Revision to USP Pending Monographs Guideline

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USP revised the Pending Monographs Guideline to clarify that excipients are eligible for the Pending approach, provided that the requirements are met. The Guideline now includes references to the National Formulary (NF) and states "The purpose of Pending Monographs is to have an official USP or NF monograph ready as soon as possible after FDA grants final product approval". The Guideline also has been revised to state that a company is not permitted to use labeling such as "USP" or "NF" based on adherence to a Draft or Authorized Pending monograph. These labels are only permitted in reference to official, legally enforceable monographs published in the *USP–NF*.

This version updates and replaces USP Pending Monographs Guideline Version 2.4 as of May 1, 2010.