



USP Gummy Supplements Roundtable Discussion

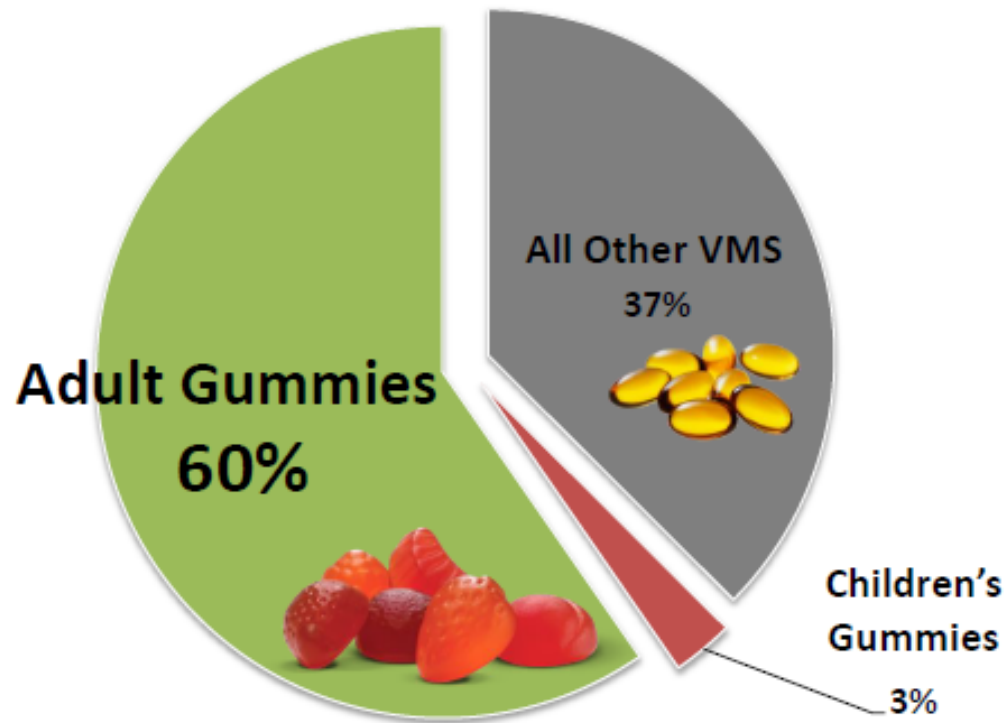
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Gummy Dietary Supplements

Much of the growth in the dietary supplement industry in the past few years can be attributed to dietary supplements marketed as chewable gel products known as a “gummies”.

60% of Total VMS Category Growth
(2015 YTD \$ Growth)





USP Gummy Supplements Roundtable

- **Held on March, 3, 2016**
- **About 40 shareholders representing major gummy manufacturers, ingredient suppliers, contract laboratories, and trade associations**
- **Facilitate/Stimulate conversation between USP, Industry & FDA with the goal of developing standards for “Gummy” dietary supplements**
- **Discussion focus:**
 - **Technical, Operational, and Quality attributes of “Gummy” dietary supplements**
 - **Science, Quality and Public Health implications for the development of USP quality standards**



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Key Discussion Topics

1. Raw Materials:

- Suitability/Usefulness of USP monographs for “basic” food ingredients
- Operational necessities / Rapid Testing for Bulk Tankers

2. Manufacturing Processes

- Inherent equipment/process variabilities
- In-Process controls
- Overage considerations based on manufacturing processes

3. Quality Parameters

- ID testing
- Sample preparation / Assay methods in gummy matrices
- Stability / Overage considerations

4. Performance testing

- Disintegration and/or Dissolution testing

5. Packaging, Labeling, Shipping & Handling

- Stability during transportation & long-term storage

6. Compendial / Nomenclature - related

- Nomenclature
- Monograph



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Industry Input

- **Raw Materials:**
 - FCC-grade “basic” food ingredients / Concerns with usefulness of compendial monographs for “basic” food ingredients
 - Need for Rapid Testing methods (Bulk Tankers)
- **Finished Products:**
 - Nomenclature – Use term “Gummy”, as Gummy matrix is different from “Chewable Tablet”, etc. Change in Nomenclature will not change safety profile, and historically there are very few adverse events reported, compared to other dosage forms
 - Monograph – focus on Gelatin-based gummies. Other bases (Pectin, Starch, etc.) may require separate monographs
 - Realistic Quality Acceptance Criteria is essential for “Gummy” products. Both product attributes and operational process considerations need to be addressed
 - Dissolution/Disintegration testing – only if meaningful (i.e. release of encapsulated components). Due to its nature (sugar, glucose syrup, gelatin), vast majority of gummies easily dissolve in water
 - Child-Resistant packaging – not required in compendial standard, already used by the industry



USP Gummy Supplements Roundtable

- **Very active discussion**
- **Great opportunity to meet face-to-face with other industry experts to discuss common challenges**
- **Terrific opportunity to hear perspectives across the industry, as well as from standard-setting and regulatory agencies**
- **As a member of industry, we greatly value those types of interactions**

USP Exploring creating “Gummy” advisory group



Discussion



Thank You