The Food and Drug Administration's Approach to Evaluating Nicotine Replacement Therapies
Part 15 Public Hearing
January 26, 2018
FDA White Oak Campus
10903 New Hampshire Ave.
Bldg 31, Rm 1503A

Agenda

9:00 – 9:10 am Opening Remarks
Dr. Rachel Sherman — Food and Drug Administration
Presiding Officer
Principal Deputy Commissioner

9:10 - 9:25 am
James Boiani — Epstein Becker & Green, P.C.
"Recommendations for Enhanced Regulatory Flexibility in NRT Development"

9:25 - 9:30 am Questions from the Panel

9:30 – 9:45 am
David Graham — NJOY
"Opportunities & Challenges in Expanding the Scope of FDA Approved OTC NRT to Include a Well-Characterized Electronic Nicotine Delivery System"

9:45 – 9:50 am Questions from the Panel

9:50 – 10:05 am
Dr. Christopher Kocun — GSK
"Strategies to Expand the Role of Nicotine Replacement Therapy Products"

10:05 – 10:10 am Questions from the Panel

10:10 – 10:25 am BREAK

10:25 – 10:40 am
Chaim (Ben) Levilev — Harmless Products Co.
"Introducing safe, natural, nicotine-free, smokeless and vaporless, non-electric therapeutic quit smoking alternatives that have been tested and proven to help people successfully quit smoking when used by itself or together with other NRT / Rx Products"

10:40 – 10:45 am Questions from the Panel

10:45 – 11:00 am
John McCarty — Intratab Labs Inc.
"Indications and the Regulatory Requirements for Approval of a Novel Nicotine Delivery System"

11:00 - 11:05 am Questions from the Panel

11:05 – 11:20 am
Matthew Myers — Campaign for Tobacco Free Kids
"Nicotine Replacement Therapies: The Need for a New Regulatory Approach"

11:20 - 11:25 am Questions from the Panel

11:25 – 11:40 am
David Spangler Consumer Healthcare Products Association
"Evaluating OTC NRT and the Power of Access"

11:40 - 11:45 pm Questions from the Panel

11:45 -12:00
Jeff Stier National Center for Public Policy Research
"NRT in a class by itself: Do the ENDS justify the means"

12:00 – 12:05 pm Questions from the Panel

12:05 – 1:05 LUNCH BREAK

1:05 – 1:20 pm
Erika Sward American Lung Association
"American Lung Association Comments on FDA's Approach to Nicotine"

1:20 - 1:25 pm Questions from the Panel

1:25 – 1:40 pm
Dr. Mark Watt Johnson & Johnson EAME Ltd
"Nicotine Replacement Therapy: Strategies to enhance access and maximize health benefits for smokers, based on international experience"

1:40 - 1:45 pm Questions from the Panel

1:45 – 2:00 pm
Dr. Dorothy Hatsukami University of Minnesota
"AACR Recommendations to Improve Nicotine Replacement Therapies"

2:00 - 2:05 pm Questions from the Panel

2:05 – 2:20
Dr. Saul Shiffman Pinney Associates and University of Pittsburgh
"A revised approach to regulating nicotine products: What is different about nicotine, and about smoking cessation"

2:20 – 2:25 pm Questions from the Panel

2:25 – 2:40 pm
Charles Garner RAI Services Company
"Product and Process Considerations for Emerging NRT Products"

2:25 – 3:25 pm OPEN PUBLIC HEARING

3:25 – 3:40 Concluding remarks
Dr. Rachel Sherman Food and Drug Administration
Presiding Officer
Principal Deputy Commissioner