FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting

March 23, 2021

FDA
10903 New Hampshire Avenue
Silver Spring, Maryland

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purposes of discussing and making recommendations regarding the benefits and risks of dermal fillers concerning the following topics: (1) risks associated with intravascular injection of dermal fillers and (2) patient preference and informed decision-making.

The morning session will focus on risks of dermal fillers, including intravascular injection-related adverse events and how best to assess and monitor patient safety. The FDA requests Panel input on several concrete steps the Agency proposes in order to address the risk of unintentional intravascular injection of dermal fillers. The afternoon session will focus on patient preference and the informed decision-making process. During the meeting, the Panel will be asked to discuss ways in which patient perspective can be better integrated into the Agency's regulation of dermal filler products. In addition, FDA will seek Panel input on what additional steps FDA and other stakeholders can take to improve the informed decision-making process.

March 23, 2021

9:00 a.m.	Call to Order and Opening Remarks Introduction of the Committee	Frank R. Lewis, Jr., MD Panel Chair
9:05 a.m.	Conflict of Interest Statement	Patricio Garcia, MPH U.S. FDA/CDRH
9:10 a.m.	Opening Remarks	Cynthia J. Chang, PhD U.S. FDA/CDRH

Risks Associated with Unintentional Intravascular Injection of Dermal Fillers

9:15 a.m.	Clinical Overview of Dermal Fillers	Julian Klosowiak, MD, PhD U.S. FDA/CDRH
9:25 a.m.	Regulation of Dermal Fillers	Kimberly M. Ferlin, PhD U.S. FDA/CDRH

9:35 a.m.	Dermal Filler Medical Device Reporting (MDR)	Amy Rogers, BSN, RN U.S. FDA/CDRH
9:45 a.m.	Assessing and Monitoring for Intravascular Injections	Henry Lee, MD U.S. FDA/CDRH
9:55 a.m.	Prevention of Filler induced Vascular Occlusion, Blindness, and Stroke	Jean Carruthers, MD, FRCSC, FRC(Ophth) Department of Ophthalmology University of British Columbia
10:10 a.m.	Clarifying Questions from the Panel	
10:25 a.m.	Break	
10:35 a.m.	Industry Presentations	
11:25 a.m.	Clarifying questions from panel	
11:40 a.m.	*Lunch*	
12:40 p.m.	Open Public Hearing	
1:40 p.m.	Clarifying questions from panel	
1:50 pm	Questions to panel	Panel Deliberations
2:50 p.m.	Break	

Patient Preference and Informed Decision Making

3:00 pm	Introductory Comments on Patient Preference and Informed Decision-Making	Cynthia J. Chang, PhD U.S. FDA/CDRH
3:05 p.m.	Incorporating Patient Perspectives in Medical Device Regulatory Decisions	Michelle Tarver, MD, PhD U.S. FDA/CDRH
3:15 p.m.	Medical Device Development Tools (MDDT) Program	Hilda F. Scharen, MSc, CAPT, USPHS U.S. FDA/CDRH

3:25 p.m.	Assessment of Effectiveness in Clinical Trials	Jacqueline Francis, MD U.S. FDA/CDRH
3:35 p.m.	Informed Decision-Making and Labeling	Alexander Sun, MD U.S. FDA/CDRH
3:45 p.m.	Clarifying questions from panel	
4:00 p.m.	Questions to Panel	Panel Deliberations
6:00 p.m.	Adjourn Panel Meeting	