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USP Dietary Supplements Stakeholder Forum
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USP Comments on FDA's Revised Draft NDI Guidance

Alissa Jijon, J.D.
Senior Counsel

- ▶ Provide overview of USP's role as a standards-setting organization in ensuring the quality and safety of dietary supplements
- ▶ Encourage FDA to consider further integration of USP standards into Revised Draft Guidance
- ▶ Explain role of monographs in helping manufacturers assess significance of manufacturing changes (relevant to whether new manufacturing methods “convert” a substance into an NDI requiring notification)
- ▶ Explain role of monographs in helping manufacturers assess impact of chemical alteration (relevant to NDIs exempt from notification)
- ▶ Acknowledge that FDA's policy disfavors “synthetic botanicals,” but contextualize the public health benefits associated with public standards for botanical ingredients (whether naturally-derived or synthetic)
- ▶ Indicate the role of monographs in reducing the NDI notification burden, increasing transparency, and promoting public health