

## More Regulation on Health Food Raw Materials

**March 15, 2012 (SFDA)**

As for the substandard accessories of health food found forbidden for safety reasons by China, State Food and Drug Administration (hereinafter referred to as SFDA) states that:

1. Those companies which manufacture health products with substandard raw materials including encapsulation materials, fillers, binders etc. should apply to replace or remove the original raw materials, and the sales of these products should stop too within the time frame given by SFDA. Any replacement or removal of the materials shall have no impact on the product safety and meet relevant standards on health product.
2. Domestic health product applicants shall go to the provincial level food and drug supervision and management body for application, while import health product companies shall go to the administrative service center of SFDA for application and any alteration in such application will be treated as altering other items.
3. Applicants shall provide their alteration application form as well as other materials required by notice of dealing with substitution matters containing phthalic acid ester. (In this notice, SFDA stated that applicants should provide materials and information on the new coating formula, coating ingredients and dosage, safe daily dose, manufacturing processes, quality standards, research materials, stability test report, self report and inspection materials on three batches of pilot products.) Food and drug supervision and management departments shall carry out license management with reference to this notice.
4. Food and drug supervision and management departments at all levels shall step up inspection. Once discovering that companies fail to stop production and sales of such product, they shall deal with them according to law and report to SFDA for further confirmation. SFDA will cancel relevant approval paper and put up a public notice.

*The U.S. – China Health Products Association is working towards the development of China's natural health product industry by advocating for a more open and transparent regulatory environment. The association is committed to increasing the trade and availability of its member's products, which will benefit the health and wellbeing of both industry and consumers alike.*