FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

February 21, 2020

Robert K. Jenner
JennerLaw
1829 Reisterstown Road, Suite 350
Baltimore, MD 21208

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 Mr. Jenner:

This letter is in response to your letter dated January 31, 2020, addressed to Stephen M. Hahn, M.D., the Commissioner of Food and Drugs, and Stacy Amin, the Chief Counsel of the Food and Drug Administration (FDA). Your letter provides further comment on the above-captioned citizen petition submitted by GlaxoSmithKline (GSK) and therefore has been filed in the docket for that petition. That petition remains pending. This response should not be construed as affecting or previewing FDA's response to that petition.

Your letter also requests the deposition testimony of Ms. Amin and Sara Beardsley, an attorney in FDA's Office of the Chief Counsel, pursuant to Title 21, Code of Federal Regulations, section 20.1 (21 C.F.R. § 20.1). This regulation prohibits any FDA employee from providing testimony before any tribunal pertaining to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner of Food and Drugs or an employee designated by him to act on his behalf. As Acting Director for the Office of Strategic Planning and Operational Policy, I have been delegated the authority by the Commissioner of Food and Drugs to review any requests made under 21 C.F.R. § 20.1.

The purpose of 21 C.F.R. § 20.1 is to enable FDA to allocate its limited resources in a manner designed to protect both the public health and FDA's impartiality. Under section 20.1, FDA may not grant a request for an employee to give testimony in litigation to which the Agency is not a party unless the Agency determines that the testimony meets three requirements: (1) it is in the public interest; (2) it promotes the objectives of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and (3) it advances the mission of FDA. 21 C.F.R. § 20.1(c). All three requirements must be satisfied for FDA to grant your request for testimony. In addition, 21 C.F.R. § 20.1 provides FDA the sole discretion to decide whether to grant a request for employee testimony. Thus, even if a requester has demonstrated that granting employee testimony would meet the regulation's requirements, FDA may still deny such a request. *Id*. § 20.1(c) ("the request *may* be granted" if § 20.1(c)'s criteria are met) (emphasis added).

Your request does not meet the requirements of 21 C.F.R. § 20.1. First, authorizing employees to testify in litigation to which the FDA is not a party would divert manpower and resources from FDA's public health mission, and, therefore, does not serve the public health interest. Your request fails to provide any adequate explanation as to how it is in the public health interest for FDA employees to cease performing their official duties to prepare for, and provide testimony in, a civil action between private parties. Federal courts have found that diverting employees from their assigned tasks interferes unacceptably with agencies' public obligations and responsibilities. See, e.g., *Boron Oil Co. v. Downie*, 873 F.2d 67, 69-70 (4th Cir. 1989); *Davis Enterprises v. EPA*, 877 F.2d 1181, 1187 (3d Cir. 1989), cert. denied, 493 U.S. 1070 (1990). The magnitude of this interference is particularly evident when the cumulative effects of providing testimony in private

lawsuits are considered. *Davis Enterprises*, 877 F.2d at 1187. Courts have repeatedly held that it is appropriate for an agency to withhold the testimony of its employees based on the concern about the cumulative effect of such a resource drain. *Id.*; see also *Moore v. Armour Pharm. Co.*, 129 F.R.D. 551, 555 (D. Ga. 1990), aff'd, 927 F.2d 1194, 1198 (11th Cir. 1991).

Second, you have failed to adequately describe how the requested testimony would promote the objectives of the FD&C Act and the FDA. These objectives include, among others, promoting and protecting the public health by ensuring that the products the FDA regulates, such as food, drugs, and medical devices, are safe and effective for use. See 21 U.S.C. § 393. You request deposition testimony on the scope of communications between the agency and counsel for GSK regarding GSK's citizen petition. However, contrary to the suggestions in your correspondence, there is nothing untoward or impermissible about FDA meeting with outside parties in the course of reviewing a citizen petition. See 21 CFR 10.30(h)(1), 10.65(c). In fact, Ms. Amin has extended an invitation to counsel for both GSK and the Zofran MDL Plaintiff's Steering Committee to request a meeting with her and other agency representatives, including from FDA's Center for Drug Evaluation and Research, to present their respective views on the citizen petition. FDA would not agree, after meeting with one party, to being deposed by the opposing party because that would not be a productive use of FDA's resources and would not promote FDA's public health objectives. Likewise, here, your request to conduct two depositions about the content of a phone conversation and an email exchange does not promote any public health objective.

Third, you have provided no evidence that the testimony of the FDA officials and employees will advance the mission of the Agency. The FDA best serves the public not by providing testimony in private litigation, but rather by the implementation and enforcement of the FD&C Act and related statutes. Providing the testimony, you seek could also set a precedent in favor of FDA granting requests for testimony to other parties seeking similar testimony for use in other private disputes, raising the potential for even further disruptions from agency work.

After reviewing your request for testimony under the provisions of 21 CFR § 20.1 and taking into consideration the requirements of that section and the substance of your request, I am denying your request for the deposition testimony of Stacy Amin and Sara Beardsley. In this particular case, the FDA has determined that you have not demonstrated that the requested testimony will serve the public interest, promote the objectives of the Act, or advance the mission of the Agency.

As you note, your request for documents is subject to the Freedom of Information Act, 5 U.S.C. §552; 21 C.F.R. Part 20, and the agency will issue a separate response to that request.

If you have any further questions about this letter, please contact Lauren DiPaola in the Office of Strategic Planning and Operational Policy at (301) 796-3910. In addition, I understand that counsel for GSK has arranged to meet with FDA on March 5, 2020, and that Ms. Amin's invitation to counsel for the Zofran MDL Plaintiff's Steering Committee to request a meeting with her and other agency representatives remains open.

Sincerely,

Marla Hendriksson -S

Digitally signed by Marla Hendriksson -S
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Acting Director
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