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Labeling compliance and online claims for Ayurvedic herbal supplements on the U.S. market associated with the purported treatment of COVID-19

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ABSTRACT

During the COVID-19 pandemic, many consumers increased their use of supplements that claimed to support immune health, including Ayurvedic preparations. The goal of this study was to analyze labeling compliance and online claims for Ayurvedic herbal supplements associated with the purported treatment of COVID-19. The physical product labels for 51 herbal supplements labeled as ginger, tulsi/holy basil, amla, vacha/calamus root, guduchi/giloy, cinnamon, ashwagandha, tribulus, or turmeric were assessed for U.S. regulatory compliance. Disease claims, structure/function claims, and general well-being claims were also examined. The online listings for products purchased online (n = 42) were examined for claims and for the presence of the required legal disclaimer. Collectively, 61% of products had at least one instance of noncompliance on the physical label. The most common violations included missing/noncompliant disclaimer (33%), noncompliant "Supplement Facts" label (29%), noncompliant statement of identity (27%) and noncompliant domestic mailing address or phone number (25%). Structure/function claims occurred more frequently in the online product listings (average of 5 claims per product) compared to the physical labels (average of 2 claims per product). Disease claims were observed for 38% of online product listings and on 8% of physical labels. The use of disease claims on herbal supplements is a significant concern for public health because it may lead consumers to delay seeking professional treatment for life-threatening diseases. Overall, this study revealed a lack of labeling compliance among Ayurvedic herbal supplements and a need for greater scrutiny and monitoring of online product listings.

1. Introduction

Ayurveda is a traditional Indian system of medicine that involves a combination of supplements, diet, yoga, and lifestyle (National Institutes of Health, 2018). Although there is limited scientific evidence to support the effectiveness of Ayurvedic medicine, it is widely practiced in the U.S. and globally (National Institutes of Health, 2018). During the COVID-19 pandemic, many consumers took a keen interest in supplements that claimed to support immune health, heart health, and stress relief, with U.S. herbal supplement sales increasing to a record breaking US$11.261 billion in 2020, a 17.3% increase over 2019 (Smith et al., 2021). Numerous Ayurvedic supplements have been suggested for the purported prevention or treatment of COVID-19, including ashwagandha (*Withania somnifera*), ginger (*Zingiber officinalis*), tulsi (*Ocimum sanctum*), amla (*Emblica officinalis*), vacha (*Acorus calamus*), guduchi (*Tinospora cordifolia*), cinnamon (*Cinnamomum verum*), tribulus (*Tribulus terrestris*), and turmeric (*Curcuma longa*) (Ministry of AYUSH, 2020; Rastogi et al., 2022; Sen, 2020; Yakhchali et al., 2021). In 2020, ashwagandha demonstrated the greatest sales growth among all dietary supplements in the mainstream channel, with sales totaling US $31.7 million, an increase of 185.2% compared to 2019 (Smith et al., 2021).

Despite the increasing popularity of herbal supplements, botanical or chemical adulteration and product mislabeling are important areas of concern (Abraham & Kellogg, 2021; Balekundri & Mannur, 2020; Liu & Lu, 2017; Vaclavik et al., 2014; Wheatley & Spink, 2013; You et al., 2022, pp. 1–20). A number of studies have reported the detection of undeclared ingredients, unsubstantiated claims and other forms of mislabeling in dietary supplements (Avery et al., 2017; Cohen et al., 2014; Dahm et al., 2022; Hellberg et al., 2019; Isaacs & Hellberg, 2019; Levinson, 2012; Morovic et al., 2016; Schoonees et al., 2013; Silva et al., 2020), including herbal supplements (Navarro et al., 2019; Newmaster et al., 2013; You et al., 2022). For example, Navarro et al. (2019) reported detection of herbal and dietary supplement mislabeling at an overall rate of 51% among supplements implicated in liver injury. Another study examining consumers of Ayurvedic medicine found that 28% of the supplements tested showed elevated levels of lead, 48%

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showed elevated levels of mercury, and 16% showed elevated arsenic levels (Breeher et al., 2015). Among the study participants, 40% had elevated blood levels of lead and 5% of those tested had elevated blood mercury levels. Furthermore, popular botanicals marketed for immune health, such as elderberry, turmeric, and functional mushrooms, have been associated with inaccurate labeling due to adulteration with lower grade ingredients, undeclared plants, and synthetic compounds, which is partially attributed to pandemic-related issues with supply chains (You et al., 2022). With regards to the physical labeling of dietary supplements, previous studies on animal-derived dietary supplements have revealed noncompliance rates of 48–59% (Isaacs & Hellberg, 2019; Silva et al., 2020).

Herbal supplements are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA), which requires manufacturers to evaluate the safety and labeling of products prior to marketing (Food and Drug Administration, 2022a). They must also meet all the requirements of the Federal Food, Drug, and Cosmetic Act, as amended by DSHEA and Food and Drug Administration (FDA) regulations. Herbal supplement labels are required to include a statement of identity (e.g., "dietary supplement"), net quantity of contents, "Supplement Facts" label, ingredient list, and name and place of business of the manufacturer, distributor or packer with a domestic mailing address and/or telephone number (Food and Drug Administration, 2005). There are additional specifications regarding how this information is displayed on the package and what details must be included. For example, the "Supplement Facts" label must include the name and quantity of dietary ingredients (including the part of the plant from which the ingredient is derived), serving size, and servings per container (unless it is the same as the information shown in the net quantity of contents).

Dietary supplement labels may also include a variety of claims, such as health claims, structure/function claims, and general well-being claims (Food and Drug Administration, 2022b). Health claims require significant scientific agreement and can only be used if they are authorized by the FDA. Structure/function claims explain the role of a nutrient or dietary ingredient intended to affect normal structure or function of the human body. Structure/function claims are not permitted to link the nutrient or dietary ingredient directly or indirectly to a disease or state of health leading to a disease. General well-being claims describe the general well-being provided by consuming a nutrient or dietary ingredient. Structure/function claims and general well-being claims are not pre-approved by FDA, but the manufacturer must be able to provide substantiation that the claim is truthful and not misleading. Labels containing these types of claims are required to include a word-for-word disclaimer stating: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

While most studies on herbal supplement safety and mislabeling have focused on ingredient testing and verification, there is a lack of research examining regulatory compliance associated with the physical product label and online claims made for these products. Adherence to U.S. labeling regulations is essential to prevent consumers from being misled regarding the nature and contents of the product. Therefore, the objective of this study was to analyze labeling compliance and online claims for Ayurvedic herbal supplements associated with the purported treatment of COVID-19.

2. Materials and methods

2.1. Sample collection

Herbal supplement products (n = 51) used in Ayurvedic medicine were examined in this study for label compliance and online product descriptions. The products were selected from nine types of herbs that are used for immune system health in Ayurvedic medicine and have been suggested for the purported treatment or prevention of COVID-19 (Ministry of AYUSH, 2020; Rastogi et al., 2022; Sen, 2020; Yakhchali et al., 2021): ginger, tulsi/holy basil, amla, vacha/calamus root, guduchi/giloy, cinnamon, ashwagandha, tribulus, and turmeric. In addition to belonging to one of the categories listed above, additional criteria for sampling included single-species products marketed as herbal supplements in powder, capsule, or tablet form, with no requirement for a specific country of origin. Although calamus root (vacha) has been prohibited from use in food products in the United States (21 CFR § 189.110), products marketed as herbal supplements and claiming to contain vacha/calamus root were available online and were collected for use in this study. In order to allow for a greater sample size and variety of products, samples were purchased from multiple online retailers (n = 42 products) as well as from local retail outlets located within 30 miles of Chapman University, Orange, CA (n = 9 products). All products were purchased during the period of July to December 2021. The supplements were in the form of capsules (n = 38), powders (n = 10), and tablets (n = 3), and were associated with 44 different brand names. Following collection, each sample was photographed and cataloged.

2.2. Label analysis

All herbal supplements were examined for the following information required by law for dietary supplements: statement of identity, net quantity of contents "Supplement Facts" label, ingredient statements, and name and place of business of manufacturer, packer, or distributor including a domestic address or phone number (21 CFR § 101 and 21 USC § 343). The font size of the principal display panel and information panel was measured to ensure the letters were a minimum of one-sixteenth (1/16) inch in height based on the lower case letter "o," Phone numbers listed on the labels were called to verify that they were in service and associated with the company. Domestic mailing addresses were verified online with the United States Postal Service Zip Code Lookup tool (https://tools.usps.com/zip-code-lookup.htm).

Structure/function claims and general well-being claims were examined for compliance with U.S. regulations (21 CFR § 101 and 21 USC § 343), including the presence of the required legal disclaimer: "This statement has (These statements have) not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" (21 CFR § 101.93). In addition to making sure that the wording of these claims was compliant with regulations, the placement of the disclaimer was examined to ensure that it was either adjacent to the claim with no intervening material or linked to the claim with a symbol. The presence of supporting scientific evidence was also investigated for the most common structure/function claims made. However, a decision regarding whether the claim was substantiated was not made due to the possible existence of evidence not available to the authors and the need for the FDA to evaluate the claim.

All products were examined for the presence of disease claims as defined in 21 CFR § 101.93(g), with guidance from the Final Rule for Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body (2000), the FDA Small Entity Compliance Guide on Structure/Function Claims (Food and Drug Administration, 2002), and the FDA Office of Dietary Supplement Programs (ODSP). For this purpose, disease is defined as "… damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition" (21 CFR § 101.93(g)). Statements about products that explicitly or implicitly claimed to diagnose, mitigate, treat, cure, or otherwise prevent disease (other than a classical nutrient deficiency disease) were considered disease claims, as defined in 21 CFR § 101.93(g).

2.3. Online product description analysis

The online product descriptions for all 42 supplements purchased from online retailers were examined for the presence of structure/function claims, general well-being claims, and/or disease claims. Any online descriptions with structure/function claims and/or general well-being claims were also examined for the presence of the required legal disclaimer noted above.

3. Results

3.1. Labeling compliance

All 51 herbal supplements examined in this study were compliant with declaring the net quantity of contents and the name of manufacturer/packer/distributor. However, 31 (60.8%) had at least one instance of noncompliance with U.S. labeling regulations (Table 1). Overall, there were 67 instances of noncompliance observed, with an average of 2.2 violations per noncompliant product and a maximum of 8 violations in one product (sample no. K27). When comparing the types of violations, noncompliant disclaimers for structure/function or general well-being claims were observed in the greatest number of products (n = 17), followed by noncompliant "Supplement Facts'' labels (n = 15), noncompliant statements of identity (n = 14), and noncompliant domestic mailing addresses or phone numbers (n = 13).

Approximately half (48.6%) of the 35 products with structure/function or general well-being claims had noncompliant disclaimers: 2 were completely missing the disclaimer (K07, K46), 6 had noncompliant wording, 5 had noncompliant placement (i.e., intervening text between a claim and the disclaimer, with no symbol (e.g., asterisk) linking the information), and 4 had both noncompliant wording and noncompliant placement. The most common form of noncompliant disclaimer wording, which was observed in 6 products, involved the use of the abbreviation FDA instead of the full spelling 'Food and Drug Administration'. An additional 4 products had modified versions of the disclaimer, such as "These statements have not been evaluated by the Food and Drug Administration and this product is an herbal food supplement and not intended to treat, cure, or prevent a disease" (K19) or "This information has not been evaluated by the Food & Drug Administration. This information is not intended to diagnose, treat, cure, or prevent any disease" (K38) instead of "This statement has (These statements have) not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Among the 15 products that had noncompliant "Supplement Facts" labels, the most common issues were having a font size that was less than 1/16 of an inch (n = 5) and missing the part of the plant that the supplement was derived from (n = 5). Two products were completely missing the "Supplement Facts" label, and four products had numerous problems with the format of the panel (e.g., missing panel title, servings per container, serving size, etc.). With regards to the 14 products with a noncompliant statement of identity, 10 had incorrect wording and 4 had a font size that was less than 1/16 of an inch.

Of the 13 products with a noncompliant domestic mailing address or phone number, 8 only had international addresses or phone numbers listed, 2 did not have any mailing address or phone number listed, 1 had an invalid mailing address (not recognized by USPS) and no phone number listed, and 2 had no mailing address and a phone number that was out of service. All 13 of these products listed a website and/or email address on the label: 5 included a website only and 8 included a website and email address. The majority of samples (n = 11) with a noncompliant domestic mailing address or phone number were imported, with 10 products from India and 1 product from Canada.

3.2. Disease claims

As shown in Table 1, a total of 8 disease claims were observed on the physical label across 4 different products advertised as ginger (K15), amla (K20), vacha (K27), and guduchi (K46). Three of these supplements used the term "medicine" or "medicinal" to describe the product, which implies that this product may be used to mitigate, treat, cure, or prevent a disease. Additionally, the amla product (K20) stated "respiratory & immune cell defense"; the vacha product (K27) used the terms "anti-stammering drug", "potent psycho-pharmacological agent", and "anti-epileptic"; and the guduchi product (K46) mentioned that the product "strengthens the body's resistance to fight infections". These statements were considered to be disease claims because they referred to the use of the product as a drug and/or they implied that the product may be used to treat or prevent certain diseases (Food and Drug Administration, 2002).

Of the 42 products purchased online, 16 had disease claims within the online listing for the product (Table 2). A total of 44 separate online disease claims were observed for these products, none of which were observed on the physical label for the same product. The greatest number of online disease claims was observed for guduchi/giloy (n = 12), followed by vacha/calamus root (n = 11) and tulsi/holy basil (n = 10), while products advertised as ginger or tribulus did not have any online disease claims. The most common types of online disease claims were associated with toxin removal/detoxification (n = 6), reference to the product as a medicine or having medicinal properties (n = 6), and reference to hay fever or respiratory conditions (n = 5), including asthma. Claims of toxin removal/detoxification were only considered disease claims if they were associated with information that implied a disease condition (FDA Office of Dietary Supplement Programs, personal communication, 10/17/2022). There were multiple online disease claims that either implied treatment of arthritis (n = 3) or directly mentioned the disease (n = 1). Three online claims implied the prevention or treatment of microbial or parasitic infections by using phrases such as "Improve … the body's resistance to infection", "Anti-microbial", and "Helps to destroy the worms in stomach." Additional online claims included those related to reducing/relieving depression (n = 3), anxiety (n = 1), insomnia (n = 1), and inflammation (n = 2); hepatoprotection (n = 2); curing constipation (n = 1); helping children with speech problems (n = 1); and treating "a wide variety of ailments" (n = 1).

3.3. Structure/function and general well-being claims

Numerous structure/function claims (n = 95) and general well-being claims (n = 8) were observed on the physical product labels (Table 1). These types of claims were observed in 35 products, for an average of 2 claims per product and a maximum of 8. The structure/function claims covered a wide range of topics, with the most common being those related to digestive support (n = 10), stress support/cortisol levels (n = 9), cognition/brain health (n = 7), joint support (n = 7), immune support (n = 6), and sugar metabolism/healthy blood sugar (n = 5). When the structure/function and general well-being claims were examined based on product type (Table 3), products marketed as vacha/calamus root had the highest frequency of claims, with an average of 3.5 claims per product and a total of 21 claims. The most common claims associated with vacha products were related to cognition/brain health, digestive support, and nervous system support. This was followed by turmeric, with an average of 2.8 claims per product and a total of 14 claims overall. The most common claims associated with turmeric products involved joint support, gastrointestinal tract/colon support, and liver support. Products marketed as guduchi/gilroy had the lowest frequency of claims, with 1.2 claims per product and a total of 7 claims overall.

As shown in Table 4, 32 of the 42 products purchased online had structure/function or general well-being claims in the online listing for

Table 1
Compliance information for herbal supplements examined in the study (n = 51). Instances of noncompliance are highlighted with light gray shading. All samples were compliant with net quantity of contents and name of manufacturer/packer/distributor.

Sample	Statement of identity	Wording of structure/function and disease claims	Category of claims (DC, GW, SF)[a]	Disclaimer	"Supplement Facts" panel	Domestic mailing address or telephone number	Instances of noncompliance
K01	Compliant	N/A	N/A	N/A	Compliant	Compliant	0
K02	Compliant	Curcumin may support healthy joints and help maintain a healthy cardiovascular system.	SF(2)	Noncompliant wording	Compliant	Compliant	1
K03	Compliant	N/A	N/A	Present (not required)	Compliant	Compliant	0
K04	Compliant	Studies suggest that Ginger root may provide nutritive support for digestive and joint health.	SF(2)	Noncompliant wording	Compliant	Compliant	1
K05	Compliant	N/A	N/A	N/A	Compliant	Compliant	0
K06	Compliant	It is a powerful adaptogen that helps your body adapt to the negative effects of stress. Preliminary research has suggested that holy basil may help maintain normal cortisol levels, support healthy adrenal glands, and help maintain normal blood sugar levels.	SF(4)	Compliant	Compliant	Compliant	0
K07	Compliant	Adaptogen	SF(1)	Absent	Compliant	Compliant	1
K08	Noncompliant font size	Respiratory and Immune Support	SF(2)	Compliant	Compliant	Noncompliant – invalid phone number, no mailing address	2
K09	Compliant	Rejuvenate...Adaptogenic: increases the body's resistance to stress. Increases stamina, energy, & muscle strength. Improves healthy functioning of adrenal & reproductive systems.	GW(1); SF(7)	Compliant	Compliant	Noncompliant - no phone number or mailing address	1
K10	Compliant	Provides antioxidant protection... relieve occasional nausea. Supports cardiovascular system. Supports healthy immune system. Supports healthy digestive system. Supports healthy inflammatory response.	SF(6)	Compliant	Compliant	Compliant	0
K11	Compliant	Healthy stress response. Ashwagandha is a powerful adaptogenic herb used for centuries as a natural source of vitality.	SF(2)	Noncompliant wording	Noncompliant font size	Compliant	2
K12	Compliant	Rejuvenating superfruit. Amla has traditionally been used to provide rejuvenation.	GW(1); SF(1)	Noncompliant wording	Compliant	Compliant	1
K13	Compliant	Promotes a feeling of calmness and relaxation. Stress support. Supports a healthy,	SF(2)	Noncompliant placement	Compliant	Compliant	1

the product, with an average of 5 online claims per product and a maximum of 21 (K36). Overall, a total of 159 online structure/function claims and 7 online general well-being claims were recorded for these products. The online structure/function claims covered an extensive range of topics, with the most common being those related to digestive support (n = 11), immune support (n = 11), stress support (n = 11), cardiovascular health (n = 9), energy (n = 8), memory/brain health (n = 7), rejuvenation (n = 7), and joint support (n = 6). When the online structure/function and general well-being claims were examined based on product type (Table 4), products marketed as guduchi/giloy had the highest frequency of online claims, with an average of 5.5 online claims per product and a total of 33 online claims. The most common claim for this product was associated with immune support. Additional online claims identified in multiple guduchi/giloy products included those for stress support, maintaining healthy body temperature, rejuvenation, strengthening/combating general debility and weakness, and tissue support.

Of the 32 products with online structure/function or general well-being claims, 1 had a compliant disclaimer, 3 were missing the disclaimer and 28 had a noncompliant disclaimer. A total of 24 products had a combination of noncompliant wording and noncompliant placement of the disclaimer (i.e., intervening text with no symbol linking the claim(s) to the disclaimer), 3 products had the correct wording but noncompliant placement of the disclaimer, and 1 product had the correct disclaimer placement but incorrect wording. The most commonly observed noncompliant wording (n = 18) was: "Statements regarding dietary supplements have not been evaluated by the FDA and are not intended to diagnose, treat, cure, or prevent any disease or health condition."

4. Discussion

4.1. Labeling compliance

This study found 100% compliance for herbal supplement labels with regards to net quantity of contents and name of manufacturer/packer/distributor. However, 61% of products were found to be noncompliant, with the main types of violations being noncompliant disclaimers for structure/function or general well-being claims, noncompliant "Supplement Facts" labels, noncompliant statements of identity, and noncompliant domestic mailing addresses or phone numbers. Similar to the current study, a previous study on labeling compliance of bovine liver dietary supplements also reported an overall noncompliance rate of 59% (Silva et al., 2020). These rates are slightly higher than a prior study that reported 48% noncompliance for shark cartilage dietary supplements (Isaacs & Hellberg, 2019). Similar to the current findings, previous studies also observed numerous products that lacked a domestic mailing address or phone number and had noncompliant disclaimers (Isaacs & Hellberg, 2019; Silva et al., 2020). Taken together, these findings indicate persistent problems with labeling compliance for various dietary

		natural response to stress.					
K14	Compliant	Beneficial for respiratory health, lungs, & bronchial system.	SF(1)	Compliant	Compliant	Compliant	0
K15	Noncompliant wording	Ginger...has been used for thousands of years for medicinal purposes. Ginger contains Gingerol, a substance with powerful medicinal properties.	DC(1)	Noncompliant placement and wording	Compliant	Compliant	3
K16	Noncompliant font size	N/A	N/A	Present (not required)	Compliant	Compliant	1
K17	Compliant	N/A	N/A	Present (not required)	Noncompliant - missing part of plant	Noncompliant – no phone number, invalid mailing address	2
K18	Compliant	For occasional nausea.	SF(1)	Compliant	Compliant	Compliant	0
K19	Noncompliant wording	Supports stomach spasm relaxation.	SF(1)	Noncompliant wording	Compliant	Questionable - phone number goes straight to an unspecified voice mail, invalid mailing address	2
K20	Compliant	Daily Immune Support. Helps boost immunity. Helps strengthen & normalize immune system by its restorative and immunomodulatory actions...respiratory & immune cell defense by its natural antioxidant properties & rejuvenative actions. Healthy Aging Response.	DC(1); GW(1); SF(3)	Compliant	Compliant	Compliant	1
K21	Compliant	For joint support. Supporting the joints, liver, immune system, heart, GI tract and more.	GW(1); SF(5)	Compliant	Compliant	Compliant	0
K22	Compliant	N/A	N/A	N/A	Compliant	Compliant	0
K25	Compliant	Helps balance mood levels and stress. This herb stimulates intelligence and expression. Vacha is known as a rejuvenating herb because of its effect on the nervous system.	SF(4)	Noncompliant placement	Noncompliant - incorrect wording	Compliant	2
K26	Noncompliant wording	Enhances memory. Improves cognition. All-natural Vacha is a nervine herb that promotes memory and cognitive functions. It also acts as an all natural mood stabilizer...countering the stress and tension of daily life. It is helpful in sluggishness of the liver and enhances the digestive function.	GW(1); SF(7)	Noncompliant placement and wording	Noncompliant - missing part of plant	Noncompliant - no domestic phone number or mailing address	4
K27	Noncompliant wording	Ayurvedic medicine. Vacha is a nervine tonic and an anti-stammering drug. Experimental studies have shown that it is a potent psycho-	DC (4); SF(8)	Noncompliant placement and wording	Noncompliant – absent	Noncompliant - no domestic phone number or mailing	8

supplements sold in the United States.

The proportion of products in this study with structure/function or general well-being claims that had a missing or noncompliant disclaimer (33%) is relatively high compared to previous dietary supplement studies, which have reported a range of 7–31% (Isaacs & Hellberg, 2019; Levinson, 2012; Silva et al., 2020). When examining structure/function or general well-being claims made online, an alarming 97% of products had a missing or noncompliant disclaimer. The majority of online claims were associated with a disclaimer that had noncompliant wording and was placed further down in the webpage, with intervening text and no symbol linking the claims to the disclaimer. The lack of compliance for online disclaimers adds another layer of concern for consumers that are relying on the online product descriptions for accurate product information.

Numerous products (16%) were found to have a font size less than 1/16 of an inch associated with the statement of identity and/or the "Supplement Facts" label. This is of concern because consumers may not be able to read the small fonts and therefore may not be fully informed regarding the type of product they are purchasing. Another important issue encountered with statements of identity and "Supplement Facts" labels were the use of noncompliant wording and/or missing information. Among the 10 samples with incorrect wording in the statement of identity, 9 were completely missing the term "supplement" and 1 contained the wording "herbal food supplement" (K19). According to regulations, the statement of identity "must include the term 'dietary supplement,' with the exception that the word 'dietary' may be replaced with a description of the type of dietary ingredient(s) in the product (e.g., 'herbal supplement') or the names of one or more dietary ingredients in the product (e.g., 'bee pollen supplement')" (Food and Drug Administration, 2005). Because the word "food" was included in the statement of identity for sample K19, the product was deemed noncompliant. The other products had statements of identity that referred to various types of powders (n = 6), an Ayurvedic product or medicine (n = 2), or superfood (n = 1), without including the word "supplement".

Of note, the majority of products with noncompliant wording in the statement of identity also had noncompliant or missing "Supplement Facts" labels. Among the 9 products that did not contain the word "supplement" in their statements of identity, 3 had a compliant "Supplement Facts" label, 3 had an incomplete "Supplement Facts" label, and 3 were completely missing the "Supplement Facts" label. It is possible that the products with missing or incomplete "Supplement Facts" labels were intended to be marketed as foods. However, none of these products contained "Nutrition Facts" panels, which are required for food products. The lack of a "Supplement Facts" or "Nutrition Facts" panel is confusing for consumers, who are accustomed to viewing specific types of labels depending on the type of product.

Dietary supplement labels must include a domestic mailing address or phone number at which consumers can report serious adverse events to the responsible person (Food and Drug Administration, 2009). However, 25% (n = 13) of the products examined in this study had a missing or noncompliant domestic mailing address or phone number. Of these products, 5 included a website on the label and 8 included a website and email address on the label. This finding is consistent with Silva et al. (2020), who found that the majority of supplements that were missing a mailing address/phone number listed a website on the label. These trends indicate that, while the use of a website or email in place of

		pharmacological agent, having positive effect on the memory and learning process. Many ancient texts have described vacha as an anti-epileptic and antihysteric herb. It is also known to possess carminative, digestive, diuretic, and mildly sedative properties.				address	
K28	Compliant	Supports antioxidant health.	SF(1)	Compliant	Compliant	Compliant	0
K29	Compliant	An adaptogenic herb that helps the body manage stress.	SF(1)	Compliant	Compliant	Compliant	0
K30	Noncompliant font size	N/A	N/A	Present (not required)	Noncompliant font size	Compliant	2
K31	Compliant	Supports joint, tissue, liver, colon, and cellular health.	SF(5)	Compliant	Compliant	Compliant	0
K32	Compliant	N/A	N/A	Present (not required)	Noncompliant font size	Compliant	1
K33	Noncompliant font size	Energy and stamina.	SF(2)	Compliant	Compliant	Compliant	1
K34	Compliant	Sugar metabolism support.	SF(1)	Noncompliant wording	Compliant	Noncompliant - no phone number or mailing address	2
K35	Compliant	N/A	N/A	N/A	Noncompliant - missing part of plant	Compliant	1
K36	Noncompliant wording	N/A	N/A	Present (not required)	Noncompliant - absent	Noncompliant - no domestic phone number or mailing address	3
K37	Compliant	Performance and stamina. Test booster.	SF(3)	Compliant	Compliant	Compliant	0
K38	Noncompliant wording	N/A	GW(1)	Noncompliant placement and wording	Noncompliant - missing servings per container and part of plant	Noncompliant - phone number not in service, no mailing address	4
K39	Compliant	N/A	N/A	Present (not required)	Compliant	Compliant	0
K40	Compliant	Supports healthy blood sugar levels. Joint and heart health support. Supports brain health.	SF(4)	Compliant	Compliant	Compliant	0
K42	Compliant	Supports digestive health & helps with occasional motion sickness.	SF(2)	Compliant	Compliant	Compliant	0
K43	Compliant	Male performance product. Healthy libido, energy, and stamina.	SF(4)	Compliant	Compliant	Compliant	0
K44	Compliant	N/A	N/A	Present (not required)	Compliant	Noncompliant - no domestic phone number or mailing address	1
K45	Compliant	Joint support & mobility. Promotes heart	SF(2)	Compliant	Compliant	Compliant	0

a domestic mailing address or phone number is not compliant with regulations, some manufacturers may assume that this is an appropriate alternative.

Marked differences were observed in the compliance rates for products manufactured internationally compared to those produced domestically. Among the 51 products collected in this study, 33 were produced domestically, 17 were manufactured in India, and 1 was manufactured in Canada. The only product obtained from Canada (K49) was found to be noncompliant, with a total of 3 violations. The overall rate of noncompliance for products from India was 88%, which was almost two-fold higher than the noncompliance rate observed for products manufactured domestically (45%). Similarly, the average number of violations per noncompliant product manufactured in India (2.7) was almost twice that of products manufactured in the United States (1.5). Of the 13 products with a noncompliant domestic mailing address or phone number, the majority (85%) were manufactured outside of the United States, indicating possible confusion regarding the use of a domestic address or phone number when a product is manufactured internationally. These results are similar to those reported by Isaacs and Hellberg (2019), in which all 4 products manufactured internationally were found to be noncompliant. Overall, these results point to a lack of regulatory compliance among manufacturers located outside of the United States, which may be due to an incomplete understanding of the labeling regulations and/or low incentive to follow the regulations (Isaacs & Hellberg, 2019).

4.2. Calamus root concerns

Calamus root (vacha) is prohibited from use in human food in the United States (21 CFR § 189.110) because it was previously shown to exhibit carcinogenic effects in laboratory rats (Ravindran et al., 2004). However, the current study found that calamus root/vacha continues to be marketed as an herbal supplement online. This is may be due to the fact that this plant is also utilized in external (non-food) applications in a powder or paste form (Rajput et al., 2014). Of note, two of the vacha supplements (K50 and K53) claimed to be for external use only, despite using the wording “herbal supplement” in the online listing. Given the potentially toxic effects of calamus root combined with the conflicting/confusing marketing terms used, there is a critical need to improve oversight of this product in the online marketplace.

4.3. Disease claims

Numerous products examined in this study had disease claims, with the greatest frequency of claims observed in the online product listings (Table 2). The use of disease claims for dietary supplements is illegal because it results in the product being promoted as an unapproved new drug (Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 2000). The percentage of products with disease claims on the physical label (8%) was higher than that reported by Silva et al. (2020) for bovine liver supplements (2%), but lower than previous studies on

		health.					
K46	Noncompliant wording	Ayurvedic Proprietary Medicine. Guduchi is well known rejuvenating herb...shows excellent immunomodulator activity. Enhances both cell mediated and humoral immunity and strengthens the body's resistance to fight infections.	DC(2); SF(2)	Absent	Noncompliant - missing panel title, serving size, servings per container	Noncompliant - no domestic phone number or mailing address	6
K47	Compliant	N/A	N/A	Present (not required)	Compliant	Noncompliant - no domestic phone number or mailing address	1
K48	Compliant	Supports sugar metabolism.	SF(1)	Compliant	Compliant	Compliant	0
K49	Noncompliant wording	Promotes optimal function of the lungs and respiratory system. Heightens awareness and enhances mental clarity. Supports a healthy circulatory system.	GW(1); SF(3)	Noncompliant placement	Compliant	Noncompliant - no domestic phone number or mailing address	3
K50	Noncompliant wording	N/A	N/A	N/A	Noncompliant - missing panel title, serving size, servings per container, part of plant, quantitative amount by weight per serving	Noncompliant - no domestic phone number or mailing address	3
K51	Compliant	Supports blood sugar levels already within the normal range. Digestive support with antioxidant properties.	SF(2)	Noncompliant placement	Noncompliant font size	Compliant	2
K52	Compliant	Improves the immune system. Supports comfortable movement of the joints. Aids in optimal function of the kidneys and liver.	SF(4)	Noncompliant placement	Noncompliant wording	Compliant	2
K53	Noncompliant wording	N/A	N/A	Present (not required)	Noncompliant – font size, incorrect servings per container, missing quantitative amount by weight per serving	Compliant	2
K54	Compliant	N/A	GW(1)	Compliant	Compliant	Compliant	0

[a] DC = disease claim or implied disease claim; GW = general well-being claim; N/A = not applicable; SF = structure/function claim. The number of DC and/or SF claims for each product is shown in parentheses.

shark cartilage supplements (14%) (Isaacs & Hellberg, 2019) and weight loss supplements (20%) (Levinson, 2012). In comparison, the percentage of products with disease claims observed in the online product listing (38%) was substantially higher than previous studies. When combining both mechanisms of conveying disease claims to consumers (online and physical label), a total of 52 disease claims were observed in this study across 19 different products. The increased number of disease claims found in the online product listings is alarming and may be due to the additional space allowed for online product descriptions as compared to the label and/or could indicate a reduced focus on regulatory compliance for online product descriptions. Regardless of the reasoning for this trend, it is an important public health concern due to the likelihood of generating confusion among consumers and causing them to delay or avoid seeking professional treatment for diseases or other health-related conditions (Isaacs & Hellberg, 2019). Disease claims can also present serious risks if they convince consumers to substitute ineffective treatments for proven ones, especially in the case of a serious or life-threatening disease (Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 2000). Additionally, the use of dietary supplements to treat a disease may lead to an increased risk for adverse reactions due to the use of prescription medications that the consumer is already taking.

It is important to note that the claims listed above were classified as disease claims by the authors based on the language in 21 CFR § 101.93 (g), with guidance from the Final Rule for Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body (2000), the FDA Small Entity Compliance Guide on Structure/Function Claims (Food and Drug Administration, 2002), and the FDA Office of Dietary Supplement Programs (ODSP). While the authors have carefully considered these determinations, classification of a disease claim is ultimately at the discretion of the FDA, which does not comment on the specific safety, labeling, or claims made for products with parties other than the responsible firm.

4.4. Structure/function and general well-being claims

The wide range of structure/function claims observed in the current study reflects the various purported benefits of these Ayurvedic supplements. Similar to the findings reported above for disease claims, a greater frequency of structure/function claims was observed for the online product listings (average of 5 claims per product) as compared to the physical label (average of 2 claims per product). The online product listings also included a wider variety of structure/function claims made within specific product categories as compared to the claims made on the physical label. For example, the structure/function claims made on the physical labels for guduchi/giloy products were grouped into 6 different categories (Table 3), while the online structure/function claims for these same products were grouped into 24 different categories (Table 4).

Interestingly, several products had acceptable structure/function claims on the physical label that were related to disease claims in the online product listing. For example, a cinnamon product (K45) contained the structure/function claim of “joint support & mobility” on the physical label, but included the wording “joint pain relief” in the online listing, making it an implied disease claim for arthritis (Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 2000). In another example, a guduchi product (K52) contained the structure/function claim of “improves the immune system” on the physical label but modified the wording online to state “improve the immune system and

Table 2
Disease claims (DC) observed within the online product listings for supplements purchased online (n = 42).

Product Category	Samples Purchased Online	Disease Claims (n)	Wording of Disease Claim(s)
Amla	K12, K16, K20	2	Hepatoprotective (K20); Detoxification (K20)
Ashwagandha	K09, K11, K13	4	Effective in relieving … anxiety and insomnia (K11); reduce body's inflammation (K11); Ayurvedic medicine (K13)
Cinnamon	K30, K34, K40, K45, K48, K51	4	Joint pain relief … promotes stronger, more comfortable joints … anti-inflammatory properties (K45); Powerful anti detox supplement (K45); Can be instrumental in decreasing the health & wellness dangers related to cholesterol (K51); aids in glucose levels found in the blood to return to normal faster. This is a huge benefit for anyone to consider who may be dealing with higher than normal blood sugar levels (K51)
Ginger	K10, K15, K18, K22, K42	0	N/A
Guduchi/giloy	K36, K38, K44, K46, K47, K52	12	Effective in the treatment of a wide variety of ailments (K36); Helps break up stagnation and natural toxins in the body (K36); Alleviate skin disorders (K36); Piles, constipation or indigestion, giloy is known to cure it all (K36); This medication has the ability to destroy toxins … this medicine (K38); Reduces … anxiety (K47); Fights respiratory problems (K47); Anti-inflammatory and anti-arthritic properties (K47); Helps detox (K47); Combats premature aging (K52); Improve … the body's resistance to infection (K52); Helpful in eye conditions (K52)
Tribulus	K32, K33, K35, K37, K39, K43	0	N/A
Tulsi/holy basil	K07, K08, K14, K17, K49	10	Botanical medicine (K07); Protection against environmental chemicals (K07); Helps reduce ama (toxins) (K14); Help liquefy mucus, making it beneficial for the occasional cough, the respiratory system and the body's natural response to allergens (K14); Studies have also shown it to help reduce both anxiety and depression (K17); Helps fight … cardiac … stress (K17); Anti-inflammatory (K17); Anti-microbial (K17); Hepatoprotective (K17)
Turmeric	K21	1	Healthy joint support and pain relief[a]. Promotes … immune activity around your joints and muscles (K21)
Vacha/calamus root	K19, K25, K26, K27, K50, K53	11	Used medicinally for a wide variety of ailments (K19); Reduction of inflammation of airways, cough bouts & fever (K19); Promotes relief from pain and inflammation of rheumatic joints (K19); Helps for emesis of toxins, clearing out toxins through urine and stools (K19); Helps to promote relief from acidity & indigestion (K19); Ayurvedic medicinal benefits … As a medicine (K25); There are many advantages of vacha such as … clearing nasal congestion … improving … asthma (K25); Helps to destroy the worms in stomach (K53); It is also beneficial for those children who have speech problem (K53); The trituration accentuates medicinal properties of the herb (K53)

[a] "Healthy joint support" is an acceptable structure/function claim; however, joint pain relief is a disease claim because it implies an effect on arthritis.

the body's resistance to infection", thereby making it a disease claim (Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 2000).

When considering the combined online listings and physical labels for all product types, some of the most common structure/function claims were those related to digestive support and related issues, stress support, brain health, joint support, immune support, cardiovascular support, energy/rejuvenation, and sugar metabolism/healthy blood sugar (Tables 3–4). It is difficult to determine whether these claims are substantiated due to the wide range of purported health benefits and the possibility of additional scientific evidence not available to the authors. However, according to the National Institutes of Health (NIH), there is limited scientific evidence regarding the benefits of Ayurvedic preparations (National Institutes of Health, 2018).

Claims of digestive support and related issues (e.g., gastrointestinal tract/colon support, stomach spasm relaxation, and carminative support) were most common among vacha/calamus root, ginger, and turmeric (Tables 3–4). The compounds in vacha have been associated with a variety of health-promoting properties (Olas & Bryś, 2018), including some animal-based studies suggesting antidiarrheal and antispasmodic activity (Mukherjee et al., 2007). Ginger has also been found to have beneficial effects on digestion in several animal studies (Srinivasan, 2017), as well as providing nausea relief in cancer patients (Ma et al., 2021). Claims of gastrointestinal tract/colon support associated with turmeric were likely related to the anti-inflammatory properties of turmeric and its active compound curcumin, with studies showing potential improvements in several gastrointestinal conditions, including ulcerative colitis and dyspepsia (Hay et al., 2019).

The main supplements associated with claims of stress support in this study were ashwagandha, tulsi/holy basil, and vacha/calamus root (Tables 3–4). Ashwagandha, which received multiple claims associated with stress support, calmness, and relaxation, has shown anti-stress activity in several animal trials, as well as an ability to reduce serum cortisol levels in a clinical trial (Dar et al., 2015). The anti-stress properties of tulsi/holy basil have been demonstrated in several animal studies (Jothie Richard et al., 2016; Kulkarni & Adavirao, 2018). Vacha/calamus root has demonstrated an immunoprotective effect in rats exposed to stress (Sarjan et al., 2017); however, there is a lack of research on the ability of this herb to be used for anti-stress support.

The majority of claims surrounding brain health were associated with vacha/calamus supplements (Tables 3–4), including claims of promoting cognition, intelligence, and memory. While vacha has been used regularly in Ayurvedic medicine for the treatment of memory loss and other mental disorders, there is limited scientific research supporting these claims. According to Mukherjee et al. (2007), vacha extracts have demonstrated acetylcholinesterase (AChE) inhibitory activity, which is associated with cognitive performance and memory. Another study found that oral administration of vacha in rats helped to prevent memory deficits and stress through the modulation of oxidative stress and inflammation (Esfandiari et al., 2018). However, further research is needed in this area to verify the cognitive health benefits of vacha.

Claims of joint support in this study were associated with turmeric, cinnamon, ginger, and guduchi/giloy products (Tables 3–4). These claims appear to be largely based on studies examining osteoarthritis and rheumatoid arthritis rather than studies showing that these supplements support already healthy joints. For example, a few studies have provided evidence to suggest that Ayurvedic formulations are similarly effective as conventional drugs for treating arthritis (Chopra et al., 2013; Furst et al., 2011; Kuptniratsaikul et al., 2014). One study examining Ayurvedic formulations that included guduchi, ginger, and amla, among other herbs, suggested that these formulations provided pain reduction and improved function for patients with osteoarthritis (Chopra et al., 2013). Turmeric and its active compound curcumin have been found to exhibit anti-inflammatory properties that may help to limit inflammation in patients with rheumatoid arthritis and osteoarthritis (Hay et al., 2019). A small trial showed that cinnamon may have a beneficial effect on reducing inflammation in patients with rheumatoid arthritis, but more research is needed in this area (Singletary, 2019).

Claims of immune support were spread across multiple supplement categories, including guduchi/gilroy, amla, ginger, tulsi/holy basil, turmeric, and vacha/calamus root (Tables 3–4). While compounds with

Table 3
Number and type of structure/function (SF) and general well-being (GW) claims observed on the physical label for each category of herbal supplement examined in this study. Sample numbers with SF or GW claims are underlined.

Product Category	Sample Number	Total # of SF or GW Claims	Top SF or GW Claims	Less Common SF or GW Claim(s)
Amla	K03, K12, K16, K20	6	General well-being (n=2); rejuvenation (n=2)	Healthy aging (n=1); immune support (n=1)
Ashwagandha	K01, K05, K09, K11, K13, K29	13	Stress support/calmness/ relaxation (n=5)	Adrenal system support (n=1); energy (n=1); general well-being (n=1); muscle strength (n=1); rejuvenation (n=1); reproductive system support (n=1); stamina (n=1); vitality (n=1)
Cinnamon	K30, K34, K40, K45, K48, K51	10	Healthy blood sugar/sugar metabolism (n=4); heart health (n=2); joint support (n=2)	Brain health (n=1); digestive support (n=1)
Ginger	K04, K10, K15, K18, K22, K42	11	Digestive support (n=3); relieve occasional nausea/motion sickness (n=3)	Antioxidant protection (n=1); cardiovascular support (n=1); immune support (n=1); inflammatory response support (n=1); joint support (n=1)
Guduchi/giloy	K36, K38, K44, K46, K47, K52	7	Immune support (n=2)	General well-being (n=1); joint support (n=1); kidney function (n=1); liver function (n=1); rejuvenation (n=1)
Tribulus	K32, K33, K35, K37, K39, K43	8	Performance/libido/testosterone booster (n=3); stamina (n=3), energy (n=2)	N/A
Tulsi/holy basil	K06, K07, K08, K14, K17, K49	12	Respiratory support (n=3); stress support/maintain cortisol levels (n=3)	Adrenal support (n=1); awareness and mental clarity (n=1); circulatory system support (n=1); general well-being (n=1); immune support (n=1); maintain blood sugar (n=1)
Turmeric	K02, K21, K28, K31, K54	14	Joint support (n=3); GI tract/colon support (n=2); liver support (2)	Antioxidant health (n=1); cardiovascular support (n= 1); cellular health (n=1); general well-being (n=1); heart support (n=1); immune support (n=1); tissue support (n=1)
Vacha/calamus root	K19, K25, K26, K27, K50, K53	21	Cognition/intelligence/memory (n=4); digestive support/ stomach spasm relaxation/carminative (n=4); nervous system support (n=3); balance mood (n=2); stress support (n=2)	Diuretic (n=1); general well-being (n=1); immune support (n=1); liver support (n=1); sedative/antihysteric (2)

immunomodulatory activity have been reported in guduchi/giloy (Sharma et al., 2012) and turmeric (Singletary, 2020), extensive research could not be found in this area. Amla and tulsi/holy basil have been reported to be immunomodulators, with immunostimulatory properties (Baliga & Dsouza, 2011; Mahajan et al., 2013). Previous research has demonstrated immunomodulatory and immunosuppressive effects of vacha/calamus root and ginger, which appear to be largely related to their anti-inflammatory properties (Mukherjee et al., 2007; Olas & Bryś, 2018; Srinivasan, 2017). Because some of these supplements may provide an immunosuppressive effect while others are immunostimulatory, generic claims of "immune support" may be confusing to consumers who do not understand the specific effects that the supplement will have on their immune system.

Claims associated with cardiovascular health were primarily associated with tribulus and cinnamon (Tables 3–4). Previous research has demonstrated several potential cardiovascular benefits of *Tribulus terrestris*, including hypolipidemic activity and an antihypertensive effect (Chhatre et al., 2014). While some studies have indicated a beneficial effect of cinnamon on cardiovascular health (Das et al., 2022), a recent meta-analysis reported no association between cinnamon consumption and cardiovascular risk (Krittanawong et al., 2022).

Claims associated with energy and/or rejuvenation were spread across multiple product categories, including amla, ashwagandha, guduchi/giloy, and tribulus (Tables 3–4). Prior studies on ashwagandha have suggested that it improves energy levels in college students (Baker et al., 2022), enhances energy expenditure in mice fed a high-fat diet (Lee et al., 2020) and improves cardiorespiratory endurance in healthy athletic adults (Choudhary et al., 2015). While amla, guduchi, and tribulus are recognized rejuvenators in Ayurvedic medicine, there is limited peer-reviewed research demonstrating a direct association between consumption of these herbs and energy levels or rejuvenation. Tribulus is often marketed as a testosterone booster, with claims of increasing strength and muscle mass; however, several studies have reported no effects of tribulus supplementation on body composition, strength during training or exercise performance (Pokrywka et al., 2017).

Most of the claims in the current study for maintaining healthy blood sugar/sugar metabolism were associated with cinnamon (Tables 3–4). However, research on this topic has shown inconsistent results, with several studies demonstrating some degree of improvement in regulation of blood glucose and others showing no effect (Singletary, 2019). With regards to the effects of other Ayurvedic herbs on blood sugar, a small short-term clinical trial suggested that a formulation containing 5 Ayurvedic herbs (i.e., Salacia oblonga root, Tinospora cordifolia stem, Emblica offinalis Gaertn, Curcuma longa, and Gymnema Sylvestre) may help with attenuation of hyperglycemia in patients with type 2 diabetes (Kurian et al., 2014).

5. Conclusions

Overall, this study revealed a high proportion of noncompliance, with 61% of herbal supplement products examined having at least one instance of noncompliance on the physical label. The most prevalent noncompliant items on the physical labels were missing/noncompliant disclaimers, noncompliant "Supplement Facts'' panels, noncompliant statements of identity, and noncompliant domestic mailing addresses or phone numbers. Violations such as missing/noncompliant disclaimers and noncompliant statements of identity are concerning because they interfere with the consumer's ability to understand the intended purpose of the product as a dietary supplement. Furthermore, the lack of a domestic mailing address or phone number is an important area of concern because it limits the ability of consumers to report adverse events to manufacturers. Numerous structure/function claims were observed on the physical labels and the online listings, some of which did not appear to be substantiated by the scientific literature. A relatively high proportion (38%) of products purchased online were found to have disease

Table 4
Number and type of structure/function (SF) and general well-being (GW) claims observed within the online product listing for each category of herbal supplement examined in this study. Sample numbers with online SF or GW claims are underlined.

Product Category	Samples Purchased Online	Total # of SF or GW Claims	Top SF or GW Claims	Less Common SF or GW Claim(s)
Amla	K12, K16, K20	13	Adaptogenic (n=2); immune support (n=2); overall well-being/wellness support (n=2); rejuvenation (n = 2)	Antioxidant protection (n=1); balancing the body (n=1); healthy aging (n=1); liver support (n=1); vitality (n=1)
Ashwagandha	K09, K11, K13	22	Adaptogenic/stress support (n=3); energy (n=3); rejuvenation (n=2); reproductive support (n=2)	Adrenal support (n=1); combat mental fatigue (n=1); curb cravings (n=1); general well-being (n=1); immune support (n=1); mood enhancer (n=1); muscle strength (n=1); nervous system support (n=1); restore metabolism (n=1); sleep support (n=1); stamina (n=1); vitality (n=1)
Cinnamon	K30, K34, K40, K45, K48, K51	12	Heart health (n=2); promote metabolism (n=2); regulate healthy blood sugar levels (n=2)	Antioxidant protection during aging (n=1); brain support (n=1); joint health (n=1); support health cholesterol levels (n=1); support overall health (n=1); weight management support (n=1)
Ginger	K10, K15, K18, K22, K42	11	Digestive support (n=3); relieve occasional nausea/motion sickness (n=3)	Cardiovascular support (n=1); healthy inflammatory response (n=1); immune support (n=1); joint comfort (n=1); soothes sour stomach (n=1)
Guduchi/giloy	K36, K38, K44, K46, K47, K52	33	Immune support (n=5); adaptogenic/stress support (n=2); maintain healthy/normal body temperature (n=2); rejuvenation (n=2); strengthening/for use in general debility and weakness (n=2); tissue support (n=2)	Aphrodisiac (n=1); benefits the liver (n=1), kidneys (n=1), joints (n=1), and blood (n=1); benefits to overall health (n=1); calms the mind (n=1); energy (n=1); development of brain and intelligence (n=1); digestive aid (n=1); keep cells healthy (n=1); healthy elimination (n=1); healthy nervous system (n=1); healthy reproduction (n=1); increase appetite (n=1); longevity (n=1), promote a clear, radiant complexion (n=1); vitality (n=1)
Tribulus	K32, K33, K35, K37, K39, K43	19	Cardiovascular support (n=3); energy (n=3); testosterone booster/estrogen blocker (n=3); build muscle/gain muscle mass (n=2); performance (n=2); stamina (n=2)	Lose extra fat (n=1); mood enhancer (n=1); rejuvenation (n=1); support fertility (n=1)
Tulsi/holy basil	K07, K08, K14, K17, K49	19	Respiratory support (n=3); adaptogenic/stress support (n=2)	Adrenal support (n=1); balance and healing (n=1); blood sugar regulation (n=1); circulatory system support (n=1); colon health (n=1); ease occasional head discomfort (n=1); energy (n=1); heightens awareness and enhances mental clarity (n=1); immune support (n=1); joint function (n=1); metabolism (n=1); performance (n=1); soothe occasional cough (n=1); well-being (n=1)
Turmeric	K21, K31	12	Cellular health (n=2); joint/musculoskeletal support (n=2)	Brain support (n=1); circulation (n=1); colon support (n=1); detoxification support (K31); healthy antioxidant defense (n=1); immune support (n=1); addresses inflammation caused by overexertion due to strenuous exercise (n=1); liver support (n=1); tissue support (n=1)
Vacha/calamus root	K19, K25, K26, K27, K50, K53	24	Digestion/stomach spasm relief/gas trouble (n=4); promotes/improves memory (n=3); hair growth/healthy scalp (n=2); helpful in sluggishness of the liver (n=2); mood stabilizer/healthy state of mind (n=2); nervous system support (n=2); stress support (n=2)	Improves skin (n=1); increase appetite (n=1); respiratory support (n=1); sedative (n=1); supports physical and mind strength (n=1); voice clarity (n=1); well-being (n=1)

claims in the online product listings and nearly all online listings with structure/function claims were associated with a missing/noncompliant disclaimer. The use of disease claims, unsubstantiated structure/function claims, and/or structure/function claims without a proper disclaimer is a major public health concern, as many consumers are not likely to understand the regulatory differences between dietary supplements and drugs. This misunderstanding may present serious risks to consumers that delay seeking proper medical attention for the treatment of life-threatening diseases.

Declarations of interest

None.

CRediT authorship contribution statement

Chevon R. Jordan: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Calin M. Harris:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – review & editing. **Miranda I. Miranda:** Investigation, Data curation. **Diane Y. Kim:** Investigation, Data curation. **Rosalee S. Hellberg:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration, Resources, Funding acquisition.

Data availability

Data will be made available on request.

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References

Abraham, E. J., & Kellogg, J. J. (2021). Chemometric-guided approaches for profiling and authenticating botanical materials [review]. *Frontiers in Nutrition, 8*. https://doi.org/10.3389/fnut.2021.780228

Avery, R. J., Eisenberg, M. D., & Cantor, J. H. (2017). An examination of structure-function claims in dietary supplement advertising in the U.S.: 2003-2009. *Preventive Medicine, 97*, 86–92. https://doi.org/10.1016/j.ypmed.2017.01.008

Baker, C., Kirby, J. B., O'Connor, J., Lindsay, K. G., Hutchins, A., & Harris, M. (2022). The perceived impact of ashwagandha on stress, sleep quality, energy, and mental clarity for college students: Qualitative analysis of a double-blind randomized control trial. *Journal of Medicinal Food, 25*(12), 1095–1101. https://doi.org/10.1089/jmf.2022.0042

Balekundri, A., & Mannur, V. (2020). Quality control of the traditional herbs and herbal products: A review. *Futur J Pharm Sci, 6*, 67. https://doi.org/10.1186/s43094-020-00091-5

Baliga, M. S., & Dsouza, J. J. (2011). Amla (*Emblica officinalis* Gaertn), a wonder berry in the treatment and prevention of cancer. *European Journal of Cancer Prevention, 20*(3), 225–239.

Chhatre, S., Nesari, T., Somani, G., Kanchan, D., & Sathaye, S. (2014). Phytopharmacological overview of *Tribulus terrestris*. *Pharmacognosy Reviews, 8*(15), 45–51. https://doi.org/10.4103/0973-7847.125530

Chopra, A., Saluja, M., Tillu, G., Sarmukkaddam, S., Venugopalan, A., Narsimulu, G., Handa, R., Sumantran, V., Raut, A., Bichile, L., Joshi, K., & Patwardhan, B. (2013). Ayurvedic medicine offers a good alternative to glucosamine and celecoxib in the treatment of symptomatic knee osteoarthritis: A randomized, double-blind, controlled equivalence drug trial. *Rheumatology, 52*(8), 1408–1417. https://doi.org/10.1093/rheumatology/kes414

Choudhary, B., Shetty, A., & Langade, D. G. (2015). Efficacy of Ashwagandha (*Withania somnifera* [L.] Dunal) in improving cardiorespiratory endurance in healthy athletic adults. *Ayu, 36*(1), 63–68. https://doi.org/10.4103/0974-8520.169002

Cohen, P. A., Maller, G., DeSouza, R., & Neal-Kababick, J. (2014). Presence of banned drugs in dietary supplements following FDA recalls. *JAMA, 312*(16), 1691–1693. https://doi.org/10.1001/jama.2014.10308

Dahm, O. J., Sampson, G. L., Silva, A. J., & Hellberg, R. S. (2022). Use of molecular methods to authenticate animal species and tissue in bovine liver dietary supplements. *Journal of Dietary Supplements, 19*(3), 381–394. https://doi.org/10.1080/19390211.2021.1887424

Dar, N. J., Hamid, A., & Ahmad, M. (2015). Pharmacologic overview of withania somnifera, the Indian ginseng. *Cellular and Molecular Life Sciences, 72*, 4445–4460. https://doi.org/10.1007/s00018-015-2012-1

Das, G., Gonçalves, S., Basilio Heredia, J., Romano, A., Jiménez-Ortega, L. A., Gutiérrez-Grijalva, E. P., Shin, H. S., & Patra, J. K. (2022). Cardiovascular protective effect of cinnamon and its major bioactive constituents: An update. *Journal of Functional Foods, 97*, Article 105045. https://doi.org/10.1016/j.jff.2022.105045

Esfandiari, E., Ghanadian, M., Rashidi, B., Mokhtarian, A., & Vatankhah, A. M. (2018). The effects of *Acorus calamus* L. In preventing memory loss, anxiety, and oxidative stress on Lipopolysaccharide-induced neuroinflammation rat models. *International Journal of Preventive Medicine, 9*, 85. https://doi.org/10.4103/ijpvm.IJPVM_75_18

Food and Drug Administration. (2002). *Small entity compliance Guide on structure/function claims*. Retrieved 8/31/2022 from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims.

Food and Drug Administration. (2005). *Dietary supplement labeling Guide*. Retrieved 8/25/2022 from https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide.

Food and Drug Administration. (2009). *Guidance for industry: Questions and answers regarding the labeling of dietary supplements. as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act* Retrieved 8/25/2022 from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-labeling-dietary-supplements-required-dietary.

Food and Drug Administration. (2022a). *Dietary supplements*. Retrieved 8/25/2022 from https://www.fda.gov/food/dietary-supplements.

Food and Drug Administration. (2022b). *Label claims for conventional foods and dietary supplements*. Retrieved 8/26/2022 from https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements.

Furst, D. E., Venkatraman, M. M., McGann, M., Manohar, P. R., Booth-LaForce, C., Sarin, R., Sekar, P. G., Raveendran, K. G., Mahapatra, A., Gopinath, J., & Kumar, P. R. (2011). Double-blind, randomized, controlled, pilot study comparing classic ayurvedic medicine, methotrexate, and their combination in rheumatoid arthritis. *Journal of Clinical Rheumatology : Practical Reports on Rheumatic & Musculoskeletal Diseases, 17*(4), 185–192. https://doi.org/10.1097/RHU.0b013e31821c0310

Hay, E., Lucariello, A., Contieri, M., Esposito, T., De Luca, A., Guerra, G., & Perna, A. (2019). Therapeutic effects of turmeric in several diseases: An overview. *Chemico-Biological Interactions, 310*, Article 108729. https://doi.org/10.1016/j.cbi.2019.108729

Hellberg, R., Isaacs, R., & Hernandez, E. (2019). Identification of shark species in commercial products using DNA barcoding. *Fisheries Research, 210*, 81–88. https://doi.org/10.1016/j.fishres.2018.10.010

Isaacs, R. B., & Hellberg, R. S. (2019). Shark cartilage supplement labeling practices and compliance with U.S. regulations. *Journal of Dietary Supplements, 18*(1), 44–56. https://doi.org/10.1080/19390211.2019.1698687

Jothie Richard, E., Illuri, R., Bethapudi, B., Anandhakumar, S., Bhaskar, A., Chinampudur Velusami, C., Mundkinajeddu, D., & Agarwal, A. (2016). Anti-stress activity of ocimum sanctum: Possible effects on hypothalamic–pituitary–adrenal Axis. *Phytotherapy Research, 30*, 805–814. https://doi.org/10.1002/ptr.5584

Krittanawong, C., Isath, A., Scott, C. Z., Wang, Z., Kaplin, S., Jneid, H., Lavie, C. J., & Virani, S. S. (2022). Association between cinnamon consumption and risk of cardiovascular health: A systematic review and meta-analysis. *The American Journal of Medicine, 135*(1), 110–117. https://doi.org/10.1016/j.amjmed.2021.07.019

Kulkarni, K. V., & Adavirao, B. V. (2018). A review on: Indian traditional shrub tulsi (ocimum sanctum): The unique medicinal plant. *Journal of Medicinal Plants Studies, 6*(2), 106–110.

Kuptniratsaikul, V., Dajpratham, P., Taechaarpornkul, W., Buntragulpoontawee, M., Lukkanapichonchut, P., Chootip, C., Saengsuwan, J., Tantayakom, K., & Laongpech, S. (2014). Efficacy and safety of *Curcuma domestica* extracts compared with ibuprofen in patients with knee osteoarthritis: A multicenter study. *Clinical Interventions in Aging, 9*, 451–458. https://doi.org/10.2147/CIA.S58535

Kurian, G. A., Manjusha, V., Nair, S. S., Varghese, T., & Padikkala, J. (2014). Short-term effect of G-400, polyherbal formulation in the management of hyperglycemia and hyperlipidemia conditions in patients with type 2 diabetes mellitus. *Nutrition, 30*(10), 1158–1164.

Lee, D.-H., Ahn, J., Jang, Y.-J., Seo, H.-D., Ha, T.-Y., Kim, M. J., Huh, Y. H., & Jung, C. H. (2020). *Withania somnifera* extract enhances energy expenditure via improving mitochondrial function in adipose tissue and skeletal muscle. *Nutrients, 12*(2), 431. https://doi.org/10.3390/nu12020431

Levinson, D. (2012). *Dietary supplements: Structure/function claims fail to meet federal requirements. OEI-01-11-00210*. Department of Health and Human Services, Office of Inspector General.

Liu, Y., & Lu, F. (2017). Adulterated pharmaceutical chemicals in botanical dietary supplements: Novel screening approaches. *Reviews in Analytical Chemistry, 36*(3). https://doi.org/10.1515/revac-2016-0032

Mahajan, N., Rawal, S., Verma, M., Poddar, M., & Alok, S. (2013). A phytopharmacological overview on Ocimum species with special emphasis on Ocimum sanctum. *Biomedicine & Preventive Nutrition, 3*(2), 185–192. https://doi.org/10.1016/j.bionut.2012.08.002

Ma, R.-H., Ni, Z.-J., Zhu, Y.-Y., Thakur, K., Zhang, Y.-Y., Hu, F., Zhang, J.-G., & Wei, Z.-J. (2021). A recent update on the multifaceted health benefits associated with ginger and its bioactive components. *Food & Function, 12*, 519–542. https://doi.org/10.1039/D0FO02834G

Ministry of Ayush. (2020). Government of India. D.O. *No. S. 16030/18/2019 – NAM. 6th March. 2020 Advisory from Ministry of AYUSH for meeting the challenge arising out of spread of coronavirus (COVID-19) in India*. Retrieved 8/26/2022 from https://www.ayush.gov.in/docs/125.pdf.

Morovic, W., Hibberd, A. A., Zabel, B., Barrangou, R., & Stahl, B. (2016). Genotyping by PCR and high-throughput sequencing of commercial probiotic products reveals composition biases. *Frontiers in Microbiology, 7*, 1747. https://doi.org/10.3389/fmicb.2016.01747

Mukherjee, P. K., Kumar, V., Mal, M., & Houghton, P. J. (2007). Acorus calamus.: Scientific validation of ayurvedic tradition from natural Resources. *Pharmaceutical Biology, 45*(8), 651–666. https://doi.org/10.1080/13880200701538724

National Institutes of Health. (2018). *Ayurvedic medicine: In depth*. Retrieved 8/25/2022 from https://www.nccih.nih.gov/health/ayurvedic-medicine-in-depth.

Navarro, V., Avula, B., Khan, I., Verma, M., Seeff, L., Serrano, J., Stolz, A., Fontana, R., & Ahmad, J. (2019). The contents of herbal and dietary supplements implicated in liver injury in the United States are frequently mislabeled. *Hepatology communications, 3*(6), 792–794. https://doi.org/10.1002/hep4.1346

Newmaster, S. G., Grguric, M., Shanmughanandhan, D., Ramalingam, S., & Ragupathy, S. (2013). DNA barcoding detects contamination and substitution in North American herbal products. *BMC Medicine, 11*, 222. https://doi.org/10.1186/1741-7015-11-222

Olas, B., & Bryś, M. (2018). Is it safe to use Acorus calamus as a source of promising bioactive compounds in prevention and treatment of cardiovascular diseases? *Chemico-Biological Interactions, 281*, 32–36.

Pokrywka, A., Morawin, B., Krzywański, J., & Zembroń-Lacny, A. (2017). 9 - an overview on tribulus terrestris in sports nutrition and energy regulation. In D. Bagchi (Ed.), *Sustained energy for enhanced human functions and activity* (pp. 155–165). Academic Press. https://doi.org/10.1016/B978-0-12-805413-0.00009-0.

Rajput, S. B., Tonge, M. B., & Karuppayil, S. M. (2014). An overview on traditional uses and pharmacological profile of Acorus calamus Linn. (Sweet flag) and other Acorus species. *Phytomedicine, 21*(3), 268–276. https://doi.org/10.1016/j.phymed.2013.09.020

Rastogi, S., Pandey, D. N., & Singh, R. H. (2022). COVID-19 pandemic: A pragmatic plan for ayurveda intervention. *Journal of Ayurveda and Integrative Medicine, 13*(1), Article 100312. https://doi.org/10.1016/j.jaim.2020.04.002

Ravindran, P. N., Pillai, G. S., & Nirmal Babu, K. (2004). 5 - under-utilized herbs and spices. In K. V. Peter (Ed.), *Handbook of herbs and spices* (pp. 53–103). Woodhead Publishing. https://doi.org/10.1533/9781855738355.1.53.

Regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. *21 CFR Part 101. Federal Register, 65*(4), (2000), 1000–1050.

Sarjan, H. N., Divyashree, S., & Yajurvedi, H. N. (2017). The protective effect of the Vacha rhizome extract on chronic stress-induced immunodeficiency in rat. *Pharmacien Biologiste, 55*(1), 1358–1367. https://doi.org/10.1080/13880209.2017.1301495

Schoonees, A., Young, T., & Volmink, J. (2013). The advertising of nutritional supplements in South African women's magazines: A descriptive survey. *S A J Clin Nutr, 26*(2), 12–18. https://doi.org/10.1080/16070658.2013.11734445

Sen, B. (2020). Potentiality and possibility of medicinal plants on ayurvedic principle in prevention and treatment of COVID-19. *Journal of Ayurveda and Holistic Medicine, 6*, 100–107.

Sharma, U., Bala, M., Kumar, N., Singh, B., Munshi, R. K., & Bhalerao, S. (2012). Immunomodulatory active compounds from Tinospora cordifolia. *Journal of Ethnopharmacology, 141*(3), 918–926. https://doi.org/10.1016/j.jep.2012.03.027

Silva, A. J., Dahm, O. J., & Hellberg, R. S. (2020). Bovine liver supplement labeling practices and compliance with U.S. regulations. *Journal of Dietary Supplements, 19*(1), 4–19. https://doi.org/10.1080/19390211.2020.1834048

Singletary, K. (2019). Cinnamon: Update of potential health benefits. *Nutrition Today, 54*, 42–52. https://doi.org/10.1097/NT.0000000000000319

Singletary, K. (2020). Turmeric: Potential health benefits. *Nutrition Today, 55*(1), 45–56. https://doi.org/10.1097/NT.0000000000000392

Smith, T., Majid, F., Eckl, V., & Morton Reynolds, C. (2021). Herbal supplement sales in US increase by record-breaking 17.3% in 2020. *HerbalGram, 131*, 52–65. http://herbalgram.org/resources/herbalgram/issues/131/table-of-contents/hg131-mkrpt/.

Srinivasan, K. (2017). Ginger rhizomes (*Zingiber officinale*): A spice with multiple health beneficial potentials. *PharmaNutrition, 5*(1), 18–28. https://doi.org/10.1016/j.phanu.2017.01.001

Vaclavik, L., Krynitsky, A. J., & Rader, J. I. (2014). Mass spectrometric analysis of pharmaceutical adulterants in products labeled as botanical dietary supplements or herbal remedies: A review. *Analytical and Bioanalytical Chemistry, 406*(27), 6767–6790. https://doi.org/10.1007/s00216-014-8159-z

Wheatley, V. M., & Spink, J. (2013). Defining the public health threat of dietary supplement fraud. *Comprehensive Reviews in Food Science and Food Safety, 12*, 599–613. https://doi.org/10.1111/1541-4337.12033

Yakhchali, M., Taghipour, Z., Mirabzadeh Ardakani, M., Alizadeh Vaghasloo, M., Vazirian, M., & Sadrai, S. (2021). Cinnamon and its possible impact on COVID-19: The viewpoint of traditional and conventional medicine. *Biomedicine & Pharmacotherapy, 143*, Article 112221. https://doi.org/10.1016/j.biopha.2021.112221

You, H., Abraham, E. J., Mulligan, J., Zhou, Y., Montoya, M., Willig, J., Chen, B. K., Wang, C. K., Wang, L. S., Dong, A., Shamtsyan, M., Nguyen, H., Wong, A., & Wallace, T. C. (2022). Label compliance for ingredient verification: Regulations, approaches, and trends for testing botanical products marketed for "immune health" in the United States. *Crit Rev Food Sci Nutr*. https://doi.org/10.1080/10408398.2022.2124230