美中健康产品协会

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致中华人民共和国全国人大常委会法制工作委员会：

关于食品安全法（修订草案）针对保健食品的若干建议

2014 年 7 月 30 日

简介

美中健康产品协会（The U.S.- China Health Products Association）是根据美国国家税务局规定设立的非盈利性协会组织。该协会代表全球多家健康产品企业，共同致力于膳食补充剂（Dietary Supplements）和其它天然保健产品的制造、市场推广、分销、零售、宣传、贸易展会组织、倡导、教育、分析检测/认证以及研究等。

美中健康产品协会对于此次草案的修订表示十分期待，因为这将是中国保健食品行业改革的重要一步。中国保健食品行业有着巨大的发展潜力，是中国消费者市场不可缺少的组成部分。中国保健食品行业的发展也直接关系到亿万中国居民的健康生活。

本协会和成员十分感谢全国人大常委会法制工作委员会在立法过程当中付出的努力，希望委员会能够抽出宝贵的时间阅读和考虑本协会关于《食品安全法（修订草案）》中针对“保健食品”的若干建议。

本协会仔细研究和讨论了《食品安全法（修订草案）》关于“保健食品”的第 65 条和第 66 条规定，提出如下疑问和建议：

1. 第 65 条中关于“保健食品”的定义问题

本协会和成员一致认为“保健食品”这一术语定义太过宽泛。目前中国市场上，不论是膳食补充剂、酸奶、饮料，还是中药制成品和其他一些预包装食品，都有归类到保健食品名目下，这使得消费者、行业和政府部门在“保健食品”定义的问题上产生疑惑。由此，本协会建议将整个行业聚合到国际普遍认可的“膳食补充剂”的概念框架之下。

美国国会在 1994 年《膳食补充剂健康与教育法案》（DSHEA）中对膳食补充剂做了如下定义：

“膳食补充剂是一种口服产品，包含膳食所需的营养元素。这些产品中的膳食补充元素可能包括：维他命、矿物质、草药或其它植物成分、氨基酸、及其他物质例如酶、有机组织、腺体组织以及代谢物。膳食补充剂也可以是某种提取物或合成物，产品形式包括药片、胶囊、软胶囊、囊形片、口服溶液以及粉末。”[1]

美国《膳食补充剂健康与教育法案》（DSHEA）主要是用以整合膳食补充剂行业，使之区别于一般意义上的药品。这是美国法律一个重要部分，它能够向政府、行业和消费者说明膳食补充剂产品只是用于辅助正常膳食，确保营养摄入，支持身体主要功能。膳食补充剂产品不得声称能够治疗或治愈某种疾病，因为它不属于药品的范畴。

2. 第 65 条规定：“首次进口的保健食品应当是出口国（地区）主管部门准许上市销售的产品”。

这是否就是说，在国外合法销售的膳食补充剂产品，也就是所说的“保健食品”，只需要在中国出入境检验检疫部门进行备案，即可获得在华合法销售资格？

3. 第 65 条规定，“保健食品声称的保健功能，应当具有科学依据”。

目前国家食药监局有关保健食品的功能性声称的规定共有 27 项。保健食品必须要经过漫长的注册流程，包括动物试验和人体测试，才能获批

[1] http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#what_is

使用某项功能声称，而这个过程与药品审批十分相似。协会认为，在目前声称项目和注册程序上，主要存在三个问题。

首先，27 项功能声称限制了保健食品所实际达到功能的表述。例如，多年来，氨基葡萄糖和软骨素得到各种国际资源雄厚的科研支持，研究表明其有利于关节健康。但是“有利于关节健康”这一声称并未列入功能范围。因为功能范围的局限性，许多产品被排除在外。

其次，不管成分是否之前已经通过测试、或已知是安全的、或已知有特定功能，每次企业提交注册申请时，每个产品都必须完成所有的测试程序。一个更实际的解决方案是采用基于根据科学研究认可的成分及其已知功能列表，使用该列表上的部位/功能声称系统。

举例来说，中国国家卫生和计划生育委员会（NHFPC）列出了可用于保健食品原料的物质名录，其中包括 Omega-3 脂肪酸（EPA、DHA）和 21 种益生菌。但是，如果将这些原料应用于片剂、胶囊和软胶囊形态的保健食品中，却需要在国家食药监局进行“蓝帽子”注册。协会认为，既然国家卫生和计划生育委员会已经确定了名录中原料的食用安全性，就没有必要再次对含有此类原料的保健食品进行注册批准。这样繁复的程序将耗费保健食品生产企业大量的时间和资本。

第三，中国目前实行的注册体系需要进行动物实验，但在美国和欧盟都不适用。对膳食补充剂的动物实验也是没有必要的，因为这些补充剂都已有多年的细致研究和论证。

据报道，今年国家食药监局正计划在化妆品行业中取消对部分产品的动物实验，我们高度支持此项决定。同时我们也希望国务院出台有关停止对膳食补充剂进行不必要的动物实验的法规。

4．第 65 条规定：“可用于保健食品生产但不得用于其他食品生产的物质目录（以下称可用于保健食品原料目录）和允许保健食品声称的保健功能的目录，由国务院食品药品监督管理部门会同国务院卫生行政部门、国家中医药管理部门制定、调整并公布”。

关于这两本名录，请问有关部门能否确定一个具体公布的时间，何时可待查询？最重要的一点是，名录公布之后，在不需要注册保健食品蓝帽子标识的情况下，同一产品配方当中能否添加两种及其以上的可用于保健食品的物质？

5. 第 66 条规定："使用新原料的保健食品和首次进口的保健食品应当经国务院食品药品监督管理部门注册。但是，对成品及其原料的安全性和保健功能可以通过国家标准、规范等通用要求进行评价的首次进口的保健食品实行备案管理"。

考虑到法律语言的使用对于国内外保健食品生产企业产生效果的公平性，本协会建议将该句改为"使用新原料的保健食品**或**首次进口中国的保健食品应当经国务院食品药品监督管理部门注册。"

6. 第 66 条规定："对成品及其原料的安全性和保健功能可 以通过国家标准、规范等通用要求进行评价的首次进口的保健食品实行备案管理"。

本协会想了解评价工作是否收取相关费用，多久能得到评价结果？举例来说，美国的食品和药品监督机构的这种评价工作不收取任何费用，只需 75 个工作日便可得知评价结果。

此外，这些经由备案制审查通过的保健食品是否会得到"蓝帽子"标识？本协会建议，不论是经由备案制审查通过的保健食品，还是经由注册制批准的保健食品，都应该被批准使用"蓝帽子"标识。否则，消费者在选购保健食品时会只倾向于经由注册制批准的"蓝帽子"保健食品，这对于经由备案制审查通过的保健食品是不公平的。

7. 第 66 条规定，"国务院食品药品监督管理部门经组织技术审评，对符合安全和功能声称要求的，准予注册；对不符合要求的，不予注册并书面说明理由。对使用新原料的保健 食品作出准予注册决定的，应当及时将该新原料纳入可用于保健食品原料目录"。

如果一种保健食品不进行功能声称，是否可以经由备案制进入中国市场？举例来说，如果一家保健食品生产企业为他们生产的钙质补充剂进行“增强骨骼密度”的声称，就不再需要进行“蓝帽子”注册，只需进行产品备案？但是，对于那些不进行功能声称的钙质补充剂产品实行怎样的管理？

以下是一些关于保健食品行业的市场背景信息，以及协会认为对行业发展有利的建议：

膳食补充剂的安全问题

膳食补充剂的概念在美国已经有 100 多年的历史。然而直到 1994 年国会通过《膳食补充剂健康与教育法案》（DSHEA），整个行业才真正建立起来。在此之前，整个行业属于灰色地带，消费者不清楚膳食补充剂是一种食品，还是一种治病的药物，保障行业安全的法律监管机制也尚未建立。随着 DSHEA 的生效，整个行业有了清晰的规则，包括现场良好生产规范(cGMP)以及不良事件报告系统(AER)，专门针对膳食补充剂行业而设计。此外，联邦贸易委员会（Federal Trade Commission）负责监督膳食补充剂市场推广是否合规，以杜绝企业发布非法健康声称欺骗消费者。企业一旦有违法违规行为，将会受到严惩，包括巨额罚款，以及追究刑事责任。

2012 年上半年，美国食药监局总共接到 540,381 项有关药品的不良事件报告。而在 2007-2012 年间，美国食药监局仅收到 6,300 项关于膳食补充剂的报告，年均仅为 1,050 项。其中，还有很多报告都并未显示膳食补充剂有不良问题。基于以上比较，膳食补充剂是极为安全的。

政府医疗成本节省及对 GDP 的贡献

如果监管体系向告知式的监管方向发展，审批工作基于产品成分而非产品本身，这将给政府、行业和消费者带来十分可观的受益。其中之一便

是医疗成本的节省。中国政府花了大量财物和精力推进医疗改革，使得全民人均预期寿命从 1950 年的 45 岁提高到 2010 年的 75 岁[2]。

尽管成绩巨大，但中国政府不得不面临的问题是老龄人口急剧增加，劳动力资源逐步减少。预计到 2050 年，中国 60 岁以上人口将达到总人口的 33%[3]。这将对政府医疗成本带来巨大压力。而更为严重的是，人均医疗成本从 2002 年到 2012 年已经增加了 4 倍[4]。

如果膳食补充剂能够更为普及，这些凝聚着新兴科技和营养研究成果的产品将会有助于推动中国消费者健康和生活方式的改变，以及中国 GDP 的增长。在美国，膳食补充剂行业的发展对政府和消费者的益处已经得到证实，以下便是几个公开的报告作为佐证：

关于定向食用膳食补充剂从而节省医疗成本的报告　2013 年 9 月 23 日[5]

– 本项调研由 Frost 和 Sullivan 联合进行，由美国可靠营养委员会（Council for Responsible Nutrition）出资。本报告发布了医疗成本大幅节省的若干数据：

- 在冠心病(CHD)治疗方面，每年节省 20.6 亿美元
  如果美国所有 55 岁以上患有冠心病的老人每天服用欧米茄-3 不饱和脂肪酸

- 在冠心病(CHD)治疗方面，每年节省 15.2 亿美元
  如果美国所有 55 岁以上患有冠心病的老人每天服用叶酸、维他命 B6 和 B12

- 在冠心病(CHD)治疗方面，每年节省 43.8 亿美元

[2] United Nations - http://data.un.org/Data.aspx?d=PopDiv&f=variableID%3A68

[3] United Nations - http://esa.un.org/wpp/unpp/panel_indicators.htm

[4] World Health Organization - http://apps.who.int/gho/data/node.country.country-CHN

[5] CRN/Frost and Sullivan - http://www.frost.com/sublib/display-market-insight.do?id=285115104

如果美国所有 55 岁以上患有冠心病的老人每天摄入植物甾醇和车前子纤维补充剂

- 在老年性黄斑退化症和白内障治疗方面，每年节省 5740 万美元
  如果美国所有 55 岁以上患有以上病症的老人每天摄入叶黄素和玉米黄质补充剂

- 在骨质疏松症方面，每年节省 18.7 亿美元
  如果美国 55 岁以上患有骨质疏松症的妇女每天摄入钙和维他命 D 补充剂

- 在骨质疏松症方面，每年节省 8.51 亿美元
  如果美国 55 岁以上患有骨质疏松症的妇女每天摄入镁补充剂

关于口服营养补充剂对临床效果影响的报告 2013 年 2 月 13 日[6]

– 《护理管理杂志》（*Journal of Managed Care*）发表此研究报告，该报告也在德国莱比锡举办的欧洲临床营养与新陈代谢协会年会上发布。该研究由芝加哥大学 Tomas J Philipson 博士牵头负责，其研究团队在分析了超过 100 万病例后得出以下结论:

病人在口服营养补充剂（Oral Nutritional Supplements）后，平均住院时间缩短了 2.3 天（减少 21%），节省成本 4736 美元（降低 21.6%）。研究还发现，口服营养补充剂能够使患者在 30 天内再住院的比例降低 6.7%。

关于膳食补充剂食用者更易养成健康生活方式的报告（2012 年 3 月 22 日）[7]

— 本报告由美国可靠营养委员会（Council for Responsible Nutrition）编制，显示 71%的膳食补充剂服用者注重均衡饮食、定期体检，睡眠充

[6] American Journal of Managed Care - http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n2/Impact-of-Oral-Nutritional-Supplementation-on-Hospital-Outcomes/

[7] Council for Responsible Nutrition - http://www.crnusa.org/prpdfs/CRNPR13-ConsumerHealthHabits061113.pdf

足，经常锻炼以及保持健康体型。而对于非膳食补充剂使用人群，这个比例为 61%。

关于膳食补充剂行业对经济贡献的报告 2010 年 4 月 5 日[8]

— 本项经济调查由 Dobson 和 DaVanzo 进行，由自然产品基金会（Natural Products Foundation）赞助。报告显示了膳食补充剂行业对美国经济的贡献。当年，整个行业的总销售额突破 240 亿美元。行业对美国经济的拉动效益超过 600 亿美元，占美国总体 GDP 的 0.5%。部分具体数据如下：

- 总税收贡献为 101 亿美元；
- 膳食补充剂行业每消费 1 美元，对美国经济的拉动效益为 2.71 美元；
- 膳食补充剂行业每创造一个就业岗位，将会创造美国经济 2.29 个就业机会。整个行业约创造了 100 个不同行业的超过 50 万的就业岗位。

均衡和公平贸易

在膳食补充剂行业，中美之间具有独特的互补关系。美国是全球最大的膳食补充剂成品制造和市场国，而中国是膳食补充剂全球最大的原料供应方，用以生产美国几千种膳食补充剂产品。美国生产商 70%的膳食补充剂原料来自于中国。

据中国医药保健品进出口商会统计，2011 年，中国原料出口金额为 11 亿美元。中国出口原料一般作为膳食补充剂原料，没有阻碍地进入美国市场。依照美国食药监局《2002 年生物恐怖应对法》，中国供应商仅需进行企业在线注册，向美国食药监局提交发货通知单即可。这些步骤

[8] Dobson/DaVanzo and Natural Products Foundation - http://www.naturalproductsfoundation.org/index.php?src=news&srctype=detail&category=News&refno=20

均不收取任何费用，并且在网上几分钟便可完成。尽管原料原产地为中国，但是除非经过冗长繁琐的保健品审批注册程序，用这些原料制成的成品则无法返回中国市场。

改革中国目前监管机制，采用告知型机制，将有助于中美双方的贸易平衡。这样，美国也可以出口更多产品给中国，反过来中国也可以出口更多原料到美国。

当前国家食品药品监督管理总局关于保健食品规定的若干事项

美中健康产品协会理解中国监管部门目前所执行的监管系统目的是为了保护消费者权益不受非安全产品和虚假产品的侵害。然而，协会认为目前体系中存在监管上的矛盾及一致性问题，且缺乏透明度，这一切都阻碍了行业发展。
随着国家食品药品监督管理总局的重组，食品安全法的修订，以及关于保健食品的具体规定的即将制定，当下正是重新审视中国保健食品行业、做出必要规则调整以提高生产商和消费者安全和知情度的良机。

中国消费者将会从行业改革中受益，膳食补充剂将更为普及，且价格更为低廉，因为若无需注册审批及繁冗的产品检测，生产商能节省不少成本。

我们重点关注包括国家食药监局的注册流程、可允许的产品功能声称、成分效能限制以及在食品安全法中的澄清。

国家食药监局产品注册

在进入市场之前，制造商必须在国家食药监局对膳食补充剂进行注册。由于涉及到注册过程的复杂性和透明度问题，国内以及美国和其他外国厂家一般聘请第三方中国注册顾问，以方便注册申请。这个过程需要投入大量的时间和金钱。通常一个注册批文需要两至三年时间才能完成，费用取决于产品成分和代理费，一般平均每件产品都远超 50,000 美元（SKU）。而新原料的注册流程甚至可能需要长达五年，费用则超过 10 万美元。而这只是开始，进入市场后，注册的有效期只有五年，五年

之后必须再注册。这其实增加了不必要的行政审批程序，因为产品已经上市五年，且被国家食药监局认定为安全产品。

由于科学技术的进步，全球膳食补充剂行业不断发展和完善。但是受制于国家食药监局冗长的注册过程，膳食补充剂生产企业无法迅速推出新产品或重新定位产品，以适合消费者的最佳需求。这将导致产品种类减少，尤其是营养健康行业发展的新产品会大幅减少。此外由于注册成本巨大，也推高了产品的零售价格。

注册程序费时费钱，缺乏合理性，且对提高消费者或产品的安全性作用微小。建议国家食药监局考虑以告知式机制取代注册式机制，以产品成分不是单个产品进行监管。这种转变将使得更多的国家食药监局官员及代理机构的职能转变为市场监督，这将有助于增强市场透明度，远离危险产品。监管增强，行业会更加安全，也有助于提升消费者信心，而这两者都是目前所缺乏的。

正如这些年来我们已经目睹的，政府加强市场监督是保护消费者和建立信心最有效的手段。举个例子，我们可以看到国家食药监局加大了对奶制品和食用油行业的监管，很大程度上提高了该行业的安全性，且帮助消费者重建信心。

摄入量效能级别

国家食药监局对于摄入量效能级别的限制并不能长期符合当前的膳食补充剂的研究结果。例如，最新的研究表明，孕妇应在其日常饮食中补充下列物质以满足其增加的营养需求：钙 1300mg，铁 25mg，叶酸 600mcg。该研究符合美国国家科学院医学研究所（National Academy of Science's Institute of Medicine）规定的每日营养参考摄入量（DRI）标准，该研究所是一家非盈利组织机构，负责为公共卫生事务的政策制定者和行业领导者提供改善性建议。而中国国家食药监局在《营养素补充剂申报与审评规定（试行）》中第三条规定：

“适宜人群为孕妇、乳母以及 18 岁以下人群的，其维生素、矿物质每日推荐摄入量应控制在我国该人群该种营养素推荐摄入量（RNIs 或 AIs）的 1/3～2/3 水平。”[9]

按此规定，孕妇钙的摄入量则要减少 50% ，铁摄入量需要减少 48%，而叶酸摄入量需要减少 44% 。

因为摄入量的限制，行业没有足够的空间调整产品效能以符合当前的研究。再使用前面的例子，钙、铁和叶酸若摄入量不够则也不利于孕妇及胎儿的最佳健康。此外，摄入量限制也成为美国产品进入中国市场的贸易壁垒，这些产品已经投放市场几十年，经过时间和科学的检验，但由于摄入量问题而无法进入中国。

结论

中国的膳食补充剂行业具有巨大的潜力，越来越多的消费者有意向购买有益于身体健康的产品。监管改革将扩大中国的膳食补充剂市场，惠及国内和国外企业，将使中国的市场规模超过欧盟、日本和美国，成为膳食补充剂全球最大的市场。更为自由和开放的膳食补充剂行业将有利于政府、行业发展、最重要的是消费者的健康。

此外，扩大的膳食补充剂市场将创造更多就业机会，创造更多的税收，推动其他相关行业的发展，如零售，运输，经销和研发等领域。下列建议供国务院法制办公室作为发展中国膳食补充剂行业的基础性建议参考。

此外，中国商务部一直鼓励扩大内需。膳食补充剂属于消费品范畴，其需求扩大也有助于实现商务部的目标。膳食补充剂是中国游客在国外旅游时通常大量购买的产品种类。这样一来，人民币储备遭受损失，而中国国内的经销零售商也损失销售份额。协会认为采用膳食补充剂这一术语，并且朝着成分审批的告知式体系制度改革，不仅能提高中国人民的健康，也将有助实现中国商务部促进扩大国内消费的目标。

[9] http://www.sda.gov.cn/WS01/CL0055/10396.html

建议

- 把行业名称从“保健食品”改为“膳食补充剂（Dietary Supplement）”。这将有助于巩固行业基础，消除有关产品性质和功效的疑惑，规避了之前保健产品混乱的负面影响。

- 把行业监管体系从目前的注册式体系改为告知式体系（Notification System）。告知则将无需再注册，释放国家食药监局人力和资源，以确保市场监管得到加强，消费者权益得到保护。免除产品注册费也将大大降低消费者成本。

- 膳食补充剂审批应基于原料成分，而非产品检测。目前对产品很多项检测是多余的，因为其类似成分已经证实可以安全食用，并已在国际使用多年。实际上，已有不少原料已经被卫生部批准为新资源食品。

- 采用部位/功能声称系统。允许已基于科学证明的膳食补充剂功效更为广泛的界定。不得使用治疗任何疾病的功能声称。目前 27 项保健食品功能范围中类似于药物的功能名称，应当撤销。

- 停止对膳食补充剂产品的动物实验。这是多余和不必要的。膳食补充剂有几十年的研究支持，足以满足风险评估。

- 增加审批过程的透明度。目前，相关文件和所涉及的成本尚无明确界定。申请注册企业只能支付给注册代理公司高昂的费用，而不清楚实际所需的费用明细。

- 修订有关膳食补充剂成分摄入量的限制，或至少进行适当修改，使之成为建议性文件。我们希望这些建议摄入量能够更加灵活，且符合最新的营养科学成果建议。

- 国家食药监局应该允许所有经过卫生部批准的成分作为食品资源以多种形式为膳食补充剂使用，例如胶囊、片剂、软凝胶胶囊、咀嚼片、泡腾片、口服液和粉末等。例如，鱼油被卫生部认定为普通食品，可以添加到其他食物产品中。然而，如果鱼油想作为膳食补充剂做成软

胶囊的剂型，则必须向国家食药监局注册申请 “蓝帽子”。这样的规定毫无道理，卫生部已经批准鱼油作为普通食品可供人安全食用，那么必然作为膳食补充剂也是安全可食用的。

另一个例子是咀嚼奶片，全国普及，作为食品出售。但目前产品只能采用片剂形式，根据国家食药监局《关于进一步规范保健食品监督管理，严厉打击违法违规行为有关事项的公告（征求意见稿）》规定，难道奶片也需要“蓝帽子”的注册批文？这使得政府、行业和消费者所有人都非常困惑。

若您对我协会提交的意见有任何疑问，请联系：

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Comments to National People's Congress on China's Food Safety Law Draft

Article 65 and 66 "Health Food Reform"

July 30, 2014

Introduction

The U.S. – China Health Products Association later referred to as "the association" is a U.S. non-profit 501c6 organization incorporated under the law of the U.S. Internal Revenue Service. The association represents companies from around the world including China that are involved in the manufacturing, marketing, distributing, retailing, publishing, trade show organizing, advocating, educating, analytical testing/certifying, researching or any other business endeavor that promotes dietary supplements (膳食补充剂) and other natural health products.

USCHPA is very happy to see that the National People's Congress has taken the necessary steps to begin the reform of China's Health food industry. This is an important growth industry for China and plays a significant role in helping China's citizens lead a more healthy life.

In advance, the association and its members thank China's National People's Congress Legal Committee for taking the time to read and consider its comments and suggestions in regard to China's Food Safety Law Draft regulations focusing on the area of "Health Food Products".

The two articles of the draft Food Safety Law that deal with Health Food products are Article 65 and 66.

The association has reviewed these two articles and have the following questions, comments and suggestions:

1. Article 65 refers to these products as "Health Food".

The association and its members feel the term "health food" has too broad a meaning and can encompass many products such as dietary supplements, yogurt, beverages, certain Traditional Chinese Medicines and many packaged foods. This has lead to confusion among consumers, industry and government to what exactly is a health food. The association suggests using the term dietary supplement as that is the internationally accepted term. The association invites National People's Congress to consider using the U.S. FDA regulatory framework for dietary supplements. Products that do not fit the below designation should be considered functional foods or simply food.

The U.S. Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994 as the following:

"A dietary supplement is a product taken by mouth that contains "dietary ingredients" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft-gels, gel-caps, liquids, or powders".[10]

U.S. FDA regulations are based on notification not registration. Any ingredient that fits into the category of dietary supplement as defined by DSHEA is allowed to be used in a dietary supplement product. U.S. FDA has the legal ability to remove or deny market entry of any ingredient or product they deem is not a dietary supplement.

DSHEA clarifies to government, industry and consumers that dietary supplements are products that supplement the diet to ensure adequate in take and help support vital functions of the body. Dietary supplements are not allowed to make claims of treating or curing disease as this type of claim is reserved for drugs.

2. Article 65 states: "For health food imported to China for the first time, these products should be approved by the administrative sections in the exported country (or region)".

Does this mean that if the products are allowed to be sold as dietary supplements "Health Food" in said foreign country that China will allow them access on a notification basis?

3. Article 65 states: "Health food claims should be based on scientific study".

The association understands China's Food and Drug Administration currently has a list of 27 approved functional claims that marketers of health food products are allowed to make. Health food products can only apply these claims to their products after going

[10] http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#what_is

through a lengthy testing process including animal and sometimes human testing, which is very similar to the approval process for drugs. There are three main issues with this current list and process.

First, the list of 27 functions is too restrictive with regard to what health food products are known to support. For example, the ingredients Glucosamine and Chondroitin are supported by years of solid scientific research from a variety of international sources to benefit joint health, but “joint health” is not an approved claim. There are many other examples of products that are left out because there is not a suitable functional claim.

The association recommends going with a structure / function claim system similar to what the U.S. FDA uses for dietary supplements. This allows marketers to convey to consumers that dietary supplement ingredients can be helpful in supporting structures or functions of the body. For example, Fish Oil and Co-enzyme Q10 are both known to be beneficial to the cardiovascular system. This terminology clearly tells the consumer that these ingredients are helpful to their cardiovascular system, but it does not state that these ingredients can cure or treat cardiovascular disease. This is an important distinction and one that unfortunately has not been successfully made in China. Many consumers still believe that health food products are a type of medicine.

Second, regardless of whether or not an ingredient has been tested and known to be safe and have a specific function, it nevertheless has to go through all testing procedures every time a company submits an application to China’s Food and Drug Administration. This is redundant and adds time and fees to the registration process as well as adds unnecessary work to the staff at China’s FDA. If an ingredient has already been established to have a certain function and is safe for human consumption, it should not have to undergo testing each time a company wants to register it. A more practical solution would be to adopt a structure/function claim system based on a list of approved ingredients and their known functions according to scientific evidence.

For example, China’s National Health and Family Planning Commission (NHFPC) formerly Ministry of Health has approved a variety of food ingredients. For example, Omega-3 fatty acids such as EPA and DHA as well as a list of 21 probiotics strains all are approved as food ingredients. However, these ingredients are not currently allowed to be sold in tablets, capsules or soft gel capsules unless they receive a “blue hat” registration from China’s FDA. Since NHFPC, has already approved these ingredients as save for human consumption, they should be allowed to be freely sold as health food in capsules, tablets, soft gel capsules directly to consumers without needing to go through China’s FDA registration system. This is redundant and adds large investments of both time and capital for manufacturers and marketers.

Third, the above system of testing for a functional claim requires testing be done on animals. The practice of testing dietary supplements on animals is not practiced in the

U.S. or EU. It is unnecessary as dietary supplements have been well researched and studied over the years.

This year it was reported that CFDA is in the process of ending animal testing for the cosmetic industry and we highly commend this decision. We urge the State Council to follow up by stopping the unnecessary testing of dietary supplements on animals.

4. Article 65 states: "The list of materials that can be used in health food products but forbidden in food products, as well as the health claims list made by the Food and Drug Administrative Department of the State Council, Health administrative departments of the State Council and the State Pharmaceutical Management Department, will be adjusted and released to the public".

When will this list be available? Most importantly will companies be allowed to combine these approved ingredients together to create formulas without having to go through the current 2 to 3 years of testing that is required for a blue hat registration? Since these ingredients are on an approved list and have already been thoroughly studied, the association recommends that companies should be allowed to combine these ingredients to create formulas.

Article 66 states: "For health food using new raw materials and health food imported for the first time, registration management applies; for health food imported for the first time and its raw material, if the safety and health function can be assessed by current national standards and regulations, recording management applies".

In order to keep regulatory language equal for both domestic and foreign companies, the association suggests changing the wording to, "For health food using new raw materials or health food that is offered to the Chinese market for the first time, registration management applies; for health food offered to the Chinese market for the first time and its raw material, if the safety and health function can be assessed by current national standards and regulations, recording management applies".

Article 66 states: For those products which meet the requirement of safety standard and health claims, registration will be approved.

The association would like to know if there will be a fee for this evaluation approval and how long will it take? For example, for New Dietary Ingredient evaluations by U.S. FDA the process is free of charge and takes up to 75 days.

Also will products that go through the notification / record process be issued "blue hats" just like products that need to go through the entire registration process? The association recommends that both products that have health claims and those that are approved on

a notification basis should all have the “blue hat” logo. Otherwise it could send a message to consumers that notified products have less of a health benefit, which is not the case.

Article 66 states: for other food with claims of special health functions, recording management applies.

Does this mean if the product does not claim a function it can be offered to the China market on a notification / record basis? For example, if a company wants to make the claim increases bone density for a calcium supplement they would need to go through “blue hat” registration process. But what if a company wants to sell calcium without making any claims? Can this company then get approval without going through “blue hat” registration process?

Below is some industry background information and suggestions, which the association feels will improve the industry:

Safety of Dietary Supplements

Dietary supplements have a long history in the U.S. dating back over 100 years. However, it wasn’t until 1994 with the passing of DSHEA did the industry really become organized. Prior to 1994, the industry was in a gray area, consumers were unclear if dietary supplements were food or a type of medicine that could cure or treat disease. Also, legislation to oversee the safety of the industry was lacking. With DSHEA in affect, the industry has clear regulations including current Good Manufacturing Practices (cGMP) and Adverse Event Reporting (AER) both of which are specific to the dietary supplement industry. Furthermore, the Federal Trade Commission oversees compliance in regard to the marketing of dietary supplements to ensure marketers are not making illegal health claims to cheat consumers. Those companies that break the law are severely penalized facing heavy monetary fines and in some cases criminal penalties including jail time.

In the first six months of 2012, the U.S. FDA received 540,381 reports of adverse events in relation to drugs. Between the years 2007 -2012, U.S. FDA only received 6,300 reports for dietary supplements, which is an average of 1,050 per year. Furthermore, many of those reports could not positively connect the adverse event to the dietary supplement in question. Based on the above comparison, dietary supplements are extremely safe.

Savings in Government Healthcare Costs and Overall Benefit to GDP

If the regulatory system moves toward a system of notification and one based on ingredient not product approvals, the benefits to government, industry and consumers will be substantial. One such benefit would be savings in health care expenditures. The Chinese government has spent a great deal of effort and money reforming the healthcare

system, which has resulted in the increased life expectancy of its citizens from age forty-five in 1950 to seventy-five in 2010.[11]

Although this is a great accomplishment, it has resulted in the creation of an expanding elderly population with a shrinking work force. By 2050, the population of those sixty years or older will triple to 33% of the total population.[12] This will place increased economic pressure on the government to fund healthcare costs. To make the situation worse, healthcare expenditures per capita have increased five fold from 2002 to 2012.[13]

If dietary supplements become more readily available in potencies that reflect the latest in scientific and nutritional research, dietary supplements will compliment these efforts by promoting health and lifestyle changes for Chinese consumers as well as contribute to the country's overall GDP. These savings and benefits to the government and consumers alike have been clearly documented in the U.S. Here are some published examples:

Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements[14]
September 23, 2013 – This study was conducted by Frost and Sullivan with funding from the Council for Responsible Nutrition. The report revealed huge annual savings in Healthcare costs as follows:

- **$2.06 billion** annual savings in costs related to Coronary Heart Disease (CHD)
  If all US adults aged 55 and older diagnosed with CHD took daily supplements of Omega-3.

- **$1.52 billion** annual savings in costs related to Coronary Heart Disease (CHD). If all US adults aged 55 and older diagnosed with CHD took daily supplements of the B vitamins folic acid, B6 and B12.

- **$4.38 billion** annual savings in costs related to Coronary Heart Disease (CHD). If all US adults aged 55 and older diagnosed with CHD took daily supplements of phytosterol and psyllium fiber.

- **$57.4 million** annual savings in costs related to Macular Degeneration and Cataracts. If all US adults aged 55 and older diagnosed with Macular Degeneration and Cataracts took daily supplements of lutein and zeaxanthin.

[11] United Nations - http://data.un.org/Data.aspx?d=PopDiv&f=variableID%3A68
[12] United Nations - http://esa.un.org/wpp/unpp/panel_indicators.htm
[13] World Health Organization - http://apps.who.int/gho/data/node.country.country-CHN
[14] CRN/Frost and Sullivan - http://www.frost.com/sublib/display-market-insight.do?id=285115104

- **$1.87 billion** annual savings in costs related to Osteoporosis Fractures. If women over the age of 55 diagnosed with osteoporosis took daily supplements of Calcium and Vitamin D.

- **$851 million** annual savings in costs related to Osteoporosis Fractures. If women over the age of 55 diagnosed with osteoporosis took daily supplements of Magnesium.

Impact of Oral Nutritional Supplementation on Hospital Outcomes[15]
February 13, 2013 – was published in the *Journal of Managed Care* as well as presented to the European Society for Clinical Nutrition and Metabolism annual congress in Leipzig, Germany. The study was led by Dr. Tomas J. Philipson from the University of Chicago who with his team analyzed over 1 million inpatients and came to the following conclusions:

Patients that were given Oral Nutritional Supplements (ONS) had a shorter hospital stay by 2.3 days (21.0% decline) and decreased episode cost of $4,734 (21.6% decline). Also the study found that ONS reduced readmission levels of these patients after 30 days by 6.7%.

Dietary Supplement Users Tend to Make Healthier Lifestyle Choices[16]
March 22, 2012 – The report was conducted by the Council for Responsible Nutrition and found that 71% of supplement users made better choices in regard to eating a balanced diet, visiting their doctor on a regular basis, getting a good night's sleep, exercise regularly and maintaining a healthy weight compared to 61% or non-supplement users.

The Economic Contribution of the Dietary Supplement Industry[17]
April 5, 2010 – The economic study was conducted by Dobson and DaVanzo and funded by the Natural Products Foundation to record the impact the dietary supplement industry has on the U.S. economy. At that time, the dietary supplement industry was worth over $24 billion in sales. The industry's overall economic impact to the U.S. economy exceeded $US 60 billion or 0.5 percent of the U.S. GDP. Some of the report's detailed findings:

- Total tax contribution to the U.S. economy was $10.1 billion

- For every dollar spent by the dietary supplement industry, $2.71 is contributed to the U.S. economy

[15] American Journal of Managed Care - http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n2/Impact-of-Oral-Nutritional-Supplementation-on-Hospital-Outcomes/

[16] Council for Responsible Nutrition - http://www.crnusa.org/prpdfs/CRNPR13-ConsumerHealthHabits061113.pdf

[17] Dobson/DaVanzo and Natural Products Foundation - http://www.naturalproductsfoundation.org/index.php?src=news&srctype=detail&category=News&refno=20

- For every job created by the dietary supplement industry, 2.29 jobs are created in the U.S. The dietary supplement industry is responsible for creating approximately half a million jobs across 100 different industries.

Balanced and Fair Trade

The U.S. and China have a unique and dependent relationship in regard to the dietary supplement industry. The U.S. is the largest manufacturer and marketer of finished dietary supplement products and China is the largest supplier of dietary supplement raw materials, which are used to produce thousands of U.S. finished dietary supplements. Upwards of 70 percent of the raw materials used by U.S. manufacturers are sourced from China.

China exports billions of dollars worth of dietary supplement ingredients to the U.S. on an annual basis. In accordance with U.S. FDA's "Bioterrorism act of 2002", Chinese suppliers need only register their facility and give notice of shipment to U.S. FDA. Both these requirements are free of charge and can be done online in a matter of minutes. Although these ingredients originate from China, these same ingredients are not allowed back into China as finished products without going through lengthy and costly registration procedures. Restructuring China's current regulatory system to one of notification will allow both the U.S. and China to benefit by creating a more balanced exchange of goods.

The U.S. would be able to export more products to China, which in turn would increase the export of raw materials from Chinese suppliers to the U.S. Furthermore, opening up the dietary supplement market will help Chinese ingredient suppliers balance their business by the increase of domestic business. Currently many ingredient suppliers in China rely too much on export for their businesses' livelihood. This is not a balanced business structure.

Specific Issues with Current CFDA Regulations for Health Food Products

U.S. – China Health Products Association understands that China's regulators have set up the current system in order to protect consumers from fraudulent and unsafe products. However, it is the association's opinion that the current system suffers from regulatory contradictions, harmonization issues and a lack of transparency that stifles industry growth. With the reorganization of CFDA, the revising of the Food Safety Law and new regulations on health food products on the horizon, this is the perfect opportunity to review the health food product industry in China and make necessary regulatory adjustments to improve safety and access for manufacturers and consumers alike. Industry reform will also benefit Chinese consumers by increasing the availability of dietary supplements, which are freely available in the U.S. and other international markets. Consumers will also enjoy lower prices due to manufacturers saving money on the high costs of registration and redundant product testing.

Areas of concern are CFDA's product registration process, ingredient potency restrictions and allowable functional claims, which were already discussed above in regard to article 65 of the Food Safety Law Draft.

CFDA Product Registration

Prior to market entry, manufacturers must register dietary supplements with the CFDA. Due to the complexities and transparency issues involved in the registration process, domestic as well as U.S. and other foreign manufacturers hire 3rd party Chinese registration consultants to facilitate registrations. The process requires enormous investments of both time and money. A typical registration can take between two and three years to complete and cost well over $100,000 per product (SKU) depending on the product's ingredients and how much the registration agent charges as their consulting fee. However, if an ingredient is new to the market, it can take as long as five years and well over $100,000. After market entry, the registration is valid for only five years and then must be renewed, which adds unnecessary administrative processing to a product that has already been in the market for five years and approved to be safe by CFDA.

The global dietary supplement industry is continuously evolving and improving due to scientific and technological advancements. Because of CFDA's lengthy registration process, dietary supplement companies are unable to introduce new products rapidly or reposition product lines to best suit consumer demands. This results in a significant reduction in the variety of products that offer the latest developments in nutritional health as well as increases retail pricing due to the high costs of registrations.

The amount of time and money required for registering products lacks justification and plays no role in enhancing consumer or product safety. CFDA should consider replacing its registration system with a notification system based on approved ingredients not individual approved products. This shift would allow more CFDA agents and officials to be allocated toward market surveillance, which would help rid the market of suspect or dangerous products. Increased surveillance will increase the safety of the industry as well as enhance consumer confidence, which are both currently lacking.

As we have witnessed over the years, government regulations that strengthen market surveillance are the most effective at protecting consumers and building confidence. As examples, we can see that CFDA's increased surveillance of the diary and cooking oil industries have certainly helped to increase safety and rebuild consumer confidence.

Potency Levels

CFDA has potency-level restrictions that do not always coincide with current dietary supplement research. For example, the latest research indicates that pregnant women should supplement their daily diets with the following substances to meet their increased nutritional needs: calcium (Ca) 1300mg, iron (Fe) 25mg and folic acid (acidum folicum) 600mcg. This research is also reflected in the Daily Reference Intakes (DRI) for nutrients

established by National Academy of Science's Institute of Medicine, which is a U.S. non-profit organization that advises policy makers and industry leaders on matters of improving public health. CFDA's *Regulations for Application and Evaluation of Nutritional Supplements* subsection IV states, "Supplements should be reduced by 1/3 to 2/3 of the recommended dosage for pregnant women." Per CFDA regulations on daily intakes, calcium would be reduced by 50 percent, iron by 48 percent and folic acid by 44 percent.

With potency limitations in place, there is no room for the industry to adjust potencies to match current research. Furthermore, using the previous example, calcium, iron and folic acid taken below the recommended levels will not be effective at supporting optimal health for pregnant women and their unborn child. In addition, limitations become a trade barrier to U.S. companies that have time-tested, scientifically based products that have been used for decades, but are not allowed to enter China due to potency issues.

Conclusion

China's dietary supplement industry has great potential and a growing number of consumers are interested in purchasing products that will enhance their overall health. Regulatory reform will expand China's dietary supplement market benefiting both domestic and foreign enterprises and will allow China to surpass the U.S. to become the largest market for dietary supplements in the world. Free and open access to dietary supplements benefits the government, the industry and most importantly consumer's health. Furthermore, supporting industry expansion will create jobs, generate more tax revenue as well as support existing Chinese industries such as retail, shipping, distribution and research / development, etc.

Furthermore, the Ministry of Commerce (MOFCOM) has been working to encourage domestic spending. The dietary supplement industry falls into the category of consumer goods and would certainly contribute to MOFCOM's goal. Dietary supplements are one of those items that Chinese typically purchase in abundance when traveling overseas. When this happens, China loses RMB and in country retailers lose sales. The association feels adopting the term dietary supplement and moving toward a system of notification based on approved ingredients, will not only improve the health of China's citizens, it will also assist MOFCOM in their pursuit of increasing domestic spending and keeping RMB spent in China. The below listed recommendations are for the National People's Congress Legal Committee's consideration as a foundation to bring China's dietary supplement industry to the forefront.

Recommendations

- Replace the term health food product with the term dietary supplement. This will help to consolidate the industry and dispel confusion about what these products are and what they do.

- Replace CFDA's product registration process with a notification system. Notification would eliminate the need for re-registration and free up CFDA personnel and resources to enforce market surveillance, which would enhance consumer protection. Removing the added expense of registering products will also reduce costs to consumers.

- Dietary supplement approvals should be based on ingredients not products. Product approvals are responsible for redundant testing of products made with similar ingredients that are already known to be safe for human consumption and have been used internationally for years. In fact, many of these ingredients have already been approved by China's Ministry of Health as new resource foods.

- Adopt a function/structure claim system that allows for a broad range of statements to be made about dietary supplement ingredient's functions based on scientific evidence. No medical treatment or disease claims should be allowed. The current 27 claims allowed are more similar to drug claims and should be abandoned.

- Stop testing dietary supplement products on animals. This is redundant and unnecessary. Dietary supplements have decades of research available to satisfy risk assessment.

- Increase the transparency of the approval process. Currently, the documents necessary and costs involved are not clearly defined. Companies are left to pay exorbitant fees to registration agents without clear understanding of the actual fees involved.

- Overhaul dietary supplement ingredient potency restrictions, or at a minimum alter the restrictions so they are utilized as recommendations that serve as guidelines. We urge that the recommendations be made more flexible to coincide with the latest in nutritional science recommendations.

- CFDA should allow all ingredients that are already approved of as new resource food by MOH to be used in dietary supplement delivery forms such as capsules, tablets, soft-gel capsules, chewable tablets, effervescent tablets, two piece capsules, liquids and powders. For example, fish oil is approved as a food by MOH and can be added to food products. However, if it is placed in a dietary supplement delivery form, it is not allowed without a CFDA "blue hat" registration. This does not make sense since MOH already approved fish oil as safe for human consumption.

  Another example is chewable milk tablets, which are popular in China and sold nationwide as food. But they are in a tablet form, shouldn't they require a "blue hat"

registration according to CFDA regulations? This confuses all involved including, government, industry and consumers.

Should you have any questions on USCHPA's report, please feel free to contact:

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