



January 23, 2020

The Honorable F. Dennis Saylor IV
United States District Judge
District of Massachusetts
1 Courthouse Way
Boston, Massachusetts 02210

Re: *In re Zofran (Ondansetron) Products Liability Litigation* MDL no 1:15-md-2657-FDS
and Citizen Petition Docket Number FDA-2019-P-5151

Dear Judge Saylor:

I am writing in response to your letter to me dated December 13, 2019, notifying me of the background and status of the above litigation and conveying your request that FDA respond to the pending citizen petition referenced above as expeditiously as possible, taking into account the agency's scientific and regulatory obligations. You state that the citizen petition response could have some potential impact on the resolution of an issue in the above litigation. I have conveyed your request to the agency component responsible for responding to the citizen petition and assure you that the agency is diligently examining the issues raised by the citizen petition and is working to respond to that petition as quickly as feasible.

Thank you for your letter.

Sincerely,

Stacy Cline Amin
Chief Counsel
U.S. Food and Drug Administration