AGENDA

FDA CDRH General Hospital and Personal Use Devices Advisory Committee Meeting

December 10, 2025

(VIRTUAL)

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 Hospital and Personal Use Devices Advisory Panel (the Panel) for the purposes of discussing issues related to an emerging technology in the context of medical devices, germicidal ultraviolet (UV) light as a mode of disinfection. FDA is seeking to obtain feedback to improve the total product lifecycle (TPLC) evaluation of UV disinfection devices. This includes (but is not limited to) discussions around stakeholder perspective, performance testing, study design considerations, antimicrobial stewardship, regulatory considerations, and pandemic preparedness.

The panel meeting will be held in a virtual format over the course of one day and includes time for open public comment, questions by the panel, and panel deliberation.

9:00 a.m.	**Call to Order and Opening Remarks** **Panel Introductions**	**William Jarvis, M.D.** Panel Chair
9:05 a.m.	**Conflict of Interest Statement**	**Evella Washington** Designated Federal Officer
9:10 a.m.	**Opening Remarks**	**RDML Raquel Peat, Ph.D., MPH** Acting Director CDRH/OPEQ/OHTIV
9:15 a.m.	**Introduction and Background**	**Katharine Segars, Ph.D.** Assistant Director CDRH/OPEQ/OHTIV
9:25 a.m.	**Overview of Medical Device Reprocessing**	**Yong Xue, Ph.D.** CDRH/OPEQ/OHTIV **Elizabeth Bulger, MD** CDRH/OPEQ/OHTIV
9:40 a.m.	**Regulatory History of Germicidal UV Medical Devices**	**Stephen Anisko, M.S.** Acting Assistant Director CDRH/OPEQ/OHTIV

9:50 a.m.	**Current Challenges for Germicidal UV (GUV) Medical Devices**	**Lianji Jin, Ph.D.** CDRH/OPEQ/OHTIV
10:00 a.m.	**Clarifying Questions from the Panel**	
10:20 a.m.	**Break**	
10:35 a.m.	**Stakeholder Presentations**	**Juan Gonzalez** Vice President of Engineering Xenex **Sade Rolon** American Hospital Association/ Association for the Health Care Environment **Jeff Veenhuis** President & CEO Surfacide Manufacturing, Inc.
11:05 a.m.	**Clarifying Questions from the Panel**	
11:30 a.m.	**Open Public Hearing***	**William Jarvis, M.D.** Panel Chair
12:30 p.m.	**Clarifying questions from Panel**	
12:40 p.m.	*Lunch*	
1:40 p.m.	**FDA Questions to the Panel**	**Dolly Singh, Ph.D.** CDRH/OPEQ/OHTIV
1:45 p.m.	**Panel Deliberations**	**William Jarvis, M.D.** Panel Chair
3:30 p.m.	**Adjourn**	**William Jarvis, M.D.** Panel Chair

*** Open Public Hearing –** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.