Date – August 2, 2024

VIA ELECTRONIC SUBMISSION

Division of Dockets
Management Food and
Drug Administration
Department of Health and Human
Services 5630 Fishers Lane,
Room 1061 (HFA-305)
Rockville, MD 20852

Citizen Petition

Dear Sir/ Madam,

The undersigned, for Zydus Pharmaceuticals (USA) Inc., respectfully submits this petition pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with regulations at 21 C.F.R. §10.25(a), § 10.30, and 21 C.F.R. § 314.161 and 314.122, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a Reference listed drug has been withdrawn for reasons of safety or effectiveness as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the Reference Listed Drug (RLD), IC-GREEN (indocyanine green for injection, USP) 25 mg (NDA# 011525) held by Renew Pharmaceuticals Ltd. (previously held by Akorn Inc.), has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

Office of Regulatory Affairs
Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
73- B Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1999

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Approved Drug Products with Therapeutic Equivalence Evaluations the "Orange Book". These drug products are eligible for submission under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("FD&C Act") as Abbreviated New Drug Applications ("ANDAs"). IC-GREEN® (indocyanine green for injection, USP) 25 mg (NDA# 011525) held by Renew Pharmaceuticals Ltd., (previously held by Akorn Inc.) was Approved on Jan 1, 1982. Currently 25 mg/vial strength appears in the Orange Book as ***discontinued*** (See excerpt of the **Orange Book** attached).

If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA referencing the listed drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness (see 21 CFR 314.161). If FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from The Orange Book (see 21 CFR 314.122, 314.161, and 314.162).

The electronic Orange Book, accessed on August 1, 2024, indicates that Renew Pharmaceuticals Ltd is not marketing IC-GREEN® (indocyanine green for injection, USP) 25 mg/vial (NDA# 011525). Therefore, because it appears that IC-GREEN® (indocyanine green for injection, USP) 25 mg/vial, have been discontinued from marketing, the Petitioner hereby requests that the FDA determine whether Renew Pharmaceuticals Ltd decision to discontinue marketing of the aforementioned product was for reasons of safety or effectiveness.

C. Environmental Impact

In Accordance with the requirements set forth in 21 C.F.R. § 25.3l (a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

Office of Regulatory Affairs
Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
73- B Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1999

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

For Zydus Pharmaceuticals (USA) Inc.

Digitally signed by Srinivas Gurram
DN: cn=Srinivas Gurram, o=Zydus Pharmaceuticals (USA) Inc., ou=Office of Regulatory Affairs, email=gsrinivas@zydususa.com, c=US
Date: 2024.08.02 16:06:16 -04'00'

Srinivas Gurram (Srini)
Senior Vice President - Head of RA and CQA lead –Americas
Zydus Pharmaceuticals (USA) Inc.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	INDOCYANINE GREEN	IC-GREEN	N011525	INJECTABLE	INJECTION	10MG/VIAL **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**				RENEW PHARMACEUTICALS LTD
DISCN	INDOCYANINE GREEN	IC-GREEN	N011525	INJECTABLE	INJECTION	25MG/VIAL		RLD		RENEW PHARMACEUTICALS LTD
DISCN	INDOCYANINE GREEN	IC-GREEN	N011525	INJECTABLE	INJECTION	40MG/VIAL **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**				RENEW PHARMACEUTICALS LTD
DISCN	INDOCYANINE GREEN	IC-GREEN	N011525	INJECTABLE	INJECTION	50MG/VIAL **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**				RENEW PHARMACEUTICALS LTD