

**FDA and Industry OMUFA Implementation Meeting
April 13, 2021**

Agenda:

- **Policies and procedures for OMUFA implementation meetings**
- **FDA updates**
- **Industry updates**
- **Discussion topics**

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Barbara Kochanowski	CHPA
Theresa Michele	CDER (OND)	David Spangler	CHPA
Karen Mahoney	CDER (OND)	Valerie Gallagher	CHPA (Perrigo)
Celia Peacock	CDER (OND)		
Mary Vienna	CDER (OEP)		
Sherry Stewart	CDER (OND)		

Policies and procedures for OMUFA progress meetings:

FDA and Industry discussed frequency, duration, policies and procedures for OMUFA Implementation Meetings.

FDA updates:

FDA noted that updated timelines for the OMUFA goals, based on an effective date of October 1, 2020, were posted on March 4, 2021.

FDA reported that the first milestone under OMUFA, delivery of a letter to Congress describing the progress of FDA in evaluating the cough and cold monograph with respect to children under age 6 years, was delivered on March 10, 2021, ahead of the March 27, 2021 date specified in the Cares Act.

FDA led a discussion on the progress of OMUFA implementation.

FDA stated that the “dashboard” is now referred to as the “annual forecast.” This terminology is consistent with the OMUFA goals document.

Industry updates:

Industry provided an update on its current priorities under OMUFA.