



Srinivas Gurram
Senior Vice President, Head of RA & CQA Lead, Americas
Zydus Pharmaceuticals (USA) Inc.
73-B Route 31 North
Pennington, NJ 08534

November 20, 2024

Re: Docket No. FDA-2024-P-3699

Dear Mr. Gurram,

This letter responds to your citizen petition received on August 02, 2024, requesting that the Food and Drug Administration (FDA) determine whether the reference listed drug, IC-GREEN, (Indocyanine Green), 25 mg/vial, NDA 11-525, was withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that IC-GREEN, (Indocyanine Green), 25 mg/vial, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain IC-Green, (Indocyanine Green), 25 mg/vial, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to email me at madeleine.giaquinto@fda.hhs.gov.

Sincerely,

MADELEINE E.
GIAQUINTO -S

Digitally signed by MADELEINE
E. GIAQUINTO -S
Date: 2024.11.20 09:53:31
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Madeleine Giaquinto
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure