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USP to Defer Decision on Green Tea Extract Cautionary Labeling

The United States Pharmacopeial (USP) Convention's Dietary Supplements Information Expert Committee in the Council of Experts has decided to defer its decision on whether a cautionary labeling statement should be included in the USP Powdered Decaffeinated Green Tea Extract monograph. This cautionary statement was originally proposed in *Pharmacopeial Forum* 33(6) (Nov-Dec 2007) and subsequently revised based on comments received on that proposal. The Committee's work on this matter, including the revised cautionary statement, is described in the recently published paper entitled *Safety of Green Tea Extracts: A Systematic Review* by the US Pharmacopeia, *Drug Safety* 2008; 31(6): 469-484.

The reason for the deferral is to allow the Committee time to review its safety classification policy for dietary supplements, which also is described in the above-referenced paper. The current policy specifies that an article determined to fall within "class 2" shall include a warning statement in the labeling section. The Committee intends to reexamine this policy and decide whether any modifications should be made to its classification system.

The Committee remains concerned about safety issues surrounding green tea extracts as used in dietary supplements. As it reviews its safety classification policy, it will also continue to monitor and evaluate clinical case reports and other information relating to the safety of dietary supplements containing these extracts.

Meanwhile, the USP Powdered Decaffeinated Green Tea Extract Monograph has been published without the cautionary labeling statement in the 2nd Supplement to *USP 31-NF 26* and will become official as scheduled on December 1, 2008. If the Committee determines after its further deliberations regarding its safety classification policy and the safety issues surrounding green tea extracts that a cautionary labeling statement for dietary supplements is warranted, the monograph may be revised to include such a requirement.

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