

GUIDANCE:

Compliance with the Food Allergen Labeling and Consumer Protection Act for Marketers of Chinese Herbal Products

July 2021 (Revised)

Prepared by the American Herbal Products Association



This version replaces a document of the same title published in December 2019. This version includes the addition of sesame as a major food allergen. This document is the property of the American Herbal Products Association (AHPA) and is for AHPA purposes only. Unless given prior approval from AHPA, it shall not be reproduced, circulated, or quoted, in whole or in part, outside of AHPA, its Committees, and its members. Cite as: American Herbal Products Association. July 2021. GUIDANCE: Compliance with the Food Allergen Labeling and Consumer Protection Act for Marketers of Chinese Herbal Products. AHPA: Silver Spring, MD.

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This document is specifically relevant to addressing the current legal status of the ingredients identified herein. No other issues related to the manufacture, marketing, labeling or sale of food, dietary ingredients, and dietary supplements, or any other class of consumer goods are addressed herein.

While AHPA believes the information herein is accurate, AHPA advises all individuals and entities using this information to discuss all aspects of their application of this information with an attorney or qualified consultant, or with personnel at relevant regulatory agencies.

While AHPA believes that this guidance provides information on the major food allergens that may require labeling in traditional Chinese ingredients and formulas, the following guidance should not be considered to be an exhaustive list of all traditional Chinese ingredients or formulas that may contain major food allergens.



Table of Contents

Introduction.....	1
Background on FALCPA	2
Major food allergens.....	2
Tree nuts requiring labels	3
Exemptions to FALCPA labelling.....	4
Chinese herbal products that may contain allergens.....	4
Traditional Chinese ingredients that may contain allergens	4
Egg.....	5
Tree nuts.....	5
Wheat.....	5
Soybeans	6
Sesame	7
Traditional Chinese formulas that may contain allergens	7
Tree nuts.....	7
Wheat.....	7
Soybeans	9
Sesame	10
Additional resources	11



Introduction

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) established specific labeling requirements for foods, including dietary supplements, that contain those food ingredients identified under this law to be “major food allergens.” The primary labeling requirements for food ingredients covered by FALCPA is simply that these be disclosed on the label of a food product that contains any major food allergen. Although the law is on first glance quite straightforward, failure to properly identify allergens on food labels has become one of the most common reasons for food recalls over the past several years.

A number of AHPA’s members market products that consist of or contain ingredients used in Chinese herbal traditions such as Traditional Chinese Medicine (TCM), and some of these ingredients require labeling as allergens. These AHPA members therefore have a need to understand the requirements of this law when using these ingredients.

This guide presents a summary of FALCPA and identifies those ingredients and preparations found in traditional Chinese herbal ingredients and formulas that may require labeling as major food allergens when included in a product labeled as a food or dietary supplement. It includes the recent revision to FALCPA that recognizes sesame as an additional major food allergen.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of more than 350 member companies, consisting primarily of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products as foods, dietary supplements, cosmetics, and non-prescription drugs, and also including companies that provide expert services to the herbal trade. Founded in 1982, AHPA's mission is to promote the responsible commerce of herbal products.

AHPA acknowledges the contributions of many members of the AHPA Chinese Herbal Products Committee in developing this guidance.

Comments on this document, especially from those users knowledgeable in Chinese herbal product formulation, are welcome and should be submitted to AHPA at the email or mailing address listed below. Revisions may be made to this guidance as additional insights are gained through its practical use.

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Background on FALCPA

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282¹) was enacted in August 2004, and addresses, among other issues, the labeling of foods that contain what the law defines as “major food allergens.” The law became effective on January 1, 2006. In addition, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER) (Public Law 117-11)² amended the FALCPA definition of “major food allergen” to include sesame as an additional food, among other requirements. The FASTER law takes effect on January 1, 2023.

FALCPA applies to both domestically manufactured and imported packaged foods, including dietary supplements that are subject to FDA labeling regulations.

Major food allergens

The major food allergens identified in FALCPA that require disclosure on food and supplement product labels are:

- milk,
- egg,
- fish (e.g., bass, flounder, or cod),
- Crustacean shellfish (e.g., crab, lobster, or shrimp),
- tree nuts (e.g., almonds, pecans, or walnuts),
- wheat,
- peanuts,
- soybeans, and
- sesame.

With certain exceptions, major food allergens also include food ingredients that contain protein derived from a food ingredient that is a major food allergen.

While other food ingredients may cause allergic reactions when ingested by specific individuals, only the major food allergens identified in FALCPA are required to be disclosed on food labels. Voluntary disclosure of allergenic potential of other ingredients in foods or supplements may also be made at the discretion of companies that sell such products.

¹ The text of FALCPA is available at <https://www.fda.gov/food/food-allergens-and-gluten-free-guidance-documents-and-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>. Accessed July 6, 2021.

² The text of FASTER is available at <https://www.congress.gov/117/plaws/publ11/PLAW-117publ11.pdf>.



Tree nuts requiring labels

Only specific tree nuts are required to be labeled as major food allergens under FALCPA. FDA published a list of their current best judgment as to “tree nuts” that require disclosure within the meaning of FALCPA in their October 2006 *Guidance for Industry: Questions and answers regarding food allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004*.³ The common name and scientific and family names of these tree nuts are as follows:

- almond, *Prunus dulcis* (Rosaceae)
- beech nut, *Fagus* spp. (Fagaceae)
- Brazil nut, *Bertholletia excelsa* (Lecythidaceae)
- butternut, *Juglans cinerea* (Juglandaceae)
- cashew, *Anacardium occidentale* (Anacardiaceae)
- chestnut (Chinese, American, European, Seguin), *Castanea* spp. (Fagaceae)
- chinquapin, *Castanea pumila* (Fagaceae)
- coconut, *Cocos nucifera* L. (Arecaceae (alt. Palmae))⁴
- filbert/hazelnut, *Corylus* spp. (Betulaceae)
- ginkgo nut, *Ginkgo biloba* L. (Ginkgoaceae)
- hickory nut, *Carya* spp. (Juglandaceae)
- lichee nut, *Litchi chinensis* Sonn. (Sapindaceae)
- macadamia nut/bush nut, *Macadamia* spp. (Proteaceae)
- pecan, *Carya illinoensis* (Juglandaceae)
- pine nut/pinon nut, *Pinus* spp. (Pineaceae)
- pili nut, *Canarium ovatum* Engl. in A. DC. (Burseraceae)
- pistachio, *Pistacia vera* L. (Anacardiaceae)
- shea nut, *Vitellaria paradoxa* C.F. Gaertn. (Sapotaceae)
- walnut (English, Persian, Black, Japanese, California), heartnut, butternut; *Juglans* spp. (Juglandaceae)

³ This guidance document is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4>. Accessed July 6, 2021

⁴ AHPA notes that the FDA list of tree nuts includes the former standard classification of Arecaceae as Palmae.



FALCPA requires that the specific type of tree nut must be declared on the label. No obligation to disclose any other tree nuts as major food allergens is established under FALCPA, such as any other tree nuts that may be used in traditional Chinese ingredients and formulas.

Exemptions to FALCPA labelling

Raw agricultural commodities (e.g., fresh fruits and vegetables) are exempt from labeling under FALCPA, as well as “highly refined oils” derived from one of the major food allergens and food ingredients derived from such highly refined oils. In traditional Chinese medicine, some herb processing may include usage of oils refined from major allergens such as soy beans. Marketers should consider whether such oils may contain allergenic protein as the term “highly refined oil” is not defined by FDA or in FALCPA.

No exemption is provided for small businesses.

Chinese herbal products that may contain allergens

Information collected by AHPA from experts with extensive experience in the composition and processing of ingredients and formulas used in Chinese herbal traditions was used to identify those ingredients and formulas that are composed of a major food allergen or that may contain major food allergens due to the method of preparation or processing of an ingredient (known as “pao zhi”). Data were collected for both individual ingredients as well as prepared formulas which may consist of two or more individual ingredients. The information reported here is intended as guidance as to the traditional Chinese ingredients or formulas that may require labeling for the presence of major food allergens.

While AHPA believes that the following provides information on the major food allergens that may be present in traditional Chinese ingredients and formulas, the following information should not be considered to be an exhaustive list of all ingredients or formulas that may contain major food allergens.

Traditional Chinese ingredients that may contain allergens

The following traditional Chinese ingredients consist of foods that are major food allergens or are processed or prepared using such foods. The ingredients are identified by common (*pinyin*) name in *italics* followed by the traditional Chinese pharmaceutical name and English name (in parentheses).



Egg

Egg is present in the following ingredient:

- *ji zi huang*, Gallus gallus (egg yolk)

Tree nuts

Tree nuts are present in the following ingredients:

- *bai guo*, Semen ginkgo (ginkgo nut)
- *he tao ren*, Semen juglandis (walnut)
- *li zhi he*, Semen litchi (lichee nut)
- *song zi ren*, Semen pini (pine nut/pinon nut)

Wheat

Wheat is present in the following ingredients:

- *ban xia qu*, Rhizoma pinelliae massa fermentata (Pinellia rhizome medicated leaven)
- *fu xiao mai*, Triticum aestivum (light or shiveled wheat grain)
- *jian shen qu*, Massa fermentata preparata (prepared medicated leaven)
- *shen qu*, Massa fermentata (medicated leaven)
- *xiao mai*, Fructus tritici (wheat grain)
- *yi tang*, Maltosum (barley malt sugar)⁵

Wheat may be present in the following ingredients due to processing with ingredients that contain wheat. Marketers of products containing these ingredients should determine if such processing has been performed:

- *bai zhu*, Rhizoma atractylodis macrocephalae (white atractylodes rhizome)
- *bie jia*, Carapax amydae sinensis (Chinese soft-shelled turtle shell)
- *cang zhu*, Rhizoma atractylodis (black atractylodes rhizome)
- *chuan xiong*, Rhizoma ligustici chuanxiong (Szechuan lovage root)
- *ci shi*, Magnetitum (magnetite)
- *e jiao*, Asini gelatinum (gelatin)
- *gui ban*, Plastrum testidinus (fresh water turtle shell)

⁵ This ingredient can be derived from numerous grains, which can include wheat.



- *huang jing*, Rhizoma polygonati (Siberian Solomon seal rhizome)
- *lu jiao jiao*, Gelatinum cornu cervi (deer horn gelatin)
- *rou cong rong*, Herba cistanchis deserticolae (fleshy stem of bloomrape)
- *shan yao*, Radix dioscoreae oppositae (Chinese yam rhizome)
- *xiang fu*, Rhizoma cyperi rotundi (nut grass rhizome)
- *zhi shi*, Fructus immaturus citri aurantii (bitter orange immature fruit)

Wheat may be present in the following ingredients due to processing with wheat bran (*chao* or *fu chao*). Marketers of products containing these ingredients should determine if such processing has been performed:

- *bai zhu chao*, Rhizoma atractylodis macrocephalae (white atractylodes rhizome)
- *cang zhu fu chao*, Rhizoma atractylodis (black atractylodes rhizome)
- *chen pi chao*, Pericarpium citri reticulatae (dried tangerine peel)
- *he zi fu chao*, Terminaliae chebulae fructus (terminalia, myrobalan fruit)
- *jiang cao fu chao*, Herba cum radice patriniae (patrinia herb and root)
- *qian shi fu chao*, Semen euryalis ferocis (euryale ferox seed)
- *sang piao xiao chao*, Ootheca mantidis (mantis egg case)
- *shan yao fu chao*, Radix dioscoreae oppositae (Chinese yam rhizome)
- *ze xie fu chao*, Rhizoma alismatis (water plantain rhizome)
- *zhi ke fu chao*, Fructus citri aurantii (bitter orange mature fruit)
- *zhi shi fu chao*, Fructus immaturus citri aurantii (bitter orange immature fruit)

Soybeans

Soybeans are present in the following ingredients:

- *da dou huang juan*, Sojae semen germinatum (germinated soybean, soybean sprout)
- *dan dou chi*, Sojae semen preparatum (fermented soybean)
- *hei dou*, Sojae semen nigrum (dried soybean)



Soybeans may be present in the following ingredients due to processing or preparation:

- *e jiao*, Asini gelatinum (gelatin) [may be thickened with soybean oil⁶]
- *zhi he shou wu*, Radix polygoni multiflori praeparata (Fo-Ti) [may be cooked with black soybean]

Sesame

Sesame is present in the following ingredient:

- *hei zhi ma* or *hu ma ren*, Sesami semen nigrum (black sesame seed)

Traditional Chinese formulas that may contain allergens

The following traditional Chinese formulas may contain foods that are major food allergens or may be processed or prepared using such foods. The formula name is identified by traditional formula name in *pinyin* and the synonymous English name; the allergenic ingredient is noted in brackets.

Tree nuts

The following formulas may contain tree nuts due to ingredients, preparation, or processing:

- *ding chuan tang*, Arrest Wheezing decoction; [ginkgo nut (Semen ginkgo)]
- *ren shen hu tao tang*, Ginseng & Walnut formula; [walnut (Semen juglandis)]
- *wu ren wan*, Five seed formula; [pine nut (Semen pini)]
- *yi huang tang*, Change Yellow Discharge decoction; [ginkgo nut (Semen ginkgo)]
- *yin chen pai shi tang*, Artemisia Scoparia decoction; [lichee nut (Semen litchi)]

Wheat

The following formulas may contain wheat due to wheat-containing ingredients:

- *gan mai da zao tang*, Licorice & Jujube combination; [wheat (*xiao mai*)]
- *huang qi jian zhong tang*, Astragalus formula; [Maltosum (*yi tang*)]

⁶ Highly refined oils derived from one of the major food allergens and any ingredient derived from such highly refined oils are exempt from FALCPA allergen labeling requirements.



The following formulas may contain *shen qu* (medicated leaven) as an ingredient, which contains wheat:

- *ban xia bai zhu tian ma tang*, Pinellia & Gastrodia combination
- *bao he wan*, Citrus & Crataegus formula
- *ge hua jie cheng san*, Pueraria flower formula
- *huang qi ji xue wan*, Ji Xue formula
- *jia jian bao he wan*, Stomach Harmonizing formula
- *jin jian fei er wan*, Ginseng & Hoelen formula
- *qing shu yi qi tang*, Astragalus & Atractylodes combination
- *shang zhong xia tong yong tong feng wan*, Cinnamon & Angelica formula
- *xiang sha ping wei san*, Cyperus, Cardamom & Atractylodes formula
- *yue ju wan*, Cyperus & Atractylodes combination
- *zhen gan xi feng tang*, Hematite & Scrophularia combination

The following formulas may contain wheat due to ingredients processed with wheat bran (*chao* or *fu chao*). Marketers of products containing these ingredients should determine if such processing has been performed:

- *bu huan jing zheng qi san*, More Valuable than Gold Righteous Qi Powder
- *bu zhong yi qi san*, Ventral Qi Teapills
- *da cheng qi wan*, Major Support the Qi Pills
- *dang gui san*, Angelica Dang Gui Pills
- *guan jie yan wan*, Joint Obstruction Teapills
- *he zi pi san*, Terminalia Powder
- *jia wei xiao yao san*, Augmented Free and Easy Wanderer
- *jian pi wan*, Strengthen the Spleen Pills
- *jin suo gu jing wan*, Golden Lock Teapills
- *ju pi tang*, Orange Peel Formula
- *kang ning wan*, Curing Pills
- *liu jun zi wan*, Six Gentlemen Teapills
- *mu xiang shun qi wan*, Saussurea Qi Promoting Pills



- *nu ke ba zhen wan*, Eight Treasure Pills, Women’s Precious Teapills
- *ping wei san*, Magnolia & Ginger formula, Calm Stomach Teapills
- *shen ling bai zhu san*, Codonopsis, Poria & Atractylodes formula
- *shu gan pian*, Soothe the Liver Teapills
- *si jun zi wan*, Four Gentlemen Teapills
- *wan dai tang*, End Abnormal Vaginal Discharge formula
- *xiang sha liu jun zi wan*, Six Gentlemen Plus Teapills
- *xiang sha yang wei wan*, Cardamon & Saussurea Pills
- *xiao yao san*, Rambling powder, Free and Easy Wanderer
- *yang ying wan*, Nourish Nutritive Qi Pills
- *yi gong san*, Extraordinary Merit Powder
- *yu ping feng san*, Jade Defender, Jade Windscreen
- *zhi shi dao zhi wan*, Immature Citrus Abduct Stagnation Pills
- *zhi shi xiao pi wan*, Immature Citrus Disperse Glomus Pills
- *zhi zhu wan*, Immature Bitter Orange & Atractylodes Macrocephala Pills

Soybeans

The following formulas may contain soybeans due to ingredients, preparation or processing:

- *xie bai san*, Mulberry & Lycium formula; [fermented soy bean (*dan dou chi*)]
- *yin qiao san*, Lonicera & Forsythia formula; [fermented soybean (*dan dou chi*)]
- *zhi zi chi tang*, Gardenia & Soja combination; [fermented soybean (*dan dou chi*)]

The following formulas may contain *e jiao* (gelatin) as an ingredient, which may be processed with soybean oil or with wheat. As previously noted, highly refined oils derived from major food allergens do not require labeling, so the following list is provided for informational purposes only as regards the presence of soybean. The list may not be complete so attention should be paid to other formulas that contain this ingredient.

- *jiao ai tang*, Gelatin & Mugwort combination
- *qing zao jiu fei tang*, Eriobotrya & Ophiopogon combination
- *wen jing tang*, Tangkuei & Evodia combination
- *xiong gui jiao ai tang*, Tangkuei & gelatin combination
- *zhi gan cao tang*, Licorice combination



- *zhu ling tang*, Polyporus combination
- *zi wan tang*, Aster combination

Sesame

The following formulas may contain sesame due to ingredients, preparation, or processing:

- *qi bao mei ran dan*, Seven treasures pill
- *qing zao jiu fei san*, Eliminate Dryness and Rescue the Lungs formula
- *qing zao jiu fei tang*, Eliminate Dryness and Rescue the Lungs formula
- *sang ma wan*, Mulberry leaf and sesame seed pill
- *shou wu pian*, Polygonum Multiflorum Pills
- *xiao feng wan*, Great Windkeeper Teapills
- *xiao feng san*, Disperse Wind pills
- *yi yi ren tang*, Coicis decoction



Additional resources

Users of this guidance may also consult the following U.S. FDA resources regarding labeling of food and dietary supplement products under FALCPA.

Food Allergens and Gluten-Free Guidance Documents and Regulatory Information:

<https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergens-and-gluten-free-guidance-documents-and-regulatory-information>

Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers:

<https://www.fda.gov/food/food-allergens-and-gluten-free-guidance-documents-and-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers>

Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4):

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4>

