



NDA 011525/S-043

## SUPPLEMENT APPROVAL

Renew Pharmaceuticals Limited  
c/o Cardinal Health Regulatory Sciences  
Attention: Nealie Newberger  
Sr Scientist, CMC  
7400 W 110th St. Suite 150  
Overland Park, KS 66210

Dear Nealie Newberger:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 24, 2025, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for IC-Green (sterile indocyanine green for injection).

This “Changes Being Effected” supplemental new drug application provides for the Applicant’s response to FDA Labeling CBE Supplement Request (Reference ID: 5672371) Dated October 7, 2025, which:

1. Clarified that [REDACTED] (b) (4) not included in the [REDACTED] (b) (4) [REDACTED].
2. Clarified the drug product composition table.
3. Added "Discard unused portion" to container labeling.

### **APPROVAL & LABELING**

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 011525/S-043.**” 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, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, 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 Omolara Oyinlola-Adeyemi, Regulatory Business Process Manager, at (240) 402 - 3842.

Sincerely,

*{See appended electronic signature page}*

David Claffey, PhD  
Supervisor  
Division of Product Quality Assessment III  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



David  
Claffey

Digitally signed by David Claffey

Date: 4/22/2026 07:12:22AM

GUID: 508da71e00029e20b201195abff380c2