Originator/Date:	Reviewed by/Date:	Approved Date:
Barbara A. Rusin / October 21, 2021	Barbara A. Rusin / October 21, 2021	Oct 27, 2021

Standard Operating Procedure

Purpose

The purpose of this SOP is to provide definition of and requirements for use of Risk Communications and Use Limitations Statements for L-Nutra products.

Scope

This SOP applies to all external-facing materials including digital, video, and print materials in Domestic markets.

This SOP does not define every instance in which statements and disclaimers should be used.

Responsibilities

- It is the responsibility of Medical Affairs and Marketing Teams to develop Risk Communications and Use Limitations for L-Nutra products.
- It is the responsibility of Marketing Teams to ensure third parties are aware of and adhere to requirements included in this SOP, and to provide current Risk Communications and Use Limitations to them.
- All L-Nutra personnel are responsible to notify Compliance when they identify a lack of adherence to this procedure either internally or by third parties.
- It is the responsibility of the Management of Regulatory Compliance to seek and receive legal review and approval of risk statements and disclaimers when appropriate.
- Management of Regulatory Compliance is responsible to maintain this SOP.
- L-Nutra Management is responsible to ensure adherence to this SOP.

Procedure

1. Risk Communications and Use Limitations statements are a single document developed specific to each L-Nutra product type. They are maintained in a shared folder available to all L-Nutra personnel, and are subject to MLR review and approval prior to use in accordance with SOP 10.002 MLR Review and Approval Process. Copies are not stored in personal drives or computers for reference/use.

2. Changes to any Risk Communications and Use Limitations are communicated to all stakeholders by appropriate L-Nutra personnel.

3. All stakeholders are responsible to implement updates in their assets as appropriate and necessary.

4. Risk Statement and Use Limitations include any information deemed necessary to inform consumers and/or healthcare professionals (HCPs) of risks, limitations, and/or potential adverse experiences associated with fasting and/or L-Nutra products, and fall into the following categories which are addressed further below:
   4.1. General Use Statements
   4.2. Risk Statements
   4.3. Use Limitations
   4.4. Dietary Supplement Health and Education Act (DSHEA) statement
   4.5. Consumer Commitments

5. General Use Statements define the intended user population for L-Nutra products and may be used in any promotional asset in which the intended user population is referenced. They are considered claims and may be included on any L-Nutra or financially affiliated third party asset as deemed appropriate.

6. Risk Communications
   6.1. Risk Communications include the following:
      6.1.1. Adverse Expectations, which include common side effects from fasting (i.e., headache, dizziness, fatigue, etc.) and those which may occur due to L-Nutra food products (i.e., allergic reactions, bloating, etc.).
      6.1.2. Avoidance Statements which define activities or situations which should be avoided while a consumer is fasting or following a low calorie diet (i.e., strenuous exercise, heat extremes, etc.).
      6.1.3. Allergen Statements which define nutritional ingredients in L-Nutra products which are known or suspected allergens (i.e., tree nuts, soy, etc.).

   6.2. To ensure balance of claims and consumer safety, Risk Communications are included in the following:
      6.2.1. Product websites managed by L-Nutra – as FAQs or stand-alone statements which are easily identifiable and accessible to readers.
      6.2.2. Websites of financially affiliated third-party on which L-Nutra products are sold and over which L-Nutra has a controlling power (i.e., Amazon or other marketplaces).
      6.2.3. Social media sites controlled by L-Nutra or financially affiliated third parties, as deemed appropriate.
      6.2.4. Product labeling (i.e., packaging, inserts, etc.), as deemed necessary and appropriate.

7. Use Limitations statements provide information on who should not use L-Nutra product(s). These statements are included on:
   7.1. Product promotional websites managed by L-Nutra – as FAQs or stand-alone pages which are easily identifiable and accessible to readers.

7.2. All social media sites managed by L-Nutra or financially affiliated third parties, as deemed appropriate.
7.3. All third-party sites on which products are sold and over which L-Nutra has controlling power, and when applicable and appropriate.
7.4. All product labeling (i.e., packaging, inserts, etc.) as deemed necessary and appropriate.

8. The DSHEA statement is used, as deemed necessary and appropriate, on materials which promote the sale of ProLon FMD and in which claims are made. Such materials may include:
   8.1. Promotional L-Nutra websites
   8.2. Social media sites managed by L-Nutra
   8.3. Print, digital, and visual / video advertisements
   8.4. Third-party sites on which products are sold and over which L-Nutra has controlling power
   8.5. Financially affiliated third party websites, social media sites, or other materials

1. Consumer Agreement (i.e., Healthy Start Commitment, Shopping Cart Agreement, etc.)
   1.1. A Consumer Agreement may be developed as deemed necessary and appropriate for any L-Nutra product to ensure consumers are adequately informed of risks and/or use limitations, and that the consumer actively agrees to them prior to purchase.
   1.2. Any Consumer Agreement developed for a product is included in the Risk Statements and Use Limitations for that product, along with directions as to where (i.e., which websites) and when use is required.

References

- SOP 10.002 MLR Review and Approval Process
- Dietary Supplement Health and Education Act (DSHEA) of 1994

Document History

Revision:	Reasons for Change:
1	Initial procedure
2	Clarification of statements and when use is required. Update referenced SOP.

Approvals

FULL NAME	TITLE	SIGNATURE
Joseph Antoun	Chief Executive Officer	joseph Antoun joseph Antoun (Oct 27, 2021 15:13 CDT)
Will Hsu, MD	Chief Medical Officer	William Hsu
Michael Wolfe	Chief Revenue Officer	Michael Wolfe
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