



August 16, 2023

To,
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
Room 1061, 5630 Fishers Lane
Rockville, Maryland 20852

Re: Citizen Petition- Docket Number: FDA-2013-P-1002

Dear Sir/Madam,

On July 28, 2023, the Food and Drug Administration sent a letter to Zydus Pharmaceuticals (USA) Inc., to determine if Zydus Pharmaceuticals (USA) Inc wished to keep the petition referenced above active.

Zydus Pharmaceuticals (USA) Inc., wishes to inform the agency that we remain interested in a response to the petition referenced above.

During the course of the review of this letter, if there are any questions or comments, please do not hesitate to contact the undersigned via telephone: (609) 730-1900 Extn. :110, direct line: 609-559-0718, facsimile: (609) 730-1999 or e-mail: gsrinivas@zydususa.com. Alternatively, you may reach out to Mr. Dhaval N. Desai- Senior Manager, Regulatory Affairs via telephone: 609-559-0730.

Sincerely,

Signature

16-Aug-23

Date

Srinivas Gurram (Srin)

Senior Vice President- Head of Regulatory Affairs and CQA Lead- Americas
Zydus Pharmaceuticals (USA) Inc.
73-B, Route 31 North, Pennington,
NJ 08534, USA
Email: gsrinivas@zydususa.com

Office of Regulatory Affairs

Zydus Pharmaceuticals (USA) Inc.

(A wholly owned subsidiary of Zydus Lifesciences Limited)

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