



NDA 208630/S-003

**SUPPLEMENT APPROVAL**

NX Development Corp  
Attention: Alan M. Ezrin, Ph.D.  
President and Chief Executive Officer  
1827 South Bayshore Lane  
Miami, FL 33133

Dear Dr. Ezrin:

Please refer to your Supplemental New Drug Application (sNDA) dated August 3, 2018, received August 3, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gleolan (aminolevulinic acid hydrochloride) for oral solution, 1500 mg.

This “Prior Approval supplemental new drug application provides for the following change(s) for Gleolan:

Package insert:

Correct the typographical error in the adverse reactions section of the package insert, replace “hypertension” with “hypotension.”

Remove the following statement in the package insert: “Manufactured by LYOCONTRACT GmbH, Pulverwiese 1, Ilsenburg, 38871, Germany”

Carton and Container Labeling:

- Revise role of NXDC to state, “Distributed by: NX Development Corp” along with the address
- Addition of statement “Product of Germany”
- Addition of the actual UPC Code
- Change in vial contents under “Each vial contains”, from grams to milligrams to be consistent with the package insert and for clarity
- Addition of post-reconstitution instructions to stress the importance of 24-hour post reconstitution hold time
- Deletion of the statements under “Storage”- “see USP controlled room temperature” due to redundancy with the stated temperature

## **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 enclosed, agreed-upon labeling text.

## **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 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 from 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(l)(1)(i)] in MS Word format, that includes the changes 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).

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the enclosed carton label submitted on August 3, 2018 and immediate container label submitted on August 16, 2018 as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 208630/S-003.**” Approval of this submission by FDA is not required before the labeling is used.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

### **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 Alberta Davis-Warren, Regulatory Project Manager, at 301-796-3908.

Sincerely,

*{See appended electronic signature page}*

Libero Marzella, M.D., Ph.D.  
Director  
Division of Medical Imaging Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

Content of Labeling  
Carton and Container Labeling

-----  
**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
-----

/s/  
-----

ALEXANDER GOROVETS  
08/22/2018

7