



Third Party Non-Compliance Policy

SOP # 11.001.002

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Effective Date November 16, 2021

Originator/Date:
Barbara A. Rusin / October 21, 2021

Reviewed by/Date:
Barbara A. Rusin, 2021

Approved Date:
Oct 27, 2021

POLICY

Purpose

This Policy communicates the actions L-Nutra may consider in the event an affiliated third party, as identified within the Policy Scope, does not adhere to contractual obligations related to Regulatory Compliance.

Scope

This Policy applies to all Domestic affiliated third parties, including but not limited to, affiliates, social media influencers/ambassadors, Key Opinion Leaders (KOLs) / speakers, and others who may be contracted to represent L-Nutra.

This Policy does not apply to non-affiliated third parties.

This Policy is applicable to Regulatory Compliance requirements within contracts or agreements, including but not limited to the below-listed items. Specifics of what is considered compliant vs non-compliant activity is stated in each contract or agreement.

- Attendance / Completion of mandatory Compliance Training sessions and activities
- Submission of presentation materials (i.e., slide decks, hand-outs, other materials) for Medical Legal Regulatory Review Board (MLR) review, and use of only MLR approved presentations
- Submission of blogs, articles, and interview/podcast materials for MLR review, and use of only MLR approved materials

This policy describes the disciplinary process for use of non-compliant materials and/or failure to correct such materials as required.

Responsibilities

- Each affiliated third party is responsible to read and understand this Policy.
- L-Nutra personnel delegated to manage third parties are responsible to read and understand this Policy, and implement appropriate steps, as needed and directed by Regulatory Compliance and Management.
- Management of Regulatory Compliance is responsible to ensure availability of this Policy to internal and external stakeholders, to support implementation and adherence to the Policy, and to review and provide Policy updates as necessary.
- L-Nutra management is responsible to ensure adherence to this Policy.



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Procedure

1. Affiliated third parties to include Speakers, Key Opinion Leaders (KOLs), Affiliates, Influencers, and HCPs in the ProLon Professional Program have made available to them through a shared electronic portal, at a minimum, the following resources:
 - 1.1. Current approved claims listings for relevant products
 - 1.2. Product-related Risk and Use Statements
 - 1.3. L-Nutra Speaker Guidelines
 - 1.4. L-Nutra Social Media Guidelines
 - 1.5. Relevant L-Nutra policies and procedures
 - 1.6. Sample approved assets which may include, but is not limited to, website content, landing pages, emails, brochures, flyers, etc.
2. All affiliated third parties adhere to the restrictions and requirements as listed in the provided resources, including use of only approved claims in a direct or implied manner.
3. All affiliated third parties have ability to contact Regulatory Compliance for guidance as needed through compliance@l-nutra.com.
4. All affiliated third parties submit for MLR review and approval only the materials as listed in their respective contracts. Submission is to compliance@l-nutra.com. Failure to submit materials for review and approval as required prior to use is considered a non-compliance subject to disciplinary action (see Step 10, below).
5. Speakers and KOLs are required to complete regular training activities related to Regulatory Compliance as listed in the current contractual agreement. Failure to complete the required training results the following:
 - 5.1.1 The party shall be removed from the "active" Speaker / KOL list
 - 5.1.2 The party will not provide any services until attendance of a mandatory training session. Training is provided by L-Nutra in a reasonable time frame and at an agreed upon time.
 - 5.1.3 If the party fails to attend the training session, or complete training in a timely manner, their agreement may be terminated at the sole discretion of L-Nutra and in accordance with allowances within the current contract or agreement.
 - 5.1.4 If it is the party's second or greater instance of non-compliance to Regulatory Compliance obligations, the contractual agreement may be terminated at the sole discretion of L-Nutra and in accordance with allowances within the current contract or agreement.
 - 5.1.5 If the non-compliance to Regulatory Compliance obligations is considered to be of a serious, egregious, or otherwise of especially damaging nature by L-Nutra, at the sole discretion of L-Nutra, the contractual agreement may be terminated at the sole discretion of L-Nutra and in accordance with allowances within the current contract or agreement.
6. Affiliates / Influencers and HCPs in the ProLon Professional Program may be provided Regulatory Compliance training materials (i.e., guidelines, policies,



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procedures, videos, etc.). Confirmation of receipt / review of these materials is necessary.

7. Training modules may be provided by Regulatory Compliance to any or all affiliated third parties through the electronic portal.
8. Surveillance for Non-Compliance
 - 8.1. L-Nutra maintains a surveillance program intended to capture non-suspected compliant materials from internal and external sources.
 - 8.2. All suspected non-compliant materials are reviewed by Regulatory Compliance following SOP 10.011 Non-Compliance Investigation and Management.
 - 8.3. Affiliated parties can report suspected non-compliant materials to Regulatory Compliance at compliance@l-nutra.com.
9. Regulatory Compliance reviews all reports of materials with suspected non-compliant claims, statements, photos, etc. L-Nutra will contact the affiliate and request immediate correction and/or removal of materials confirmed to be non-compliant. If the affiliate party refuses to cooperate with requests for correction, approval, or other required action, temporary suspension or termination of contract will be at the sole discretion of L-Nutra.
10. Disciplinary Actions proceed in a step-wise manner for the use of non-compliant materials, or for failure to gain MLR review and approval as required by contractual obligations:
 - 10.1. In the first instance of non-compliant material use, the party will be required to correct or remove the material within the requested and prescribed timeframe (see above, Step 9). Failure to do
 - 10.2. In the first instance of use of materials without required MLR review and approval, the material must be submitted and corrected as required by and within the timeframe determined by the MLR / Regulatory Compliance.
 - 10.3. In the second instance, the affiliated party is required to be trained / re-trained to compliance requirements and/or reference materials as appropriate.
 - 10.4. In the third instance, the affiliated party will be terminated from affiliation with L-Nutra.

References

- 10.011 Non-Compliance Investigation and Management
- Applicable contractual agreements between L-Nutra and third party
- Current claims listings for relevant products
- Product-related Risk and Use Statements
- L-Nutra Speaker Guidelines
- L-Nutra Social Media Guidelines
- 21 United States Code (USC) Part 343(a)



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- 15 USC Part 45(a)(1)
- 15 USC Part 52(a)

Document History

Revision:	Reasons for Change:
1.0	Initial Release
2.0	Additional affiliate classifications, review and surveillance information, and disciplinary actions added.






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Approvals

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