

FOOD AND DRUG ADMINISTRATION (FDA)

Hearing Involving the Obstetrics, Reproductive and Urologic Drugs Advisory Committee October 17-19, 2022

AGENDA

The Office of the Commissioner is conducting a hearing under 21 CFR 314.530 on the Center of Drug Evaluation and Research's proposal to withdraw accelerated approval of Makena (hydroxyprogesterone caproate injection, 250 milligrams (mg) per milliliter (mL)). As part of the hearing process, the Obstetrics, Reproductive and Urologic Drugs Advisory Committee (the Committee) will discuss whether a confirmatory trial verified the clinical benefit of Makena and whether available evidence demonstrates that Makena is effective for its approved indication, which is to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The Committee will also discuss whether FDA should allow Makena to remain on the market while an appropriate confirmatory study is designed and conducted.

8:00 a.m.	Call to Order	Celia M. Witten, PhD, MD Deputy Director Center for Biologics Evaluation and Research Presiding Officer
8:05 a.m.	Introduction of Committee and Conflict of Interest Statement	Moon Hee V. Choi, PharmD Acting Designated Federal Officer, ORUDAC
8:10 a.m.	FDA Opening Remarks	Celia M. Witten, PhD, MD
8:15 a.m.	CDER AFFIRMATIVE PRESENTATION	Patrizia Cavazzoni, MD Sara Rothman, JD, MPH Christina Chang, MD, MPH Laura Lee Johnson, PhD Christine Nguyen, MD Peter Stein, MD
10:15 a.m.	BREAK	
10:30 a.m.	QUESTIONS FOR CDER BY COVIS	Raghav Chari, PhD Eugene C. Poggio, PhD Rebecca K. Wood, JD
11:30 a.m.	QUESTIONS FOR CDER BY THE PRESIDING OFFICER AND ADVISORY COMMITTEE	
12:30 p.m.	CLARIFYING QUESTIONS BY CDER	Christine Nguyen, MD Peter Stein, MD Patrick Raulerson, J.D.
12:45 p.m.	LUNCH	
2:00 p.m.	PRESENTATIONS BY PUBLIC PARTICIPANTS	
4:00 p.m.	ADJOURN FOR DAY 1	

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AGENDA (cont.)

DAY 2

8:20 a.m.	Call to Order/Reconvening Statement	Celia M. Witten, PhD, MD Deputy Director Center for Biologics Evaluation and Research Presiding Officer
8:25 a.m.	Roll Call	Moon Hee V. Choi, PharmD Acting Designated Federal Officer, ORUDAC
8:30 a.m.	PRESENTATIONS BY PUBLIC PARTICIPANTS	
10:00 a.m.	BREAK	
10:30 a.m.	AFFIRMATIVE PRESENTATION BY COVIS	Raghav Chari, PhD Rebecca Wood, JD Baha Sibai, MD Sean Blackwell, MD Michael Greene, MD Eugene Poggio, PhD Yolanda Lawson, MD
12:30 p.m.	LUNCH	
1:30 p.m.	QUESTIONS FOR COVIS BY CDER	Christine Nguyen, MD Peter Stein, MD Patrick Raulerson, JD
2:30 p.m.	BREAK	
2:45 p.m.	QUESTIONS FOR COVIS BY THE PRESIDING OFFICER AND THE ADVISORY COMMITTEE	
3:45 p.m.	CLARIFYING QUESTIONS BY COVIS	Raghav Chari, PhD Eugene C. Poggio, PhD Rebecca K. Wood, JD
4:00 p.m.	ADJOURN FOR DAY 2	

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AGENDA (cont.)

DAY 3

8:00 a.m.	Call to Order/Reconvening Statement	Celia M. Witten, PhD, MD Deputy Director Center for Biologics Evaluation and Research Presiding Officer
8:05 a.m.	Roll Call	Moon Hee V. Choi, PharmD Acting Designated Federal Officer, ORUDAC
8:10 a.m.	CLOSING STATEMENT BY CDER	Peter Stein, MD
8:40 a.m.	CLOSING STATEMENT BY COVIS	Raghav Chari, PhD
9:10 a.m.	ADVICE AND RECOMMENDATIONS BY THE ADVISORY COMMITTEE	
12:25 p.m.	ADJOURNMENT	