Science Board to the Food and Drug Administration
via Videoconference
December 8, 2022

AGENDA

9:00 a.m. **Opening Introductions**

Barbara Kowalcyk, PhD, Science Board Chair

9:05 a.m. **Conflict of Interest**

Rakesh Raghuwanshi, MPH, Designated Federal Officer, Science Board, FDA

9:10 a.m. **Commissioner's Update**

Robert Califf, MD, Commissioner of Food and Drugs, FDA

9:20 a.m. **Chief Scientist's Update**

Namandjé Bumpus, PhD, Chief Scientist, FDA

9:45 a.m. **CFSAN Session: Research needs for the evaluation of potential adverse health effects in children associated with oral cadmium exposure**

FDA's Closer to Zero Initiative
Conrad J. Choiniere, PhD, Director, Office of Analytics and Outreach, CFSAN, FDA

Cadmium Foundational Science
Karlyn Middleton, MS, Branch Chief/Supervisory Toxicologist, Contaminant Assessment Branch, Division of Risk & Decision Analysis, Office of Analytics and Outreach, CFSAN, FDA

Cadmium Systematic Review
Heather Schaefer, DrPH, Toxicologist, Contaminant Assessment Branch, Division of Risk & Decision Analysis, Office of Analytics and Outreach, CFSAN, FDA

A scoping review of infant and children health effects associated with cadmium exposure
Brenna Flannery, PhD, Senior Toxicologist, Contaminant Assessment Branch, Division of Risk & Decision Analysis, Office of Analytics and Outreach, CFSAN, FDA

Cadmium Physiologically Based Pharmacokinetic (PBPK) models
Regis Pouillot, PhD, MPH, Risk Assessor, Risk Analysis Branch, Division of Risk & Decision Analysis, Office of Analytics and Outreach, CFSAN, FDA

Cadmium-Bone Effects Association Model
Sofia Santillana-Farakos, PhD, Interdisciplinary Scientist, Risk Analysis Branch, Division of Risk & Decision Analysis, Office of Analytics and Outreach, CFSAN, FDA

11:20 a.m. **Open Public Hearing**

12:20 p.m. **Lunch Break**

1:00 p.m. **CFSAN Session Discussion**

Questions:

1a. Are you aware of research ongoing or completed that could address the research needs identified above for the evaluation of potential adverse health effects in children associated with oral Cd exposure?

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1b. What suggestions or ideas do you have to facilitate the conduct of the desired research?
2a. What factors should be considered when evaluating data for neurocognitive effects (such as IQ outcomes)?

2b. What factors should be considered when evaluating endpoints that fall within the same domain of neurocognition (e.g., Full scale IQ vs cognitive scores)?

3. Do you have any other comments or suggestions not captured by responses to questions 1 and 2?

2:15 p.m. **Cross-cutting regulatory science research at FDA**

Tina Morrison, PhD, Director, Office of Regulatory Science and Innovation, Office of the Chief Scientist, Office of the Commissioner, FDA

3:45 p.m. **Final Thoughts, and Closing Comments**

Barbara Kowalcyk, PhD, Science Board Chair