

APC BRIEF: Compounding Bulk Ingredients with USP Dietary Supplement Monographs

FDA takes the position that bulk ingredients the subject of a USP Dietary Supplement Monograph are not allowed to be used in compounding unless they are on the 503A positive ingredient list. In other words, FDA states that the Dietary Supplement Compendium is not an “applicable” USP Monograph under Section 503A(b)(1)(A)(i)(I) of the FDCA. The USP Dietary Supplements Compendium currently lists 260 dietary supplement monographs. By excluding those monographs from Section 503A, the FDA has effectively stripped dietary supplements from use within compounding practice, thereby constraining physician practices heretofore regulated by the states and in ways contrary to state regulation.

Physicians often prescribe dietary supplements to be used in conjunction with other prescribed medications, compounded or commercially available, for a wide range of conditions. A physician should be able to prescribe both drugs and dietary supplements and work within the physician, patient, pharmacist triad to meet the standard of care and the specific medical needs of a particular patient.

FDA’s interpretation of this provision of the FDCA will greatly limit patient access to this important individualized treatment utilizing compounded dietary supplements as adjunctive care with other prescribed medications. Many of these substances are readily available to the public at retail establishments like GNC and CVS and many others, yet FDA’s policy prohibits trained health care professionals from prescribing and compounding with them to meet patient needs without going through a nomination and PCAC review process that results in FDA rejecting the vast majority of nominated substances.

For these reasons, APC has, through multiple comments and stakeholder listening sessions, asked that FDA reconsider the current interpretation of this provision of the FDCA) and allow compounding with bulk substances with a USP or NF drug or dietary supplement monograph. APC has also supported bipartisan federal legislation, HR 1959, the Preserving Patient Access to Compounded Medications Act by Rep. Griffith (R-VA) and Rep. Cuellar (D-TX), that would, among other things, clarify that bulk ingredients with either drug or dietary supplements monographs can be used in compounding. The text of this bill can be found at <https://www.congress.gov/bill/116th-congress/house-bill/1959/text>.

APC is also in discussions with other pharmacy and prescriber organizations about other potential ways to address this FDA policy, including the possibility of seeking the introduction of stand-alone legislation to clarify that ingredients with either drug or dietary supplement monographs can be used in compounding. What can you do now? Contact your Member of Congress and let them know you care about this issue and ask that he or she co-sponsor HR1959, The Preserving Patient Access to Compounded Medications Act. Also let us at APC know more about how this FDA policy has or could impact your pharmacy practice and the patients you serve by limiting you ability to compound with most dietary supplements.

Comments or questions? Contact APC at info@a4pc.org.