資料摘要

美國有關規管保健食品的最新發展

1. 背景

1.1 《2004年不良醫藥廣告(修訂)(第2號)條例草案》委員會在2004年11月23日的會議上，要求資料研究及圖書館服務部就2001年發出的多份有關規管保健食品的研究報告提供最新資料。本資料摘要旨在向法案委員會提供資料，說明美國有關規管保健食品的最新發展。

2. 食品法典委員會[1]

2.1 在國際上，有關針對食物的保健聲稱的規管正處於發展階段，不同國家及地區的做法有很大差異。保健聲稱的種類繁多，令這方面的規管工作變得複雜。[2] 在食品法典委員會所研究的國家及地區中，大部分國家及地區並無針對食物標籤(包括保健食品標籤)附有的保健聲稱作出規管。其次是國家及地區不准作出提述疾病的聲稱。若干國家及地區准許作出某些特定的"可減低患病風險"、"營養功能"或"其他功能"的保健聲稱，美國便是其中一例。[3]

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1 食品法典委員會是世界衞生組織與聯合國糧食及農業組織於1963年創立的國際組織，負責訂定食物標準、指引和工作守則等相關文本，以及協助統籌國際間的政府及非政府組織釐定食物標準的工作。

2 Hawkes (2004)。

3 同上。

3. 食物補充品的規管架構要點

食物補充品作出的聲稱

3.1 食物補充品標籤可使用的聲稱分為3類，即保健聲稱、營養物含量聲稱及結構／功能聲稱。食物補充品標籤不得作出疾病聲稱，宣稱可治理、治療、預防、紓減或診斷某些特定的疾病。

3.2 保健聲稱和營養物含量聲稱均須經食物及藥物管理局(Food and Drug Administration)批准。保健聲稱須通過科學證據覆檢，方可在標籤上使用。"有限保健聲稱"則須含有保留字句，註明支持該項聲稱的證據是有限的。營養物含量聲稱須通過根據食物及藥物管理局訂立的核准規例，方可在標籤上使用。

3.3 至於結構／功能聲稱，則無須經食物及藥物管理局預先批准或認可。製造商必須在食物補充品推出市場後30天內通知該局及呈遞聲稱的內容，並須確保有關聲稱屬實及無誤導成分。使用該類聲稱需作出免責聲明。

產品安全

3.4 食物補充品製造商有責任確保其產品可供安全服用，才可推出市場發售。法例並無條文規定食物補充品在推出市場前，必須先由食物及藥物管理局"批核"其安全性或成效。食物補充品一旦推出市場，食物及藥物管理局若要從市場回收該產品，必須先證明產品"不能供安全服用"。

3.5 製造商或分銷商若計劃在市場推出含有新的食物成分的食物補充品，便須通知食物及藥物管理局。製造商或分銷商必須展示可合理地預期在食物補充品內使用該食物成分安全的理據。

對廣告的規管

3.6 食物補充品的廣告由聯邦貿易委員會(Federal Trade Commission)、食物及藥物管理局和美國郵政檢查部(US Postal Inspection Service)負責規管。大體而言，法例禁止任何"不公平或欺詐的行為或行事方式"，亦禁制"實質上含誤導成分"的虛假廣告。

4. 定義

保健食品

4.1 美國沒有"保健食品"的法定定義。可供食用的產品受食物及藥物管理局當作藥物或食品加以規管。

藥物

4.2 《聯邦食物、藥物及化妝品法》(The Federal Food, Drug, and Cosmetic Act) 將"藥物"界定為：[4]

(a) 政府制訂的《美國藥典》(United States Pharmacopoeia)、《美國順勢療法藥典》(Homoeopathic Pharmacopoeia of the United States)、《國家藥方集》(National Formulary)或該等藥典及藥方集的增補本所認可的物品；
(b) 任何物品，其預定用途是診斷、治理、紓減、治療或預防人類或其他動物的疾病；
(c) 任何物品(除食品外)，其預期目的是影響人類或其他動物的身體結構或任何功能；及
(d) 任何物品，其預定用途是作為上述所指各項物品的成分。

4.3 有關"藥物"的詳細定義，請參閱附錄I。

食品

4.4 根據《聯邦食物、藥物及化妝品法》，"食品"被界定為：[5]

(a) 供人類或其他動物食用或飲用的物品；
(b) 香口膠；及
(c) 作為該等物品成分的物品。

[4] 《聯邦食物、藥物及化妝品法》第201(g)(1)條。
[5] 《聯邦食物、藥物及化妝品法》第201(f)條。

食物補充品

4.5 根據1994年《食物補充品健康及教育法》(The Dietary Supplement Health and Education Act)，食物補充品是指含有"食物成分"的口服產品，用作補充日常飲食。這些產品內的"食物成分"可包括：維生素、礦物質、草藥或其他植物、氨基酸，以及酵素、有機組織、腺體及代謝物等物質。食物補充品亦可以是提鍊物或濃縮劑，其形態可採用錠狀、膠囊狀、軟膠狀、膠丸狀、液體或粉狀等。此外，亦可採用條狀等其他形態。不過，該等形態的食物補充品不得在標籤上將有關產品當作傳統食物，或作為餐食或日常飲食的唯一項目。不論其形態為何，《食物補充品健康及教育法》將食物補充品列為"食品"之下的一個特殊類別，並規定所有這類產品必須加上食物補充品的標籤。[6]

4.6 有關"食物補充品"的詳細定義，請參閱附錄II。

5. 食物補充品作出的聲稱

5.1 食物補充品標籤可使用的聲稱分為3類，即保健聲稱、營養物含量聲稱及結構／功能聲稱。食物補充品標籤不得作出疾病聲稱，宣稱可治理、治療、預防、紓減或診斷某些特定的疾病。(有關斷定某項陳述是否疾病聲稱的準則，請參閱附錄III。)製造商與食物及藥物管理局有責任保證食物補充品作出的聲稱是有充分根據的。

<u>保健聲稱</u>

5.2 根據定義，保健聲稱包括兩個主要部分：

(a) 某種物質(不論是食物、食物配料或食物成分)；及

(b) 某種疾病或健康相關狀況。

[6] United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2001)。

聲稱的核准

5.3 任何聲稱若缺少上述其中一個部分，都不符合保健聲稱的規管定義。食物及藥物管理局透過下列兩種方法，決定可在食物補充品標籤上使用保健聲稱：

(a) 1990年《營養標籤及教育法》(The Nutrition Labeling and Education Act)訂明，食物及藥物管理局經審慎研究在保健聲稱的申請內所提交的科學證據後，可訂立規例，核准食品及食物補充品使用有關的保健聲稱。[7] 有關食物標籤(包括食物補充品標籤)可使用的核准保健聲稱一覽表，請參閱附錄IV。

食物及藥物管理局在決定是否核准某項保健聲稱時，會評估多項考慮因素，包括判斷支持聲稱所指的關係的證據是否符合*重要科學協議的標準*[8]。《營養標籤及教育法》亦容許有關人士要求該局就某項保健聲稱訂立規例；及

(b) 2003年食物及藥物管理局*《更好營養的消費者健康資訊動議》(Consumer Health Information for Better Nutrition Initiative)*訂明，倘若科學證據的質素和效力未達到食物及藥物管理局用以訂立核准規例所要求的水平，則可作出"有限保健聲稱"。

在作出有限保健聲稱時，聲稱必須含有保留字句，註明支持該項聲稱的證據是有限的。關於有限保健聲稱所使用的措辭，請參閱表1。食物及藥物管理局可自行進行覆檢，或聘請合適的第三者進行科學覆檢。該局在作出決定時，會評估覆檢報告的內容、可供公眾查閱的證據完整性，以及在徵求意見期內公眾提交的意見，並會考慮有關有限聲稱會如何影響消費者對食物的選擇。

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7 《聯邦規例守則》第21章第101.14條。

8 這項標準源自《聯邦食物、藥物及化妝品法》第403(r)(3)(B)(i)條。該條文訂明，食物及藥物管理局若"*根據可供公眾查閱的科學證據的完整性(包括透過設計完善、以符合一般認可科學程序及原則方式進行的研究所取得的證據)，經具備科學培訓資格及經驗的專家取得大體協議，認為這些證據足以證實這項保健聲稱屬實*"，則須批准傳統食物和食物補充品使用這項保健聲稱。

關於有限保健聲稱，食物及藥物管理局會在接獲申請後270天內將該局的決定通知申請人。[9] 倘若申請人或其他人士不同意食物及藥物管理局的決定，可要求該局重新作考慮。倘若有關人士能提交重要及相關的新證據，或作出具說服力的分析以證明該局對原有證據的詮釋並不正確，食物及藥物管理局會重新考慮其所作的決定。

表1 —— 有限保健聲稱所使用的措辭

科學級別	適當措辭
第一級別： 這級別符合*重要科學協議的標準*，並反映合資格的科學家對於聲稱所述的物質／疾病關係有科學根據*感到十分放心*。	不適用。
第二級別： 這級別代表合資格的科學家對於聲稱所述的物質／疾病關係有科學根據*感到頗為／相當放心*。合資格的科學家會把兩者的關係列為"相當肯定"，但並非無可置疑。	....."雖然有科學證據支持該項聲稱，但有關的證據並非不可推翻。"
第三級別： 這級別代表合資格的科學家對於聲稱所述的物質／疾病關係有科學根據*感到不太放心*。有關聲稱與權威機構的說法一致性甚低，或合資格的科學家認為支持該項聲稱的科學證據不多。	"一些科學證據顯示.....但食物及藥物管理局斷定，這些證據是有限的，而且並非不可推翻。"
第四級別： 這級別代表合資格的科學家對於聲稱所述的物質／疾病關係有科學根據*感到極不放心*。有關聲稱與權威機構所得出的結論一致性極低，或合資格的科學家認為支持該項聲稱的科學證據極少。	"為數極少及初步的科學研究顯示.....食物及藥物管理局的結論是，支持這項聲稱的科學證據甚少。"

資料來源：

(1) United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2003b).
(2) United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2003c).

[9] United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2003c)。

營養物含量聲稱

5.4 《營養標籤及教育法》容許使用根據食物及藥物管理局訂立的核准規例，在標籤上作出聲稱，註明食物的營養物含量。營養物含量聲稱說明產品內某種營養物或食用物質的含量水平，所使用的名詞為*無*、*高*及*低*，或把某種食物內的營養物含量水平與其他食物作一比較，所使用的名詞為*更多*、*較少*及*輕微*。食物補充品的百分比聲稱屬於營養物含量聲稱的另一類別，例如"40% omega-3脂肪酸，每膠囊含10毫克"。

結構／功能聲稱

5.5 結構／功能聲稱說明用以影響人類正常結構或功能的營養物或食物成分的作用，例如"鈣可強化骨骼"。此外，亦可描述某種營養物或食物成分對維持身體結構或功能的作用，例如"纖維可維持腸道正常功能"或"抗氧化劑可維持細胞的完整性"，又或形容進食某種營養物或食物成分對整體健康的作用。結構／功能聲稱亦可形容對營養素缺乏病的益處(例如維生素C與壞血病)，只要有關陳述亦說明該種疾病在美國的普及程度。

就聲稱作出的通知

5.6 食物補充品製造商若在標籤上作出結構／功能聲稱，必須在食物補充品推出市場後30天內通知食物及藥物管理局及呈遞結構／功能聲稱的內容。食物及藥物管理局不會預先審批或認可這類聲稱。製造商必須確保有關聲稱屬實及無誤導成分。

免責聲明

5.7 食物補充品製造商有責任確保結構／功能聲稱準確真實。倘若食物補充品的標籤包括結構／功能聲稱，根據《聯邦規例守則》第21章第101.93條，該項標籤須作出下述的免責聲明：

免責聲明的內容

5.8 免責聲明須註明：

"此項陳述(此等陳述)未經食物及藥物管理局檢定。本產品並非用作診斷、治療、治理或預防任何疾病。"

擺放位置

5.9 免責聲明須與產品陳述放在一起，並無其他東西阻隔，又或在產品陳述的末端及免責聲明旁邊加上符號(例如*號)，將兩者連在一起。

字體

5.10 免責聲明須採用不少於十六分之一吋的粗黑字體。

6. 產品安全

6.1 根據《食物補充品健康及教育法》，食物補充品製造商有責任確保其產品可供安全服用，才可推出市場發售。雖然藥物製品在推出市場前，必須證實可供安全服用，以及可達至預期用途，但食物補充品則不同，法例並無條文規定食物補充品在可供消費者購買前，必須先由食物及藥物管理局"批核"其安全性或成效。此外，法例亦無要求食物補充品的製造商及分銷商在接獲任何可能因使用他們的產品而健康受損或致病的報告時，必須予以記錄、調查或將報告轉交食物及藥物管理局，此方面的規定亦與藥物製品不同。根據《食物補充品健康及教育法》，食物補充品產品一旦推出市場，食物及藥物管理局如要採取行動限制公眾使用該產品或下令從市場回收該產品，便有責任先證明該產品"不能供安全服用"。

<u>推出市場前的通知</u>

6.2 《食物補充品健康及教育法》規定，製造商或分銷商若計劃在美國市場推出含有新的食物成分[10] 的食物補充品，便須通知食物及藥物管理局。除非該食物成分已被認可為食用物質，並在食品供應中使用，否則製造商或分銷商便須向食物及藥物管理局展示可合理地預期在食物補充品內使用該食物成分安全的理據。製造商或分銷商須在其將產品在州際商業市場推出或送貨之前最少75天作出通知。

[10] 新的食物成分是指在 1994 年 10 月 15 日前並未在美國推出市場的食物成分。

6.3 任何人除可作出通知外，亦可向衞生與公眾服務部部長(Secretary of Health and Human Services)提出正式申請，建議發出指令，規定在何種情況下新的食物成分按其擬定用法服用時可合理地預期為安全。部長應在申請提出後180天內作出決定。部長所作的決定是最終決定。

6.4 目前並無法定條文要求企業就其食物補充品產品的安全性或宣稱所具的效益，向食物及藥物管理局或消費者公開有關的資料。每家企業可以自行制訂公開該等資料的政策。

7. 對廣告的規管

7.1 聯邦貿易委員會協同食物及藥物管理局，規管為售予消費者的食物補充品作廣告宣傳(包括資訊性廣告)的事宜。至於通過郵遞分發的宣傳推廣資料則由另一個聯邦部門，美國郵政檢查部負責規管。聯邦貿易委員會根據《聯邦貿易委員會法》(The Federal Trade Commission Act)評估食物補充品廣告所作的聲稱。該法令禁止任何"不公平或欺詐的行為或行事方式"，亦禁制"實質上含誤導成分"的虛假廣告。[11]

8. 執法

8.1 在1994年《食物補充品健康及教育法》通過後的10年間，食物補充品產業的年均銷售額已從約80億美元(621億港元)[12] 增長至估計為160億美元(1,242億港元)至190億美元(1,475億港元)。[13] 鑒於市場龐大，評論者指國會並無就食物補充品方面為食物及藥物管理局提供足夠的執法經費。自2002年起，食物及藥物管理局開始獲得特別指定用作執行《食物補充品健康及教育法》的款項，而國會每年撥款50萬美元(388萬港元)，以供執行《食物補充品健康及教育法》之用。[14] 美國全國營養食品協會(National Nutritional Foods Association)[15] 執行理事於2003年10月在國會作證時表示，食物及藥物管理局"從未徹底實施或充分執行"《食物補充品健康及教育法》的規定。

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11 有關規管廣告的詳情，可參閱2001年發表的《美國有關健康食品的規管》研究報告第15.1至15.4段。

12 在2003年，美元兌換港元的平均匯率為1美元兌7.763港元。

13 Triplett (2004)。

14 同上。

15 美國全國營養食品協會是代表多種天然產品的製造商及零售商利益的組織。

8.2 食物及藥物管理局承認，該局用於分析食品(包括食物補充品)成分的資源有限。因此，該局會對那些被認為不能安全服用、欺詐或違反法例的產品優先採取執法行動。該局並無在食物補充品售予消費者前分析有關產品。製造商有責任確保"補充品資料"標籤及成分表正確，補充品所含成分安全妥當，以及產品的含量與標籤註明的分量相符。

8.3 評論者察覺，由於處方藥物和藥房售賣的藥物受到更嚴格的規管，所以和食物補充品相比，這些藥物可以較快地從市場上沒收。例如食物及藥物管理局在得悉一種減肥藥"芬芬"(fen-phen)懷疑與33宗罕見的心瓣病症有關後，該局在3個月內便沒收了這種藥物。至於食物補充品麻黃，要經過10年間發生155宗死亡個案後，食物及藥物管理局才能禁止麻黃在市場上發售。[16, 17] 這是因為食物及藥物管理局(而並非製造商)須要先證明有關食物補充品對消費者的安全構成風險，才能從市場上沒收這些補充品。

8.4 在宣傳方面，根據聯邦貿易委員會消費者保障局(Bureau of Consumer Protection)局長表示，自1994年通過《食物補充品健康及教育法》後，聯邦貿易委員會已採取逾100宗執法行動，針對就食物補充品刊登廣告的人作出據稱虛假或帶有誤導成分的聲稱，提出起訴或達成和解。聯邦貿易委員會與食物及藥物管理局最近組成了聯合專責小組，繼續處理類似的聲稱。

9. 最新發展

9.1 食物及藥物管理局在2004年11月宣布一項策略，概述該局計劃採取的步驟，以繼續實施及執行《食物補充品健康及教育法》。是項策略的目標是要增加食物及藥物管理局作出科學評核及規管行動的透明度、可預計性及一致性，防止消費者購入不能安全服用的食物補充品及防範食物補充品作出未經批准、虛假或帶有誤導成分的聲稱。策略的重點集中於下列3個範疇：

(a) 監察並評核產品及成分的安全性；

(b) 確保產品質量；及

(c) 監察並評核產品標籤。

16 Triplett(2004)。

17 食物及藥物管理局在2004年2月發表最終裁決，裁定含有麻黃生物鹼(麻黃)的食物補充品為公眾健康帶來不合理風險，因此不符合法定標準。現在美國國內已禁止售賣麻黃。

監察並評核產品及成分的安全性

9.2 食物及藥物管理局宣布，該局會協同聯邦機構及其他合作組織，發展取證基礎，供食物及藥物管理局用以判斷食物成分及食物補充品是否能安全服用，以及決定是否對該等成分及補充品採取執法行動。若察覺有跡象顯示有可能對產品安全構成潛在的影響[18]，食物及藥物管理局可從獨立第三者所作的覆檢中尋求意見。此外，食物及藥物管理局正採取步驟，確保含有新的食物成分的食物補充品不會不符合法定標準。

確保產品質量

9.3 2003年3月13日，食物及藥物管理局就《聯邦憲報》中現行《優良生產作業守則》對食物補充品所作的規定，發布擬議規則。[19] 該擬議規則旨在協助防止出現藥效過高或過低的產品、食物補充品中含有不當成分、帶有污染物(例如細菌、農藥、玻璃和鉛)、產品未達容器所示數量、食物補充品容器內有外來物質、包裝不當及標籤錯用等情況。食物及藥物管理局現正檢討及評估對擬議規則的意見，並計劃在2005年年初公布《優良生產作業守則》的最終規則。

監察並評核產品標籤

9.4 食物補充品標籤上如載有並無事實根據的結構／功能聲稱，可會欺騙和危害消費者。因此，食物及藥物管理局正採取下列行動，協助確保食物補充品標籤屬實及無誤導成分：

(a) 繼續鑒別載有並無科學證據支持的聲稱的食物補充品，並對有關食物補充品採取行動；

(b) 制訂並公布指引擬稿[20]，闡明何謂具有充分的科學證明，足以讓食物補充品作出結構／功能聲稱和對營養素缺乏病有益的聲稱[21]；

[18] 從聯邦、各州及地方的同類機構、不良反應事件報告、外國的執法行動、傳媒報導、消費者團體提供的資料及向專家所作的諮詢中均可能顯示該等跡象。

[19] 《聯邦憲報》第68冊第12158頁。

[20] 《聯邦憲報》第69冊第64962頁。

[21] 現時《食物補充品健康及教育法》並無為食物補充品所作的聲稱界定如何構成"充分證明"。

(c) 鑒別其標籤未能說明重要事實的產品，並對該等產品採取執法行動，主要目標是對消費者構成最重大風險的產品；

(d) 蒐集並分析市場上食物補充品的樣本，以核實產品的含量成分是否與標籤相符；及

(e) 檢視食物補充品標籤上的"補充品資料"分析表，以斷定列明為食物成分的物質是否可以合法地作為食物補充品推出市場。

黃鳳儀
2005年1月13日
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資料摘要為立法會議員及其轄下委員會而編製，它們並非法律或其他專業意見，亦不應以該等資料摘要作為上述意見。資料摘要的版權由立法會行政管理委員會(下稱"行政管理委員會")所擁有。行政管理委員會准許任何人士複製資料摘要作非商業用途，惟有關複製必須準確及不會對立法會構成負面影響，並須註明出處為立法會秘書處資料研究及圖書館服務部，而且須將一份複製文本送交立法會圖書館備存。

附錄I

藥物的定義

A.I.1 Under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (Act), the term "drug" is defined as

(a) articles recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(d) articles intended for use as a component of any article specified in clause (a), (b), or (c). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of the Act or sections 403(r)(1)(B) and 403(r)(5)(D) of the Act, is made in accordance with the requirements of section 403(r) of the Act is not a drug solely because the label or the labelling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of the Act is not a drug under clause (c) solely because the label or the labelling contains such a statement.

附錄II

食物補充品的定義

A.II.1 Under section 201(ff) of the Federal Food, Drug, and Cosmetic Act (Act), the term "dietary supplement":

(a) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(i) a vitamin;
(ii) a mineral;
(iii) an herb or other botanical;
(iv) an amino acid;
(v) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(vi) a concentrate, metabolite, constituent, extract, or combination of the above;

(b) means a product that:

(i) is intended for ingestion in tablet, capsule, powder, soft gel, gel cap, or liquid form;
(ii) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
(iii) is labelled as a dietary supplement; and

(c) does:

(i) include an article that is approved as a new drug under section 505 of the Act or licensed as a biologic under section 351 of the Public Health Service Act (42 United States Code 262) and was, prior to such approval, certification or license, marketed as a dietary supplement or as a food unless the Secretary of Health and Human Services has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labelling for such dietary supplement, is unlawful under section 402(f) of the Act; and

附錄 II(續)

(ii) not include:

- an article that is approved as a new drug under section 505 of the Act, certified as an antibiotic under section 507 of the Act, or licensed as a biologic under section 351 of the Public Health Service Act (42 United States Code 262); or

- an article authorized for investigation as a new drug, antibiotic or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the Act.

附錄III

斷定某項陳述是否疾病聲稱的準則

A.III.1 Under title 21 of the Code of Federal Regulations (C.F.R.) section 101.93(g), the Food and Drug Administration will find that a statement about a product claims to diagnose, mitigate, treat, cure or prevent disease if it claims, explicitly or implicitly, that the product:

(a) has an effect on a specific disease or class of diseases;

(b) has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(c) has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(d) has an effect on a disease or diseases through one or more of the following factors:

(i) the name of the product;
(ii) a statement about the formulation of the product;
(iii) citation of a publication or reference;
(iv) use of the term "disease" or "diseased"; or
(v) use of pictures, vignettes, symbols, or other means;

(e) belongs to a class of products that is intended to diagnose, mitigate, treat, cure or prevent a disease;

(f) is a substitute for a product that is a therapy for a disease;

(g) augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure or prevent a disease or class of diseases;

(h) has a role in the body's response to a disease or to a vector of disease;

(i) treats, prevents or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(j) otherwise suggests an effect on a disease or diseases.

附錄IV

有關食物標籤(包括食物補充品標籤)可使用的核准保健聲稱

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Calcium and osteoporosis (21 C.F.R. 101.72)	• High in calcium; • Assimilable (Bio-available); • Supplements must disintegrate and dissolve; and • Phosphorus content cannot exceed calcium content.	• Indicating the disease depends on many factors by listing risk factors or the disease, e.g. gender, race, or age; • Primary target population: females, Caucasian and Asian races, and teens and young adults in their bone-forming years; • Additional factors necessary to reduce risk: eating healthful meals and regular exercise; • Mechanism relating calcium to osteoporosis: optimizes peak bone mass; and • Food or supplements containing more than 400 mg calcium must state that total intakes of greater than 2 000 mg calcium provide no added benefit to bone health.	• Regular exercise and a healthy diet with enough calcium help teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Sodium and hypertension (21 C.F.R. 101.74)	• Low sodium.	• Requiring terms: ◆ "Sodium"; and ◆ "High blood pressure"; and • Including a physician statement if the claim defines high or normal blood pressure (e.g. "individuals with high blood pressure should consult their physicians").	• Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
Dietary fat and cancer (21 C.F.R. 101.73)	• Low fat (fish and game meats: "extra lean").	• Requiring terms: ◆ "Total fat" or "fat"; and ◆ "Some types of cancers" or "some cancers"; and • Forbidding specifying types of fats or fatty acids that may be related to the risk of cancer.	• Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Dietary saturated fat and cholesterol and risk of coronary heart disease (21 C.F.R. 101.75)	• Low saturated fat; • Low cholesterol; and • Low fat (fish and game meats: "extra lean").	• Requiring terms: ◆ "Saturated fat and cholesterol"; and ◆ "Coronary heart disease" or "heart disease"; and • Including a physician statement if the claim defines high or normal blood total (and low-density lipoprotein (LDL)) cholesterol (e.g. "individuals with elevated blood total (or LDL) cholesterol should consult their physicians").	• While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
Fiber-containing grain products, fruits, and vegetables and cancer (21 C.F.R. 101.76)	• A grain product, fruit, or vegetable that contains dietary fiber; • Low fat; and • Good source of dietary fiber (without fortification).	• Requiring terms: ◆ "Fiber", "dietary fiber", or "total dietary fiber"; and ◆ "Some types of cancer" or "some cancers"; and • Forbidding specifying types of dietary fiber that may be related to the risk of cancer.	• Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (21 C.F.R. 101.77)	• A fruit, vegetable, or grain product that contains fiber; • Low saturated fat; • Low cholesterol; • Low fat; • At least 0.6 grams of soluble fiber per Reference Amount (RA) (without fortification); and • Soluble fiber content provided on label.	• Requiring terms: ◆ "Fiber", "dietary fiber", "some types of dietary fiber", "some dietary fibers", or "some fibers"; ◆ "Saturated fat" and "cholesterol"; and ◆ "Heart disease" or "coronary heart disease"; and • Including a physician statement if the claim defines high or normal blood total (and LDL) cholesterol (e.g. "individuals with elevated blood total (or LDL) cholesterol should consult their physicians").	• Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Fruits and vegetables and cancer (21 C.F.R. 101.78)	• A fruit or vegetable; • Low fat; and • Good source (without fortification) of at least one of the followings: ◆ vitamin A; ◆ vitamin C; or ◆ dietary fiber.	• Requiring terms: ◆ "Fiber", "dietary fiber", or "total dietary fiber"; ◆ "Total fat" or "fat"; and ◆ "Some types of cancer" or "some cancers"; • Characterizing fruits and vegetables as "foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber"; • Characterizing specific food as a "good source" of one or more of the followings: dietary fiber, vitamin A, or vitamin C; and • Forbidding specifying types of fats or fatty acids or types of dietary fiber that may be related to the risk of cancer.	• Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. [*Name of food*] is high in vitamin A and C, and it is a good source of dietary fiber.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Folate and neural tube defects (21 C.F.R. 101.79)	• "Good source" of folate (at least 40 mcg folate per serving); • Dietary supplements, or food in conventional food form that are naturally good sources of folate (i.e. only non-fortified food in conventional food form); • The claim shall not be made on products that contain more than 100% of the Reference Daily Intake for vitamin A as retinol or preformed vitamin A or vitamin D; • Dietary supplements shall meet the United States Pharmacopoeia standards for disintegration and dissolution or otherwise bio-available; and • Amount of folate required.	• Requiring terms: ◆ Terms that specify the relationship (e.g. women who are capable of becoming pregnant and who consume adequate amounts of folate), "folate", "folic acid", "folacin", "folate, a B vitamin", "folic acid, a B vitamin," "folacin, a B vitamin," "neural tube defects", "birth defects, spinal bifida, or anencephaly", "birth defects of the brain or spinal cord - anencephaly or spinal bifida", or "spinal bifida or anencephaly, birth defects of the brain or spinal cord"; and • Including information on the multi-factorial nature of neural tube defects, and the safe upper limit of daily intake.	• Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Dietary sugar alcohol and dental caries (21 C.F.R. 101.80)	• Sugar free; • The sugar alcohol must be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of the above; and • When a fermentable carbohydrate is present, the food must not lower plaque pH below 5.7.	• Requiring terms: ◆ "Does not promote", "may reduce the risk of", "useful [or is useful] in not promoting", or "expressly [or is expressly] for not promoting" dental caries; ◆ "Sugar alcohol", "sugar alcohols", or the name or names of the sugar alcohols, e.g. sorbitol; and ◆ "Dental caries" or "tooth decay"; • Including a statement stating that "frequent between-meal consumption of foods high in sugars and starches can promote tooth decay"; and • Packages with less than 15 square inches of surface area available for labelling may use a shortened claim.	• Full claim: Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [*name of food*] do not promote tooth decay; or • Shortened claim (on small packages only): Does not promote tooth decay.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statement
Soluble fiber from certain food and risk of coronary heart disease (21 C.F.R. 101.81)	• Low saturated fat; • Low cholesterol; • Low fat; • Including either (1) one or more eligible sources of whole oats, containing at least 0.75 g whole oat soluble fiber per RA; or (2) psyllium seed husk containing at least 1.7 g of psyllium husk soluble fiber per RA; and • Amount of soluble fiber per RA declared in nutrition label.	• Requiring terms: ◆ "Heart disease" or "coronary heart disease"; ◆ "Soluble fiber" qualified by either "psyllium seed husk" or the name of the eligible source of whole oat soluble fiber; ◆ "Saturated fat" and "cholesterol"; and ◆ "Daily dietary intake of the soluble fiber source necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to this level of intake". Additional required label statement • Food products bearing a psyllium seed husk health claim must also bear a label statement concerning the need to consume them with adequate amounts of fluids. E.g. "*NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing.*" (21 C.F.R. 101.17(f))	• Soluble fiber from foods such as [*name of soluble fiber source, and, if desired, name of food product*], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food product*] supplies [*x*] grams of the [*necessary daily dietary intake for the benefit*] soluble fiber from [*name of soluble fiber source*] necessary per day to have this effect.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Soy protein and risk of coronary heart disease (21 C.F.R. 101.82)	• At least 6.25 g soy protein per RA; • Low saturated fat; • Low cholesterol; and • Low fat (except that food made from whole soybeans that contain no fat in addition to that inherent in the whole soybean are exempt from the "low fat" requirement).	• Requiring terms: ◆ "Heart disease" or "coronary heart disease"; ◆ "Soy protein"; and ◆ "Saturated fat" and "cholesterol"; • Specifying daily dietary intake levels of soy protein associated with reduced risk; and • Specifying amount of soy protein in a serving of food.	• Twenty-five grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies [*x*] grams of soy protein; or • Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [*name of food*] provides [*x*] grams of soy protein.

附錄IV(續)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Plant sterol/stanol esters and risk of coronary heart disease (21 C.F.R. 101.83)	• At least 0.65 g plant sterol esters per RA of spreads and salad dressings, or at least 1.7 g plant stanol esters per RA of spreads, salad dressings, snack bars, and dietary supplements; • Low saturated fat; • Low cholesterol; and • Spreads and salad dressings that exceed 13 g fat per 50 g must bear the statement "see nutrition information for fat content".	• Requiring terms: ◆ "May" or "might" reduce the risk of coronary heart disease; ◆ "Heart disease" or "coronary heart disease"; and ◆ "Plant sterol esters" or "plant stanol esters" ; except "vegetable oil" may replace the term "plant" if vegetable oil is the sole source of the sterol/stanol ester; • Specifying plant stero/stanol esters are part of a diet low in saturated fat and cholesterol; • Not attributing any degree of coronary heart disease risk reduction; • Specifying the daily dietary intake of plant sterol or stanol esters necessary to reduce coronary heart disease risk, and the amount provided per serving; and • Specifying that plant sterol or stanol esters should be consumed with two different meals each day.	• Foods containing at least 0.65 gram per serving of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies [*x*] grams of vegetable oil sterol esters; or • Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [*name of food*] supplies [*x*] grams of plant stanol esters.

Source: United States Food and Drug Administration, Center for Food Safety and Applied Nutrition (2000).

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