

## Development of SRMs for Botanical Dietary Supplements

As part of a multi-year interagency agreement among the National Institute of Standards and Technology (NIST), the National Institutes of Health's Office of Dietary Supplements (NIH/ODS), and the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) and the FDA Center for Drug Evaluation and Research (CDER), NIST is developing Standard Reference Materials (SRMs) for botanical dietary supplements. Taxonomically authentic botanical reference materials with assigned values for concentrations of active and/or marker compounds, pesticides, and heavy metals are being produced to assist in the verification of manufacturers' label claims and for use in quality control during the manufacturing process.

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Dietary supplements are products containing vitamins, minerals, herbs or other botanicals, amino acids, etc. that are consumed to increase total daily intake and/or for perceived health benefits. Many people believe that botanical supplements will improve their health and that these "natural" remedies are both effective and free from the side effects that may occur with other medications. There are occasional reports of inaccurate labeling, adulteration, contamination (with pesticides, heavy metals, or toxic botanicals), and drug interactions.

**Despite questions about the quality and safety of dietary supplements (including vitamins), about 75% of the US population continues to use them. The US consumer spends more than \$20 B on these supplements per year, with expected spending growth of 3% to 5% each year.**

Congress recognized the lack of publicly available, validated analytical methods for dietary supplements – and a lack of reference materials for validation of analytical methods – in 1994 when the Dietary Supplement Health and Education Act (DSHEA) was enacted. As part of DSHEA, NIH/ODS was directed to fund development of analytical methods and reference materials for dietary supplements.

Shown here are materials that are currently available or for which Certificates of Analysis are in review. Also shown are the constituents for which values are assigned. The constituents in all of these materials have been determined by multiple independent methods with measurements performed by NIST and collaborating laboratories. The methods utilized different sample extraction and cleanup

steps in addition to different instrumental analytical techniques and approaches to quantification.

SRM	Name	Constituents
1588b	Organics in Cod Liver Oil	Fatty acids and organic contaminants
3240	<i>Ephedra sinica</i> Stapf Aerial Parts	Ephedrine alkaloids, toxic elements
3241	<i>Ephedra sinica</i> Stapf Native Extract	Ephedrine alkaloids, toxic elements
3242	<i>Ephedra sinica</i> Stapf Commercial Extract	Ephedrine alkaloids, toxic elements
3243	Ephedra-Containing Solid Oral Dosage Form	Ephedrine alkaloids, caffeine, toxic elements
3244	Ephedra-Containing Protein Powder	Ephedrine alkaloids, caffeine, toxic elements, nutrients
3245	Ephedra Dietary Supplement Suite	(Two bottles of each of the ephedra materials listed above; see analytes listed above)
3246	<i>Ginkgo biloba</i> (Leaves)	Flavonoids, terpene lactones (ginkgolides), toxic elements
3247	<i>Ginkgo biloba</i> Extract	Flavonoids, terpene lactones (ginkgolides), toxic elements
3248	Ginkgo-Containing Tablets	Flavonoids, terpene lactones (ginkgolides), toxic elements
3249	Ginkgo Dietary Supplement Suite	(Two bottles of each of the ginkgo materials listed above; see analytes listed above)
3276	Carrot Extract in Oil	Carotenoids, tocopherols, fatty acids

These materials are provided primarily for use in method development and as control materials to support the measurement of these constituents in other similar products. These materials will help manufacturers of dietary supplement products to characterize raw materials to prevent the use of materials that are contaminated or adulterated. In addition, the SRMs will assist self-assessment of consistency and quality in finished products, and provide a foundation to which label information can be linked. The goal of this ongoing effort is to provide the dietary supplement industry and measurement communities with tools that will lead to improved quality of dietary supplements, and ultimately

mately reduce public health risks that could potentially be associated with these products.

**Future Plans:** The development of botanical dietary supplement SRMs is an ongoing effort. Materials based on saw palmetto, bitter orange, green tea, black cohosh, berries of the genus *Vaccinium*, soy, kudzu, and red clover are currently in progress. Oils extracted from a number of plants (perilla, flaxseed, evening primrose, borage), and a mixture of vegetable oils with values assigned for tocopherols and tocotrienols are also being prepared as SRMs.

