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Title: New Excipient Development from the USP Perspective

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Abstract: Although excipient monographs in the current USP-NF number about 550 — of which 468 are in the NF — the number of potentially acceptable excipients for which there are no official pharmacopeial monographs as yet are substantially larger: estimates range as high as 5-10,000 if one includes excipients employed in food products and cosmetic formulations... This presentation will focus on the current process of excipient monograph development and the ongoing efforts to make the USP-NF more inclusive *re* new excipients, thereby augmenting the array of excipients that pharmaceutical manufacturers can draw from in developing new drug formulations and delivery systems.