

## MEMORANDUM OF MEETING MINUTES

**Meeting Date and Time:** March 30, 2020, 10:00 – 11:00 A.M., EDT

**Meeting Location:** Zoom video call

**Re:** *Zofran* Citizen Petition, Docket Number FDA-2019-P-5151

### **FDA ATTENDEES:**

#### Office of the Chief Counsel

Stacy Amin, Chief Counsel, FDA

Annamarie Kempic, Deputy Chief Counsel, Litigation

Amanda Edmonds, Deputy Chief Counsel, Drugs and Biologics

Karen Schifter, Senior Counsel

Nick Beshara, Senior Advisor to the Chief Counsel

Sara Beardsley, Counsel for Administrative Law and Special Projects

#### Office of Regulatory Policy, Center for Drug Evaluation & Research

Elizabeth Jungman, Director

Janice Weiner, Senior Regulatory Counsel

Meadow Platt, Regulatory Counsel

### **ZOFRAN MULTI-DISTRICT LITIGATION (“MDL”) PLAINTIFFS’ STEERING COMMITTEE (“ZOFRAN PSC”) ATTENDEES:**

Louis Bograd

Motley Rice

Thomas Ayala

Grant & Eisenhofer

Tobi Millrood

Pogust Millrood

Kimberly Baden

Motley Rice

Kate Jaycox

Robins Kaplan

Robert Jenner

Jenner Law

## **PRESENTATION/DISCUSSION**

- Stacy Amin opened the meeting and explained that this would be a listening meeting. She invited the Zofran PSC to address: the potential effect, if any, of FDA's response to the citizen petition submitted by GlaxoSmithKline ("GSK") dated November 1, 2019, on preemption law more broadly; the potential effect, if any, of FDA's response to this citizen petition on the volume of similar citizen petitions that may be submitted in the context of other cases; and whether the Zofran PSC had any further comment on its earlier expression of interest in submitting material to the docket that GSK had designated as confidential in the MDL, given that GSK indicated to FDA that it would be willing to consider removing confidential designations upon request.
- Robert Jenner provided introductions and an overview of the presentation.
- Louis Bograd presented on the legal issues contained in the attached legal presentation memorandum.
- Thomas Ayala presented on the scientific issues in the attached PowerPoint. He also referenced but did not address in detail separate slides on pregnancy labeling (attached).
- FDA asked no additional questions and concluded the meeting.

## **ATTACHMENTS**

Zofran FDA Legal Presentation memorandum  
PowerPoint on Scientific Issues  
PowerPoint on Pregnancy Labeling