U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
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January 23, 2020

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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 Counsel:

I have received a letter from Amy Mason Saharia on behalf of GlaxoSmithKline (GSK) dated November 1, 2019 and a letter from Kimberly D. Barone Baden, Elizabeth Graham, and Tobias L. Millrood on behalf of the Zofran MDL Plaintiff's Steering Committee (Zofran PSC) dated January 8, 2020 regarding the above-captioned case. The GSK letter enclosed a copy of a citizen petition and stated that it would welcome the opportunity to discuss the citizen petition with FDA's Office of the Chief Counsel. The Zofran PSC letter requested the opportunity to discuss with me my knowledge of communications between GSK and FDA regarding GSK's citizen petition. That letter further requested that I agree to be deposed on the subject.

Pursuant to FDA regulations governing testimony by its officers and employees, I am declining the request to agree to be deposed. See 21 CFR 20.1(a). However, FDA regulations also provide that, in the course of reviewing a citizen petition, the agency may meet with interested parties and the agency grants such meeting requests in limited circumstances. See 21 CFR 10.30(h)(1), 10.65(c). To the extent either party would like to present their views on

this citizen petition in person to me and other agency representatives, including from FDA's Center for Drug Evaluation and Research, I invite you to contact my Executive Assistant, Demetrice T. Bess, at (301) 796-3978 or Demetrice.Bess@fda.hhs.gov. We expect such meetings to be listening meetings only in which you may present your clients' views to us and will last no longer than one hour. An FDA representative will prepare a summary of any such meeting and post the summary to the public docket established for the citizen petition (FDA-2019-P-5151).

Sincerely,

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