FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 29, 2019

DRAFT AGENDA

The committee will discuss supplemental new drug application (sNDA 021945/S-023) for MAKENA (hydroxyprogesterone caproate injection, 250 milligrams per milliliter) manufactured by AMAG Pharmaceuticals. In 2011, MAKENA received approval under the accelerated approval pathway (21 CFR part 314, subpart H, and section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. MAKENA was shown in the preapproval clinical trial to reduce the proportion of women who delivered at less than 37 weeks gestation, a surrogate endpoint that FDA determined was reasonably likely to predict a clinical benefit of preterm birth prevention, such as improved neonatal mortality and morbidity. As required under 21 CFR 314.510, the Applicant conducted a postapproval confirmatory clinical trial to verify and describe clinical benefit. AMAG Pharmaceuticals has disclosed that this completed confirmatory trial did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints of reducing the risk of recurrent preterm birth or improving neonatal mortality and morbidity. The committee will consider the trial's findings and the sNDA in the context of AMAG Pharmaceuticals' confirmatory study obligation.

8:15 a.m.	Call to Order and Introduction of Committee	**Vivian Lewis, MD** Chairperson, BRUDAC
8:25 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, BRUDAC
8:30 a.m.	FDA Opening Remarks	**Christine Nguyen, MD** Deputy Director for Safety Division of Bone, Reproductive and Urologic Products (DBRUP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	**APPLICANT PRESENTATIONS**	**AMAG Pharmaceuticals, Inc.**
	Introduction	**Julie Krop, MD** Chief Medical Officer Executive Vice President, Development & Regulatory Affairs AMAG Pharmaceuticals, Inc.
	Clinical Background and Unmet Need	**Michelle Owens, MD** Professor and Medical Director School of Medicine Department of Obstetrics and Gynecology The University of Mississippi Medical Center

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Meis Study Design and Results	**Baha Sibai, MD** Professor Department of Obstetrics, Gynecology, and Reproductive Sciences Investigator, MFMU University of Texas Health Science Center of Houston MFMU[1] Network
	PROLONG: Efficacy and Safety	**Laura Williams, MD, MPH** Sr. Vice President, Clinical Development & Biostatistics AMAG Pharmaceuticals, Inc.
	Prevention of Preterm Birth: Clinical Perspective	**Sean Blackwell, MD** Professor and Chair Department of Obstetrics, Gynecology, and Reproductive Sciences Principal Investigator, MFMU University of Texas Health Science Center of Houston MFMU[1] Network
	Conclusion	**Julie Krop, MD**
10:00 a.m.	Clarifying Questions to Applicant	
10:25 a.m.	**BREAK**	
10:35 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview	**Barbara Wesley, MD, MPH** Medical Officer DBRUP, ODEIII, OND, CDER, FDA
	Efficacy in Confirmatory Trial 003	**Jia Guo, PhD** Statistical Reviewer Division of Biometrics 3 (DB3) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Hydroxyprogesterone caproate (HPC) and Progesterone Utilization in the United States	**Huei-Ting Tsai, PhD** Epidemiologist Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA

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DRAFT AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

	Summary Remarks	**Christina Chang, MD, MPH** Clinical Team Leader DBRUP, ODEIII, OND, CDER, FDA

11:40 a.m. Clarifying Questions to FDA

12:00 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Clarifying Questions to Applicant or FDA

2:20 p.m. **BREAK**

2:30 p.m. Questions to the Committee/Committee Discussion and Voting

5:00 p.m. **ADJOURNMENT**