

**MINUTES OF THE
SCIENCE BOARD TO THE FDA MEETING**
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503A)
10903 New Hampshire Ave. Silver Spring, MD 20993

Monday, October 7, 2019

The Science Board to the FDA (Science Board) meeting was convened at approximately 8:38 a.m.

Members Present

Cynthia A. Afshari, PhD, DABT
Anthony Bahinski, PhD, MBA, FAHA
Kathryn Boor, PhD
Barbara B. Kowalczyk, PhD
Richard Linton, PhD
Mark R. McLellan, PhD (chair)
Lisa K. Nolan, DVM, PhD (via phone)
Theodore Reiss, MD, MBE
Dojin Ryu, PhD
Minnie Sarwal, MD, PhD (via phone)
Scott Steele, PhD
Laura Tosi, MD
Connie Weaver, PhD
Xiang-qun (Sean) Xie, MD, PhD

Designated Federal Officer

Rakesh Raghuwanshi, MPH, Office of the Chief Scientist

FDA Representatives

Amy Abernethy MD, PhD
John Chelonis, PhD
Diana Doell, PhD
Sherry Ferguson, PhD
RADM Denise Hinton
Dennis Keefe, PhD
Peter Marks, MD, PhD
Susan Mayne, PhD
Donna Mendrick, PhD
Regina Tan, DVM
T. Scott Thurmond, PhD
Carolyn Wilson, PhD
Andy Zajac, PhD

Following member introductions, Mr. Raghuwanshi provided the conflict of interest statement for the meeting.

The following is a high-level summary of the meeting. Meeting minutes are not intended to be a substitute for the actual transcript of the meeting. Additional information and specific details may be obtained from the transcript of the meeting. The transcript may be viewed on the Science Board to the Food and Drug Administration web page approximately 6 – 8 weeks after the meeting.

Science Board member introductions and FDA staff introductions

Conflict of Interest statement by Rakesh Raghuwanshi, MPH, Designated Federal Officer, Science Board, FDA

- Mr. Raghuwanshi read a statement regarding conflicts of interest and screening of Science Board members prior to the meeting
- Mr. Raghuwanshi noted that members were in compliance with ethics and conflicts of interest laws

Chief Scientist Updates by RADM Denise Hinton

- RADM Hinton talked about the success of the recent FDA Science Forum, as well as the 7th Scientific Computing Day
- She noted that the office had recently funded 28 intramural grants and 12 cooperative agreements that include public/private partnerships
- Her priorities include supporting FDA scientists in their work and addressing training and knowledge gaps
- FDA is hiring talented scientists, researchers, data engineers and others, and is a great place to contribute to public health through public service

Principal Deputy Commissioner's Update by Amy Abernethy, MD, PhD

- Dr. Abernethy talked about the Technology Modernization Action Plan, its impact on FDA infrastructure and capability to develop technology products to support the Agency's regulatory mission, and the ongoing work with stakeholders to drive technological progress that delivers value to consumers and patients
- She talked about smarter food safety and using artificial intelligence to screen imported foods
- Opioids is a top Agency priority; Dr. Abernethy provided some highlights of ongoing efforts to combat the opioids crisis
- Dr. Abernethy also mentioned the issue of vaping and FDA's collaborative scientific efforts with CDC on the matter

Response to the Science Board’s review of CBER’s Research Program by Peter Marks, MD, PhD, Director, CBER, and Carolyn Wilson, PhD, Associate Director for Research, CBER

- Drs. Wilson and Marks described CBER’s charge to the Science Board subcommittee to review CBER’s research program
- They summarized the subcommittee’s findings and conclusions/suggestions, including that CBER has a strong research program and the reviewer/researcher model is extraordinarily effective
- CBER accepts the major findings and the Center/office-specific recommendations; almost all have already been implemented, with a few exceptions due to resource limitations or other restrictions

Open Public Hearing

1. International Association of Color Manufacturers
2. Center for Science in the Public Interest
3. Good Food Institute
4. Memphis Meats

Introduction to Topics for Discussion by Susan Mayne, PhD, Director, Center for Food Safety and Applied Nutrition, FDA, and Dennis Keefe, PhD, Director of the Office of Food Additive Safety, CFSAN

- Drs. Mayne and Keefe provided background information on color additives and behavioral effects in children

CFSAN Session: Color Additives and Behavioral Effects in Children

- Dr. Thurmond provided additional background information on the issue, talked about the 2011 Food Advisory Committee meeting that evaluated FD&C color additives and ADHD in children, the exposure assessment from 2016, and the literature CFSAN has looked at since then
- The Science Board engaged in a robust discussion with the FDA scientists and subject matter experts
- Several Science Board members weighed in to answer CFSAN’s questions; specific feedback can be referenced in the meeting transcript.

Final Thoughts and Closing Comments by Mark McLellan, PhD, Science Board Chair

- Dr. McLellan closed the meeting at 12:29 p.m.

I certify that I attended the October 7, 2019, meeting of the Science Board and that these minutes accurately reflect what transpired.

_____/s/_____
Rakesh Raghuvanshi, MPH
Designated Federal Officer

_____/s/_____
Mark McLellan, Ph.D.
Chair