

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
193rd Meeting of the Vaccines and Related Biological Products Advisory
Committee (VRBPAC)
June 18, 2026
AGENDA

Topic: The committee will meet in open session to discuss and make recommendations on the safety and effectiveness of MFLUSIVA (Influenza Vaccine, mRNA), manufactured by Moderna TX Inc., with a requested indication in Biologics License Application STN 125869/0 for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine.

Time EST	Presentation/Presenter
8:30 am – 8:50 am	<p><u>Opening Remarks: Call to Order and Welcome (10 min)</u></p> <p>Arnold S. Monto, MD, Acting Chair, VRBPAC</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</u></p> <p>LCDR Cicely C. Reese, PharmD Designated Federal Officer (DFO), VRBPAC Center for Biologics Evaluation and Research (CBER), FDA</p>
8:50 am – 9:10 am	<p>FDA Introduction (20 min total including Q&A)</p> <p>Introduction</p> <ul style="list-style-type: none"> • David C. Kaslow, MD (5 min) Director Office of Vaccines Research and Review (OVR), CBER <p>Biologics License Application for STN 125869/0</p> <ul style="list-style-type: none"> • Joseph Kulinski, PhD (10 min) Review Committee Chair Division of Review Management and Regulatory Review (DRMRR) OVR, CBER <p>Q & A: 5 min</p>
9:10 am – 9:50 am	<p><u>Centers for Disease Control and Prevention (CDC) Presentations: (40 min total including Q & A)</u></p> <p>Seasonal Influenza Vaccine Surveillance and Effectiveness (30 min)</p> <ul style="list-style-type: none"> • Lisa Grohskopf, MD, MPH Medical Officer, Epidemiology & Prevention Branch, Influenza Division, Centers for Disease Control and Prevention (CDC) <p>Q & A: 10 min</p>
9:50 am – 10:10 am	<p><u>External Speaker (20 min total including Q & A)</u></p> <p>Seasonal Influenza Vaccines : Current Status and Opportunities for Improved Effectiveness (15 min)</p> <ul style="list-style-type: none"> • Richard Webby, PhD Member, St. Jude Faculty

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	<p>Department of Host-Microbe Interactions St Jude Children’s Research Hospital</p> <p>Q & A: 5 min</p>
10:10 am –10:20 am	Break (10 min)
10:20 am –11:20 am	<p><u>Sponsor Presentation: (60 min total including Q & A)</u></p> <p>Moderna Investigational Influenza Vaccine mRNA-1010 in Adults ≥ 50 Years</p> <ul style="list-style-type: none"> • Rituparna Das, MD, PhD Senior Vice President, Clinical Development, Infectious and Rare Diseases <p>Epidemiology of Seasonal Influenza in US Adults ≥50 Years and Effectiveness of Current Vaccines</p> <ul style="list-style-type: none"> • Evan Anderson, MD, FIDSA, FPIDS Vice President, Epidemiology <p>Clinical Data: Efficacy and Immunogenicity of mRNA-1010</p> <ul style="list-style-type: none"> • Rituparna Das, MD, PhD Senior Vice President, Clinical Development, Infectious and Rare Diseases <p>Clinical Safety</p> <ul style="list-style-type: none"> • Eleanor Wilson, MD, MHS Executive Director, Clinical Development, Infectious Disease <p>Benefit-Risk and Summary</p> <ul style="list-style-type: none"> • Rituparna Das, MD, PhD Senior Vice President, Clinical Development, Infectious and Rare Diseases <p>Q & A: 10 min</p>
11: 20 am – 12:20 pm	<p><u>FDA Presentation: (60 min total including Q & A)</u></p> <p>FDA Review of Efficacy, Immunogenicity, and Safety of MFLUSIVA (Influenza Vaccine, mRNA) in Adults 50 Years of Age and Older (50 min)</p> <ul style="list-style-type: none"> • Gauri Raval, MD, MPH Medical Officer Division of Clinical and Toxicology Review (DCTR) OVR, CBER <p>Timothy P. Brennan, MD, PhD, MS</p> <ul style="list-style-type: none"> • CDR US Public Health Service Clinical Reviewer DCTR, OVR, CBER

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	Q & A: 10 min
12:20 pm - 1:00 pm	<u>Lunch (40 min)</u>
1:00 pm – 2:00 pm	<u>Open Public Hearing (60 min)</u>
2:00 pm – 3:00 pm	<u>Additional Q & A for CDC, FDA, Sponsor, & other Presenters (60 min)</u>
3:00 pm – 4:00 pm	<u>Committee Discussion and Voting - Moderna Seasonal Influenza Vaccine (60 min)</u>
4:00 pm	<u>Meeting Adjourned – DFO</u>