

In September 2017, FDA announced a public meeting and called for comments on their intent to develop pre-DSHEA list of dietary ingredients. Under the Dietary Supplement Health and Education Act (DSHEA), dietary ingredients marketed in the United States before October 15, 1994, are not New Dietary Ingredients and therefore are not subject to the premarket notification requirements in section 413 of the FD&C Act. An authoritative list of such ingredients, often referred to as Old Dietary Ingredients (ODI) has never been established. USP representatives attended FDA's October 3, 2017 public meeting, and submitted comments to the docket. Comments addressed both the standard of evidence necessary to determine that an ingredient was marketed before October 15, 1994; and issues related to the process that should be used to develop the list. USP expressed support, noting that an FDA list of pre-DSHEA ingredients could improve transparency and clarity in the marketplace. In our comments we highlighted the potential utility of public standards and stressed the importance of clear consistent nonproprietary names along with identity specifications for ingredients included on USP supports a transparent open process and welcomes the chance to work with the list. stakeholders to advance dietary supplement quality and consumer safety. More information and a link to our submitted comments can be found here.