\Amend5\Amend1.doc

cc: Acting District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

000004