Bovine Liver Supplement Labeling Practices and Compliance With U.S. Regulations

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Bovine Liver Supplement Labeling Practices and Compliance with U.S. Regulations

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Disclosure of interest

Olive Dahm is employed at a dietary supplement manufacturing company. Anthony Silva and Rosalee Hellberg report no conflict of interest.
Abstract

Bovine liver supplements are sought after by consumers due to their nutrient-dense profile and high protein content. However, there is a lack of information regarding bovine liver supplement labeling practices. The objective of this study was to assess labeling practices and compliance with U.S. regulatory standards among commercially sold bovine liver supplements.

The product labels for 49 bovine liver supplements were examined for required information, including a statement of identity; net quantity of contents; “Supplement Facts” label; ingredient statement; and name and place of business of manufacturer, packer, or distributor with domestic address or telephone number. Any claims made on the supplement labels were also reviewed for compliance. Overall, 59% of the products had at least one instance of noncompliance with U.S. labeling regulations. The main categories of noncompliance were: missing a domestic mailing address or phone number (39% of products), noncompliant nutrient content claim (31% of products), and missing/noncompliant disclaimer for a nutritional support statement (6% of products). The lack of a mailing address or phone number is problematic because it prevents consumers from being able to report serious adverse events to the manufacturer. The majority (85%) of the nutrient content observed on product labels were found to be noncompliant.

Noncompliant nutrient content claims are a major concern for consumers that rely on these claims to assess the nutritional benefits of a product. Overall, the results of this study revealed a lack of labeling compliance in bovine liver supplements, indicating a need for increased awareness and monitoring.

Keywords: bovine liver; dietary supplements; labeling compliance; nutrient content claims; structure/function claims
1. Introduction

Desiccated and defatted bovine liver is used as a dietary supplement due to its high protein content, low caloric value, and nutrient dense profile (Kang et al., 2017). It is known to contain numerous vitamins and minerals, including vitamins A and E; B vitamins (B1, B6, B12, biotin, folate, and niacin); copper; iron; zinc; and omega-3 fatty acids (Duizer et al., 2017; Fayemi et al., 2018). According to the Dietary Supplement Label Database, liver is the most common animal tissue found in dietary supplements, with over 140 different products listing it as an ingredient (NIH, 2019). The primary source of liver and other animal tissues in dietary supplements is beef, followed by pork, sheep, and chicken (NIH, 2019). Previous studies have reported mislabeling of dietary supplements, including shark cartilage (Isaacs and Hellberg, 2019); probiotic supplements (Morovic et al., 2016); and herbal products (Newmaster et al., 2013). However, there is a lack of research on the labeling practices associated with bovine (subfamily Bovidae) liver supplements and their compliance with U.S. regulations.

The Dietary Supplement Health and Education Act (DSHEA) of 1994 requires manufacturing companies to evaluate the safety and labeling of their products prior to marketing (FDA, 2020a). The U.S. Food and Drug Administration (FDA) investigates misbranded or adulterated dietary supplement products that are sold in the marketplace. The failure of dietary supplement companies to follow labeling regulations could result in an FDA warning letter, and if the issue is not addressed, further regulatory action, including removal of the product from the market (FDA, 2020b). U.S. regulations require that dietary supplement labels include a statement of identity (“Dietary Supplement”), net quantity of contents, “Supplement Facts” label with ingredients and allergen disclosures, and the name and place of business of the manufacturer, packer, or distributor with a mailing address and/or telephone number (FDA, 2018). The
“Supplement Facts” label must include the name and quantity of dietary ingredients in the product, the “Serving Size”, and the “Servings per Container.” However, the “Servings per Container” is not required if it contains the same information shown in the net quantity of contents. As is the case with conventional foods, dietary supplements must inform consumers of the presence of any of the eight major allergens identified by the Food Allergen Labeling and Consumer Protection Act of 2004.

Dietary supplement labels may also include claims, such as health claims, nutrient content claims, and statements of nutritional support (FDA, 2018). Health claims must be based on a recognized scientific connection between a substance and reduced risk of a disease or other health-related condition and cannot be used unless they have been evaluated and authorized by the FDA (FDA, 2020c). Nutrient content claims describe the levels of certain nutrients in a product and have specific wording requirements defined in 21 CFR § 101. For example, a “Good Source” claim can be used if the nutrient is present at 10-19% of the Reference Daily Intake (RDI) or Daily Reference Value (DRV), both of which are expressed on the label as the Percent Daily Value (%DV). “High” claims can be used provided that the product contains 20% or more of the RDI or DRV for the nutrient. Structure/function claims, which are a type of nutritional support statement, explain the role of a nutrient intended to affect normal structure or function of the human body. Structure/function claims are not permitted if a disease is mentioned or if it is implied that the supplement will repair or treat any damage or dysfunctions in the body (FDA, 2020c). General well-being claims, which also fall under nutritional support statements, describe how consuming a nutrient impacts the general well-being of an individual. Nutritional support statements must be substantiated by competent and reliable scientific evidence and include a disclaimer box 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” (FDA, 1994; FTC, 2001; Levinson, 2012).

Dietary supplement mislabeling and/or adulteration has been reported in previous research that detected undeclared ingredients (Cohen et al., 2014; Hellberg et al., 2019; Newmaster et al., 2013), non-compliant labeling (Isaacs and Hellberg, 2019), and the use of unsubstantiated claims (Avery et al., 2017; Isaacs and Hellberg, 2019; Levinson, 2012; Schoonees et al., 2013). For example, one study assessed 29 shark cartilage dietary supplements for compliance with U.S. labeling regulations and found that 48% of samples had at least one instance of noncompliance, including noncompliant nutrient content claims and prohibited disease claims (Isaacs and Hellberg, 2019). A study examining dietary supplement advertisements circulating in various magazines from 2003-2009 in the U.S. found that many of the structure/function claims mimicked health claims and were largely unsubstantiated by clinical literature (Avery et al., 2017). In an analysis of 1,624 substantiation documents voluntarily submitted to FDA by manufacturers for structure/function claims associated with weight loss or immune system support, it was determined that only 34% of substantiation documents were human studies and none met all of FDA’s recommendations for competent and reliable evidence (Levinson, 2012).

While previous research has revealed concerns regarding labeling compliance and use of unsubstantiated claims on dietary supplements, there is a lack of information specifically on bovine liver dietary supplements. Bovine liver supplements are at-risk for noncompliant nutrient content and nutritional support statements due to consumer expectations of a high-protein, nutrient-dense product, as well as the associated health benefits. Therefore, the objective of this
study was to analyze the labeling practices and compliance with U.S. regulatory standards for bovine liver dietary supplements sold in the United States.

2. Materials and Methods

2.1 Sample collection

Dietary supplement products (n = 49) claiming to contain beef or bovine liver originally described in Dahm (2020) were examined in this study. The products were purchased from six online sources available to U.S. consumers and were associated with 46 brand names and 44 manufacturers. The supplements were primarily in the form of hard gelatin or vegetarian capsules (n = 40), while the remaining products consisted of tablets (n = 7), powders (n = 1), and soft gelatin capsules (n = 1). Following collection, each product was photographed and labeled with a specific sample number. The original sample set included 53 products; however, 4 of the products were excluded from this study because they were marketed specifically for pets.

2.2 Label analysis

Each dietary supplement label was examined for the following required information: statement of identity, net quantity of contents, “Supplement Facts” label, ingredient statements with declared allergens (if applicable), and name and place of business of manufacturer, packer, or distributor with domestic address or telephone number (21 CFR § 101 and 21 USC § 343). In accordance with FDA supplement compliance, a domestic address is defined as including a full mailing address (FDA, 2009).

All claims made on the labels, including general well-being claims, structure/function claims, and nutrient content claims were recorded and identified for compliance with U.S. regulations (21 CFR § 101 and 21 USC § 343). The wording of each claim was examined to ensure that only permitted statements were used on the label. Products with structure/function claims or general
well-being claims were examined for the presence of the required 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). Structure/function claims were also investigated for the presence of supporting scientific evidence. However, the ability of the claim to meet the definition of substantiation was not determined due to the possibility of additional evidence not available to the authors as well as the need for the FDA to evaluate and make a determination on the claim. Product labels with nutrient content claims were examined to ensure that the declared levels of nutrients were appropriate in relation to the RDI or DRV (21 CFR § 101.54). Claims about the absence of a specific ingredient or food component to facilitate the avoidance of the substance due to food allergies, food intolerance, religious beliefs, or dietary practices were not considered to be nutrient content claims (21 CFR § 101.65).

It should be noted that this study was limited to examination of the external components of the label. Laboratory verification of factors such as the net quantity of contents, the presence of allergens, country of origin, and nutrient content claims was not performed.

3. Results

Of the 49 bovine liver supplement labels examined in this study, 29 products (59%) had at least one instance of noncompliance with U.S. labeling regulations (Table 1). A total of 97 instances of noncompliance were observed, with an average of 3 violations per noncompliant product and a maximum of 16 violations in one product (sample no. 46). The lack of a domestic mailing address or phone number was observed in 19 samples, followed by noncompliant nutrient content claims in 15 samples, and missing/noncompliant disclaimers on 3 samples with structure/function claims. Violations that were only observed in one sample include a prohibited
disease claim (no. 6), missing statement of identity (no. 42), missing “Supplement Facts” label (no. 41), and missing name of manufacturer, packer, or distributor (no. 41). Interestingly, the majority (n = 11) of the samples missing a domestic address or phone number instead listed a website along with a city and state; 3 samples listed only the city and state; 3 listed only a website; and 2 did not list a website or geographical location. Of note, only one sample (no. 3) was declared to have been manufactured outside the United States and this sample was compliant with the U.S. labeling regulations assessed in this study.

The majority (73.5%) of beef liver dietary supplement products contained at least one type of claim examined in this study, with a total of 216 claims observed (Table 1). The most common type of claim was structure/function (n = 108), followed by nutrient content (n = 84), gluten-free (n = 21), general well-being (n = 2), and prohibited disease (n = 1). No health claims were identified on any samples in this study. Among the 216 claims examined in this study, 72 claims (33%) were determined to be noncompliant with U.S. regulations. The most common noncompliant claims were those associated with nutrient content (n = 71), followed by implied prohibited disease claims (n = 1).

Structure/function claims were identified in 27 products (Table 1). These products had an average of 4 structure/function claims each, with a maximum of 17 (no. 26). The most common types of structure/function claims identified in this study were associated with providing energy, vitality, stamina, and/or boosting metabolism (n = 30); supporting collagen synthesis and/or healthy skin, hair, or nails (n = 20); supporting healthy liver function or detoxification (n = 10); supporting immune health (n = 9); supporting heart health (n = 5); and supporting brain health (n = 5) (Table 1). Less common structure/function claims included statements about supporting hormone levels or mood (n = 4), healthy/strong bones or teeth (n = 4), digestive health (n = 3),
and joint health (n = 2). Two products (24, 33) included general well-being claims, with statements including support for “overall health” and “for your good health”. While these claims could also be interpreted as implied nutrient content claims for “healthy”, the intended purpose of the claim appeared to be for general well-being. Three of the samples with structure/function claims were found to be noncompliant for the required disclaimer: two used the abbreviated form of FDA (nos. 15, 16) and one sample was missing a disclaimer (no. 9). Of note, 11 products contained a disclaimer even though no structure/function or general well-being claims were stated.

A prohibited disease claim was identified in one sample (no. 6), which had the statement “the liver is involved in many significant body functions such as affording protection from disease”. Although the preceding text (Table 1) implies that the statement refers to the human liver, use of the phrase “protection from disease” on the dietary supplement label was determined to be a prohibited disease claim because the consumer may translate normal organ function to a perceived disease prevention (21 CFR § 101.93).

Nutrient content claims (n = 84) were present on the labels of 20 of the beef liver supplement products, with a maximum of 15 claims on one product label (no. 46; Table 1). Noncompliant nutrient content claims were observed on 15 of the product labels and only 7 products contained claims that were compliant with regulations, based on the information provided on the label (21 CFR § 101.54; 21 CFR § 101.60; 21 CFR § 101.61). These products claimed to be free of sodium (nos. 10, 18), free of salt (nos. 13, 18, 33), free of sugar (nos. 10, 18, 20, 33, 36), and/or an excellent source (containing 20% or more of the RDI) of vitamin B12 (nos. 10, 16). However, further laboratory testing would need to be conducted to confirm the accuracy of these claims.
Most nutrient content claims (84.5%) were determined to be noncompliant. The most common type of noncompliant nutrient content claim (n = 56) observed in this study listed a nutrient that was associated with an RDI or DRV, but the label did not show the actual amount of the nutrient in the product (FDA, 2018). The main nutrients associated with this type of noncompliant claim included vitamin A (n = 9), vitamin B12 (n = 8), iron (n = 8), folate (n = 6), choline (n = 5), copper (n = 5), zinc (n = 3), and protein (n = 4). In a few additional cases (n = 3), the nutrient was listed on the “Supplement Facts” label, but the declared amount was not sufficient to support the claim (i.e., 10-19% of the RDI or DRV for "good source" claims and 20% or more of the RDI or DRV for “high” claims). Nine samples made noncompliant nutrient content claims by stating “source of”, “contains”, or “rich in” followed by dietary ingredients without RDIs or DRVs, specifically hyaluronic acid (n = 5), amino acids (n = 4) and CoQ10 (n = 3). All 12 of these claims were determined to be noncompliant because the dietary ingredients listed are not defined as nutrients by regulation (21 CFR 101.9).

“Gluten free” claims were identified in 21 products and were deemed compliant based on the information on the label, as no ingredients known to contain gluten were listed. However, further laboratory testing would be required to confirm the absence of gluten in these products. Numerous statements were observed on supplement labels that indicated the absence of genetically modified organisms (GMOs; n = 22), hormones (n = 22), dairy or milk (n = 19), soy (n = 16), artificial colors or flavors (n = 15), wheat (n = 12), preservatives (n = 11), antibiotics (n = 9), and pesticides (n = 9). Statements related to absence of dairy, soy, and wheat appeared to focus on avoidance due to dietary preferences and were therefore not considered to be nutrient content claims (21 CFR § 101.65). Label statements about substances that are nonnutritive or do not have a nutritive function, such as “no preservatives” or “no artificial colors”, are also not
considered to be nutrient content claims and are not subject to the requirements of 21 CFR § 101.13 or 101.65.

4. Discussion

This study revealed noncompliance with U.S. labeling regulations in 59% of bovine liver supplement products, with the major categories of noncompliance being the lack of a domestic mailing address or phone number and noncompliant nutrient content claims. In comparison, Isaacs and Hellberg (2019) reported a slightly lower rate of noncompliance (48.3%) for shark cartilage dietary supplements, with the same top two categories of noncompliance as the current study (i.e., noncompliant nutrient content claims and the lack of a domestic mailing address or phone number). Overall, 98% of the products analyzed in the current study were compliant for a statement of identity, “Supplement Facts” label, and name of manufacturer/packer/distributor. Of the 19 products that were missing a domestic mailing address or phone number, 74% included a website on the label (with or without a city and state). These findings indicate that some manufacturers may be assuming that a website is an appropriate alternative to a domestic mailing address or phone number for labeling purposes. However, without a domestic mailing address or phone number on the label, the supplement is considered mislabeled (FDA, 2009). The lack of this information on the label is a major concern because it removes the ability of the consumer to report any serious adverse events associated with the product to the responsible person.

Among the dietary supplements examined in this study, a total of 108 structure/function claims and 2 general well-being claims were observed. Structure/function claims “describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body,” or “characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function”, while general well-being claims “describe general well-being from
consumption of a nutrient or dietary ingredient” (FDA, 2017). However, most structure/function
claims (85%) and the two well-being claims examined in this study did not specify the nutrient
or dietary ingredient associated with the claim. Examples include statements such as “Energy
and Stamina” (no. 4), “For the support of healthy liver function” (no. 14); and “Supports: energy
levels, fat metabolism, muscle building, exercise recovery, brain and heart health” (no. 30). In an
additional three products (nos. 16, 17, and 33), the dietary ingredient associated with the claim
was “liver”, although the claims were likely based on scientific evidence associated with specific
nutrients in liver. For example, claims made by samples 17 and 33 associated with energy were
likely due to the presence of iron in the liver supplement. Not specifying the nutrient or dietary
ingredient associated with a structure/function or well-being claim is of concern because this
makes it difficult for consumers to determine the basis for the claim.

While structure/function claims were not evaluated for substantiation in this study due to
the possibility of additional evidence not available to the authors as well as the need for the FDA
to evaluate the claim, the available scientific evidence for each claim was reviewed. A variety of
structure/function claims were observed on bovine supplement labels, with the most common
being those associated with boosting energy, vitality, stamina, and/or metabolism. Numerous
claims were also associated with supporting collagen synthesis and/or healthy skin, hair, or nails;
supporting healthy liver function or detoxification; supporting immune health; supporting heart
health; and supporting brain health. Because bovine liver is known to contain many essential
nutrients, most of the claims appeared to be associated with scientific evidence on specific
nutrients in bovine liver. For example, scientific evidence is available that supports a link
between energy levels and certain nutrients in bovine liver, including vitamin B12, iron, and zinc
(Tardy et al., 2020). Skin health has also been scientifically linked to specific nutrients in bovine
liver, including vitamins D and E (Schagen et al., 2012). Cutaneous abnormalities involving the
hair, skin, and nails have been associated with deficiencies in many of the micronutrients found
in bovine liver, including niacin, biotin, vitamins B12, A, and B; zinc; iron; and copper (DiBaise
and Tarleton, 2019). In regard to collagen synthesis, there is a well-established relationship
between nutrient intake and wound healing, however, it is unclear as to whether administration
of specific nutrients can lead to enhanced collagen synthesis (Albaugh et al., 2017). Immune
function has been linked to many of the nutrients in bovine liver, including vitamins A, B6,
folate, B12, D, and E; iron; copper; and zinc (Wintergerst et al., 2007). Regarding heart and liver
health, vitamin D deficiencies have been linked to cardiovascular heart disease and nonalcoholic
fatty liver disease (Hariri and Zohdi, 2019; Holick, 2005). As for brain function, there is
scientific evidence that supports a link between B vitamins, such as B12 and folate, and brain
health (Kennedy, 2016).

Some of the less common structure/function claims observed in the bovine liver
supplements included those associated with supporting hormone levels or mood, healthy/strong
bones or teeth, digestive health, and joint health. Many of these claims are related to scientific
studies on individual nutrients that are found in bovine liver. For example, hormone levels and
mood have been reported to be associated with consumption of B vitamins, including folate, B6,
and B12 (Kaplan et al., 2007; Rose, 1978). Claims related to healthy/strong bones and teeth are
associated with vitamin D intake (Holick, 1996; Jimenez et al., 2014). While a relationship has
been reported between vitamin D deficiency and inflammatory bowel disease, the role of vitamin
D in promoting digestive health is not well established (Del Pinto et al., 2015). Joint health may
be associated with some of the vitamins and minerals in bovine liver, such as vitamin D and zinc,
for example in the management of knee osteoarthritis (Hafsi et al., 2019; McAlindon et al., 2013).

Despite the presence of scientific research linked to nutrients in bovine liver, it is important to note that this does not necessarily mean that the structure/function claims made on the supplement labels would be considered substantiated by the FDA. In order for a claim to be substantiated, competent and reliable scientific evidence demonstrating a direct effect of the supplement or its active ingredients on a structure or function of the body must be established (Levinson, 2012). If the evidence is based on an active ingredient, the amount or potency of that ingredient should be similar to what is found in the supplement product. FDA recommends that the scientific evidence used to substantiate the claim be derived primarily from human studies using scientific methods that are widely accepted. Supporting evidence, such as meta-analyses, animal studies, and review articles, may be used to help substantiate claims; however, this type of information may not be sufficient when used alone. Studies that focus on treatment of diseases are not considered to be consistent with FDA guidance on substantiation because they raise questions about the intended meaning of the claim (Levinson, 2012). The inability to determine whether the structure/function claims observed for bovine liver supplements would be considered substantiated by FDA was a limiting factor for assessing compliance in this study.

The percentage of products with structure/function or general well-being claims that had an absent or noncompliant disclaimer (11%) is similar to a previous study on weight loss or immune support dietary supplements (7%) (Levinson, 2012), yet lower than that reported by Isaacs and Hellberg (2019) for shark cartilage products (31.3%). In regard to prohibited disease claims, this study identified a low rate (2%) of these claims compared to previous studies (14-20%) (Isaacs and Hellberg, 2019; Levinson, 2012). The occurrence of prohibited disease claims
and structure/function claims without the required disclaimer is a public health concern because it could cause confusion among consumers and delay or prevent them from seeking professional diagnosis and treatment for a disease.

Overall, 30.6% of products contained noncompliant nutrient content claims. These findings are similar to a previous study analyzing shark cartilage dietary supplements, which reported 28% of products had a noncompliant nutrient content or implied nutrient content claim (Isaacs and Hellberg, 2019). Out of the 84 nutrient content claims in this study, 71 (84.5%) were noncompliant, largely because the amount of the essential nutrient was not listed on the label. Noncompliant nutrient labeling is problematic for consumers that rely on the claims to determine the nutritional benefits of a product. For example, if the amount of a nutrient is not listed on the supplement label, consumers are unable to assess whether "Good Source" or "High" claims are accurate. Noncompliant nutrient content claims identified in this study that used terms such as “source of” or “rich in” followed by a nutrient without an RDI or DRV may be confusing or misleading for consumers, who may be led to believe that the nutrient in the claim is considered essential. For example, one product (no. 26) claimed to be “rich in…CoQ10”; however, the inclusion of a non-essential nutrient (CoQ10) with the term “rich” is a non-compliant nutrient content claim. It is important to note that the lack of laboratory analysis for gluten-free and nutrient content claims limited the scope for compliance assessment in this study.

Certain samples in this study included the terms “nutrient dense” (n = 6), “nutrient rich” (n = 3), and/or “rich source of nutrients” (n = 1), which are not specifically referred to in U.S. regulations. According to the Dietary Guidelines for Americans, “nutrient dense foods provide vitamins, minerals, and other substances that contribute to adequate nutrient intakes” (Blankenship and Tuma, 2017). While bovine liver is known to contain a number of nutrients
(Fayemi et al., 2018), none of the samples in this study using the terms “nutrient dense”, “nutrient rich”, or “rich source of nutrients” listed specific vitamins or minerals in the “Supplement Facts” label.

5. Conclusion

Overall, this study revealed that 59% of beef liver supplement labels examined had at least one instance of noncompliance with U.S. labeling regulations. The main noncompliance items identified included: missing a domestic mailing address or phone number, noncompliant nutrient content claims, and missing/noncompliant disclaimer related to structure/function claims. The lack of a domestic mailing address or phone number on over one-third of products is a major concern, as this prevents consumers from being able to report serious adverse events associated with the supplement to the responsible person. Noncompliant nutrient content claims on bovine liver supplements are problematic because they can misinform consumers and negatively impact consumer health. Consumers that depend on these claims to assess the nutritional benefits of a product may be misled by claims associated with nonessential nutrients or claims that cannot be verified based on the information on the label. Furthermore, the lack a disclaimer associated with structure/function claims may delay consumers from seeking professional treatment for medical disorders.

6. Acknowledgments

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7. References


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Table 1: Labeling practices and compliance information for bovine liver dietary supplement labels examined in this study (n = 49). Instances of noncompliance are shown with gray shading. All products were compliant with allergen declarations and net quantity of contents.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Statement of identity</th>
<th>Claims and other relevant wording on label</th>
<th>Claim type(^a)</th>
<th>Disclaimer</th>
<th>“Supplement Facts” label</th>
<th>Domestic mailing address or telephone number</th>
<th>Name of manufacturer/ packer/distributor</th>
<th>Instances of noncompliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Compliant</td>
<td>Pesticide and herbicide free.</td>
<td>N/A</td>
<td>Not present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>Compliant</td>
<td>Without the use of growth hormones, antibiotics, chemicals or GMOs.</td>
<td>N/A</td>
<td>Present (not required)</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Compliant</td>
<td>Energy and Stamina. Reduces gastric upset, nausea, and constipation associated with iron supplementation. Contains soy. Gluten free. No yeast, wheat, dairy products, artificial flavors or preservatives.</td>
<td>GF; S/F(5)</td>
<td>Present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>Compliant</td>
<td>Freeze-dried to keep the full range of immune-boosting nutrients intact and undamaged. Non-GMO. Soy, Gluten, Grain, and Dairy free. Never fed grains or given antibiotics or hormones.</td>
<td>GF; S/F(1)</td>
<td>Present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>Compliant</td>
<td>The liver is one of the largest organs. It is located in the upper right abdomen immediately under the diaphragm and attached to it by ligaments. The liver is involved in many significant body functions such as affording protection from disease, supplying blood sugar to meet the needs of muscle tissue, and regulating the clotting of blood. Contains no yeast, soy, starch, wheat, gluten, rye, rice, corn, dairy products, preservatives or artificial coloring.</td>
<td>GF; PDC(1)</td>
<td>Present (not required)</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
<td>1</td>
</tr>
<tr>
<td>Compliant</td>
<td>Contains a full spectrum of amino acids as well as other necessary and essential nutrients found only in the liver. Contains milk and soy. Hormone-free cattle.</td>
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<tr>
<td>Compliant</td>
<td>Hypoallergenic</td>
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<tr>
<td>Compliant</td>
<td>Supports healthy liver function. This product is gluten and dairy free.</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Compliant</td>
<td>Free of gluten, wheat, dairy, soy, yeast, sugar, sodium, artificial flavors, preservatives and color. An excellent source of vitamin B-12. Hormone free.</td>
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<tr>
<td>Compliant</td>
<td>Provides a naturally occurring source of protein, vitamin B, and iron. No GMOs, pesticides, or chemicals.</td>
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<tr>
<td>Compliant</td>
<td>Natural source of iron. Supports energy metabolism. Does not contain pesticides, hormones, gluten, soy, or dairy. Non-GMO.</td>
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<tr>
<td>Compliant</td>
<td>Designed to provide natural stress relief utilizing B-Complex, Citrus Bioflavonoids along with rice bran concentrate and Hepatrin complex for improved absorption. Sustained release to ensure maximum effectiveness. Free of artificial flavor &amp; color, dairy, preservatives, salt, soy, gluten, starch, and wheat.</td>
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<tr>
<td>Compliant</td>
<td>For the support of healthy liver function. Non-GMO. Not manufactured with yeast, wheat, gluten, soy, corn, milk, egg, fish, shellfish or tree nut ingredients. Free of additives and hormones.</td>
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<tr>
<td>Compliant</td>
<td>Nutrient rich super food, full of naturally occurring vitamins and minerals. Helps boost energy levels, immune system, and improves skin health. Hormone, pesticide, and GMO</td>
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</tr>
</tbody>
</table>

**Note:**
- GF: Gluten free
- NC: Not compliant
- S/F: Specific food item
- Present: Requirement is present
- Not present: Requirement is not present
- Not provided: Requirement is not provided
- Compliant: Requirement is compliant
- Non-compliant wording: Requirement is non-compliant due to wording
free. No preservatives, colors, artificial flavors. Gluten-free.

| 16  | Compliant | Muscle support. Nutrient-dense source of high-quality protein. Over 60% protein, this high iron food concentrate is a comprehensive and complete protein. The beef liver is intended to provide nutritive support to build and maintain healthy muscles. As an excellent source of vitamin B-12 and iron, beef liver helps build healthy red blood cells. | NC(2); NC(1); S/F(2) | Non-compliant wording | Compliant | Compliant | Compliant | 3 |

| 17  | Compliant | Nutrient dense super food. Liver is one of the best kept secrets for energy and performance. Positive effects felt by virtually everyone who eats it. Our liver is always pasture raised, hormone free, antibiotic free. Liver is rich in bioavailable vitamin A, B12, CoQ10, iron, folate, zinc, & much more. | NC(6); S/F(2) | Present | Compliant | Not provided | Compliant | 7 |

| 18  | Compliant | Supports energy and metabolism. Natural and nutrient rich. Non-GMO. Contains no artificial coloring, artificial flavor, preservatives, salt, sodium, soy, sugar, gluten, starch, or wheat. | GF; NC(3); S/F(2) | Present | Compliant | Compliant | Compliant | 0 |

| 19  | Compliant | Hypoallergenic. | N/A | Not present | Compliant | Compliant | Compliant | 0 |

| 20  | Compliant | Hormone and GMO-free cows. A super-food that supports heart, brain, and liver health. Free of GMOs, gluten, dairy, sugar, soy, allergens, artificial colors, artificial flavors, artificial preservatives, FD&C synthetic dyes and added sugars. | GF; NC(1); S/F(3) | Present | Compliant | Compliant | Compliant | 0 |

| 21  | Compliant | Gluten and dairy free | GF | Not present | Compliant | Compliant | Compliant | 0 |

| 22  | Compliant | Contains bioavailable forms of vitamins A, B12, D3, and heme iron. Support optimal hormonal levels. Aid liver detoxification. Improve mood and energy. Follows the principle that the nutrients, enzymes, and other | GF; NC(4); S/F(4) | Present | Compliant | Compliant | Compliant | 4 |
active factors present in healthful organs can be effective in revitalizing the same target organ that is depleted. Free of gluten, soy, dairy, and GMOs.

<table>
<thead>
<tr>
<th>No.</th>
<th>Compliant</th>
<th>Description</th>
<th>Notes</th>
<th>Compliant</th>
<th>Not provided</th>
<th>Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>Compliant</td>
<td>Essential traditional superfoods. 100% additive free. GMO free. Without the use of pesticides, hormones or antibiotics. Hypoallergenic.</td>
<td>N/A Present (not required) Compliant Not provided Compliant</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Compliant</td>
<td>One of nature's most powerful superfoods. Supports energy levels, immune function, and overall health and vitality. Hormone free. GMO free.</td>
<td>GW(1); S/F(3) Present Compliant Compliant Compliant</td>
<td>0</td>
<td></td>
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</tr>
<tr>
<td>25</td>
<td>Compliant</td>
<td>Supports digestive health. Weight loss support. Natural liver detox. Optimal energy supplement.</td>
<td>S/F(4) Present Compliant Not provided Compliant</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Compliant</td>
<td>This powerful potent superfood is rich in Vitamin A, B12, CoQ10, Zinc, Copper, Folate, Choline and Hyaluronic Acid. Promotes healthy skin, hair, nails, teeth and gum. Supports strong joints, connective tissue, and healthy collagen. Promotes strong immune and digestive system. Supports good energy, mood, and metabolism. Enhances brain, heart, and liver health. Rejuvenate the body. Hormone, pesticide, and GMO free.</td>
<td>NC(8); S/F(17) Present Compliant Compliant Compliant</td>
<td>8</td>
<td></td>
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</tr>
<tr>
<td>27</td>
<td>Compliant</td>
<td>Nutrient dense superfood. Great for: skin health, joint health, immune support, energy support. Beef liver is known to be extremely rich in vitamins, minerals, and amino acids. 100% free of hormones, pesticides, gluten &amp; GMO. Not manufactured with wheat, gluten, milk, egg, fish, shellfish or tree nut ingredients.</td>
<td>GF; NC(1); S/F(4) Present Compliant Not provided Compliant</td>
<td>2</td>
<td></td>
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</tr>
<tr>
<td>28</td>
<td>Compliant</td>
<td>Support vital metabolic functions in the body and target healthy liver function with beef liver capsules that are rich in Vitamin A and B vitamins. Benefits of this energy boosting</td>
<td>NC(2); S/F(7) Present Compliant Compliant Compliant</td>
<td>2</td>
<td></td>
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</tbody>
</table>
superfood include organ health, immune support, healthy skin and bones, and balanced metabolism. Nourish and invest in your health. Without the use of harmful antibiotics, hormones, or pesticides. 100% additive-free.

<table>
<thead>
<tr>
<th></th>
<th>Compliant</th>
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<th>Compliant</th>
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</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>Compliance Optimal Energy Supplement</td>
<td>S/F(1)</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>30</td>
<td>Compliance Nature's most potent superfood. Supports: energy levels, fat metabolism, muscle building, exercise recovery, brain and heart health. Rich in high-quality protein, Vitamin A, B12, folic acid, and most absorbable form of iron. Hormone, pesticide, gluten, and GMO free.</td>
<td>GF; NC(5); S/F(6)</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>31</td>
<td>Compliance N/A</td>
<td>N/A</td>
<td>Not present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
</tr>
<tr>
<td>32</td>
<td>Compliance No added wheat, starch, yeast, gluten, corn, soy, sugar, artificial coloring or flavoring, antimicrobial preservatives or dairy products</td>
<td>N/A</td>
<td>Not present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
</tr>
<tr>
<td>33</td>
<td>Compliance Concentrated liver for energy and stamina. For your good health. Liver is a superior source of heme iron and other blood building nutrients. Non-GMO. No sugar, salt, yeast, wheat, gluten, corn, soy, dairy products, artificial coloring, artificial flavoring, or artificial preservatives.</td>
<td>GF; GW(1); NC(3); S/F(2)</td>
<td>Present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
</tr>
<tr>
<td>34</td>
<td>Compliance Beef liver is a high-quality superfood. Provides an abundant number of micronutrients including B12, copper, folate, choline, and hyaluronic acid, which have been shown to support the body’s immune system, healthy skin, hair and nails, as well as, strong bones and collagen synthesis. Helps improve collagen and protein metabolism. Helps improve overall energy levels. 100% additive free. Non-GMO, dairy free, gluten free.</td>
<td>GF; NC(5); S/F(8)</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>35</td>
<td>Compliance 100% additive free. Hormone, pesticide, and GMO free</td>
<td>N/A</td>
<td>Present (not required)</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
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<tr>
<td>Compliant</td>
<td>Statement</td>
<td>Code</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
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<tr>
<td>36</td>
<td>This ancient nutritional powerhouse plays a fundamental role in supporting healthy skin, eyes, metabolism, immune function, strong bones, and collagen synthesis. Liver is an abundant source of nutrients, including vitamin B-12, folate, choline, copper, hyaluronic acid, and is one of the most concentrated sources of preformed vitamin A (retinol). Contains no dairy, wheat, yeast, gluten, corn, sugar, soy, shellfish, tree nuts, or preservatives.</td>
<td>GF; NC(1); NC(6); S/F(6)</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>37</td>
<td>Optimal energy supplement. Liver support.</td>
<td>S/F(2)</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>38</td>
<td>Optimal energy supplement. Liver support.</td>
<td>S/F(2)</td>
<td>Present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>39</td>
<td>Nature's most potent superfood. Nature's most concentrated source of Vitamin A. Rich in Vitamin B12, folate, copper, hyaluronic acid, choline, and amino acids. It supports energy levels, brain health, digestive system health, liver function, and heart health. Provides essential nutrients for healthy skin, hair, and nails. Hormone and GMO-free</td>
<td>NC(7); S/F(8)</td>
<td>Present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
</tr>
<tr>
<td>40</td>
<td>No gluten, wheat, yeast, milk, lactose, soy, artificial color, artificial flavor, artificial sweetener, preservatives. Non-GMO.</td>
<td>GF</td>
<td>Not present</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
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<tr>
<td>41</td>
<td>N/A</td>
<td>N/A</td>
<td>Not present</td>
<td>Not provided</td>
<td>Not provided</td>
<td>Not Provided</td>
</tr>
<tr>
<td>42</td>
<td>No hormones or additives. Pesticide free.</td>
<td>N/A</td>
<td>Not present</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
</tr>
<tr>
<td>43</td>
<td>Delivers the natural nutrient profile found in the nutrient-dense whole foods. A rich source of nutrients. Traditional superfood. Additive-free. Free of pesticides and antibiotics.</td>
<td>N/A</td>
<td>Present (not required)</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
</tr>
<tr>
<td>44</td>
<td>Free of pesticides, growth hormones, antibiotics, or chemical additives. Made</td>
<td>GF</td>
<td>Present (not required)</td>
<td>Compliant</td>
<td>Not provided</td>
<td>Compliant</td>
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</table>
without sugar, starch, preservatives, artificial colors or flavorings, or genetically modified organisms. Contains no yeast, no soy, no milk derivatives, no wheat and is gluten free.

| 45 | Compliant | Contains no preservatives or binders. Gluten free, casein free. | GF | Present (not required) | Compliant | Compliant | Compliant | 0 |
| 46 | Compliant | Natural whole food vitamin and mineral support. One of nature’s most nutrient rich superfoods. Liver is a nutritional powerhouse, abundant in vitamins and minerals and hyaluronic acid. Contains vitamins A, D, E, K2, B12, B3, B5, B6, and vital minerals like zinc, iron, copper, potassium, CoQ10 and choline for brain health. | NC(15); S/F(1) | Present | Compliant | Not provided | Compliant | 16 |
| 47 | Compliant | Liver is believed to contain more nutrients gram for gram than any other food. Delivers the natural nutrient profile found in nutrient-dense whole foods. Additive free. Free of pesticides and antibiotics. | N/A | Present (not required) | Compliant | Compliant | Compliant | 0 |
| 51 | Compliant | Grass-fed liver is the most nutrient dense superfood on the planet. The vitamins and minerals within support: skin, hair & nails, energy & stamina, thyroid health & metabolism, heart health, iron levels, hormonal production, immune function. Hormone free. Non-GMO. | S/F (11) | Present | Compliant | Not provided | Compliant | 1 |
| 53 | Compliant | No GMOs, pesticides, antibiotics, and hormones | N/A | Not present | Compliant | Not provided | Compliant | 1 |

\(^a\)GF = gluten-free claim; GW = general well-being claim; N/A = not applicable (no claim or relevant wording on label); NC = nutrient content claim; PDC = prohibited disease claim S/F = structure/function claim. The number of NC and/or S/F claims for each product is shown in parentheses.

\(^b\)S/F claim included on a barcode sticker found on the product container.