Update on the USP Green Tea Extract Monograph

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During a meeting held on February 5–6, 2009, the Dietary Supplement Information Expert Committee made a comprehensive review of various aspects of dietary supplement ingredient safety evaluation. After the review, the committee adopted a revised admission policy and safety classification system that classifies dietary ingredients for USP monograph into two classes. The revised policy is discussed.

The Expert Committee also updated their safety review for the green tea extracts with new information reported during the last two years in peer-reviewed literature and in various adverse event reporting portals. Based on the updated safety review and in accordance with the revised classification system, the committee re-classified green tea extract as an article falling within Class A—Admitted into the Compendia. Unlike the previous designation (see "Background" below), this class does not require that a caution/warning statement be included in the labeling section of the monograph. Accordingly, the Expert Committee decided to cancel the proposal in the Pharmacopeial Forum for a cautionary labeling statement[1] in the USP Powdered Decaffeinated Green Tea Extract monograph.

The Expert Committee remains concerned about safety issues concerning some green tea extracts.[2] In keeping with USP’s continuous revision approach,[3] the Expert Committee continues to monitor clinical case reports and other information relating to the safety of dietary supplements with USP monographs and may take appropriate measure commensurate with the arising evidence.

Background

The USP Dietary Supplement Information Expert Committee reviews the safety profile for dietary supplement ingredient articles proposed for placement in USP–NF and uses a safety classification system to determine whether a monograph should be developed.[4] The Expert Committee also monitors safety related information for the dietary supplement ingredients with USP monographs, for possible safety re-evaluation and re-classification depending on the new safety signals.

The Expert Committee’s initial review of the safety profile for Powdered Decaffeinated Green Tea Extract resulted in assignation of a Class 1a safety rating in February 2005 (meaning that only limited safety data were available, but based on that data there were not safety issues that should preclude development of a monograph). The Powdered Decaffeinated Green Tea Extract monograph was published in the Second Supplement to USP 31–NF 26 and became official on December 1, 2008.

Following reports of liver damage upon consumption of concentrated green tea extracts, the committee revisited the safety profile for green tea extracts in 2007. After a review[2] of the new reports, the committee re-classified the Powdered Decaffeinated Green Tea Extract as Class 2.[4]
Class 2 assignation required that safety related information is transmitted through a warning statement in the monograph labeling section. Accordingly, the now cancelled proposal to add a cautionary labeling statement in the USP monograph for the article was presented for public comments in November 2007 in Pharmacopeial Forum 33(6).[1] After reviewing additional information and several stakeholder comments, the Expert Committee decided to defer approval of the monograph cautionary labeling requirement in June 2008[5] pending a review of the safety classification system.

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References