



NDA 212501/S-003

**SUPPLEMENT APPROVAL**

Ingenus Pharmaceuticals LLC  
c/o Riconpharma LLC  
Attention: Mukteeshwar Gande  
Chief Scientific Officer  
100 Ford Road, Suite 9  
Denville, NJ 07834

Dear Mr. Gande:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 21, 2021, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cyclophosphamide injection.

We also refer to our approval letter dated November 19, 2021, which contained the following error: The action letter exhibited on page 3 contains the following error: 'In the PRESCRIBING INFORMATION under RECENT MAJOR CHANGES, the date is XX/XXXX and Revised: XX/XXXX ' The corrected dates are below: 'In the PRESCRIBING INFORMATION under RECENT MAJOR CHANGES, the date corrected is 09/2021 and Revised: 11/2021'.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain November 19, 2021, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for:

1. An additional fill volume of 2 g/ 10 mL (200 mg/mL) for Cyclophosphamide Injection.
2. Changes to Drug Substance Specifications as referenced in DMF (b) (4)
3. Administrative changes for the Drug Substance testing facility (b) (4)
4. Addition of (b) (4) excipient.
5. Addition of (b) (4)

**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.

We note that your September 17, 2021, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible

for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

### **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 Effectuated" (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(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 CONTAINER LABELS**

We acknowledge your September 17, 2021, submission containing final printed carton and container labeling.

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 Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Branch Chief, B1  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):  
Content of Labeling  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
Date: 6/25/2024 11:50:09AM  
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