WARNING-LETTER RESPONSE · CLAIMS SECTION — Demo brand, Inc.

Prepared for: Demo brand, Inc. · Demo Counsel
Letter: Unapproved New Drugs/Misbranded · dated six working days before this review
Source: (letter link)
Ruled against: Claims Verified standards v1.3.1 · 98 standards
Date: September 13, 2026

> Draft for counsel. This is a claims analysis and draft language, not legal advice and not a filed response. It does not predict what FDA will accept.

1. The response window

FDA asks for a written response within **15 working days of receipt**. Counted from the letter's date, nine working days remain at the date of this draft; the live countdown is on your dashboard. Confirm the receipt date with counsel.

2. The claims the letter quotes

The letter quotes 6 statement(s) from the company's own marketing. Each is ruled below with the corrective action: remove, or replace with the compliant wording.

1. “DemoNerve Nerve Support 60 Daily Capsules Delivers Key Nutrients to Damaged & Inflamed Nerves.”

Our ruling: [Critical] Product name implying treatment. The brand name 'DemoNerve' implies the product makes neuropathy go away, which is a treatment claim in the name itself.
Corrective action: Rename.

Rules applied

- 21 CFR 101.93(g) — FDA

https://www.ecfr.gov/current/title-21/section-101.93

> (g)(2)(i) has an effect on a specific disease or class of diseases … (x) otherwise suggests an effect on a disease or diseases

- FDCA s.201(g)(1)(B), 21 U.S.C. 321(g)(1)(B) — FDA

https://www.law.cornell.edu/uscode/text/21/321

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

2. "Consumption of DemoNerve resulted in a signification reduction [Pain] in PI-NRS after 7 days of consumption."

Our ruling: [High] works in [X] days. Time-to-result claim requires finished-product trial data supporting the exact 7-day timeframe.
Corrective action: Remove.

Rules applied

- FTC Act s.5(a), 15 U.S.C. 45(a) — FTC

https://www.law.cornell.edu/uscode/text/15/45

> Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

- FTC Health Products Compliance Guidance (December 2022) — FTC

https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance

> Before disseminating an ad, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implication. … As a general matter, substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard.

- Competition Act, R.S.C. 1985 c. C-34, s.74.01(1)(b) — Competition Bureau Canada

https://laws-lois.justice.gc.ca/eng/acts/C-34/section-74.01.html

> makes a representation to the public in the form of a statement, warranty or guarantee of the performance, efficacy or length of life of a product that is not based on an adequate and proper test thereof, the proof of which lies on the person making the representation

3. "DemoNerve targets the cause of neuropathic pains in: head & neck, feet, static nerve, hands, arms, legs…"

Our ruling: [Critical] analgesic / pain reliever / relieves pain. Claiming to target the cause of pain is an explicit drug function claim.
Corrective action: Replace with: "Supports joint and muscle comfort"

Rules applied

- FDCA s.201(g)(1)(B), 21 U.S.C. 321(g)(1)(B) — FDA

https://www.law.cornell.edu/uscode/text/21/321

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

- 21 CFR 101.93(g) — FDA

https://www.ecfr.gov/current/title-21/section-101.93

> (g)(2)(i) has an effect on a specific disease or class of diseases … (x) otherwise suggests an effect on a disease or diseases

4. “DemoNerve burning, tingling, & numbness support.”

Our ruling: [Critical] relieves symptoms of. Burning, tingling and numbness are symptoms of neuropathy; addressing them is a drug claim.
Corrective action: Remove.

Rules applied

- FDCA s.201(g)(1)(B), 21 U.S.C. 321(g)(1)(B) — FDA

https://www.law.cornell.edu/uscode/text/21/321

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

- 21 CFR 101.93(g) — FDA

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> (g)(2)(i) has an effect on a specific disease or class of diseases … (x) otherwise suggests an effect on a disease or diseases

- Food and Drugs Act, R.S.C. 1985 c. F-27, s.3 and Schedule A — Health Canada

https://laws-lois.justice.gc.ca/eng/acts/F-27/section-3.html

> No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.1.

5. “Supports damaged and needy nerves.”

Our ruling: [Critical] Disease keyword in Amazon title/bullets. 'Damaged nerves' names a pathological state rather than a normal structure/function.
Corrective action: Replace with: “Supports healthy nerve function.”

Rules applied

- Amazon Seller Central, Dietary Supplements policy — Amazon

https://sellercentral.amazon.com/help/hub/reference/external/G201829010

> Make disease claims or implied disease claims, unless the FDA approved the statement. Disease claims include claims to diagnose, cure, reduce, treat, or prevent a disease in humans

- FDCA s.201(g)(1)(B), 21 U.S.C. 321(g)(1)(B) — FDA

https://www.law.cornell.edu/uscode/text/21/321

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

- 21 CFR 101.93(g) — FDA

https://www.ecfr.gov/current/title-21/section-101.93

> (g)(2)(i) has an effect on a specific disease or class of diseases … (x) otherwise suggests an effect on a disease or diseases

6. “R-Alpha Lipoic Acid (ALA) Protect nerves from damage…”

Our ruling: [Critical] prevents. Protecting from damage is a disease prevention claim.
Corrective action: Replace with: “Supports healthy nerve function.”

Rules applied

- FDCA s.201(g)(1)(B), 21 U.S.C. 321(g)(1)(B) — FDA

https://www.law.cornell.edu/uscode/text/21/321

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

- 21 CFR 101.93(g) — FDA

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> No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.1.

3. The same claims elsewhere, not quoted in the letter

1 further finding(s) in the company's copy that the letter did not quote. FDA letters say their list is not all-inclusive, so a response that corrects only the quoted lines leaves these exposed.

SEVERITY	CLAIM	WHERE	CORRECTIVE ACTION
Critical	“DemoNerve® Capsules”	website	Rename the product to remove the implied disease-treatment reference.

4. Corrective-action schedule

Complete and date each line before the response is filed. Counsel will want the dates.

#	STATEMENT	ACTION	SURFACES CHANGED	DATE COMPLETED
1	“DemoNerve Nerve Support 60 Daily Capsules Delivers Key Nutrients to Damaged & Inflamed Ne”	[removed / replaced]	[site, listing, label, ads, email]	[DATE]
2	“Consumption of DemoNerve resulted in a signification reduction [Pain] in PI-NRS after 7 d”	[removed / replaced]	[site, listing, label, ads, email]	[DATE]
3	“DemoNerve targets the cause of neuropathic pains in: head & neck, feet, static nerve, han”	[removed / replaced]	[site, listing, label, ads, email]	[DATE]
4	“DemoNerve burning, tingling, & numbness support.”	[removed / replaced]	[site, listing, label, ads, email]	[DATE]
5	“Supports damaged and needy nerves.”	[removed / replaced]	[site, listing, label, ads, email]	[DATE]
6	“R-Alpha Lipoic Acid (ALA) Protect nerves from damage…”	[removed / replaced]	[site, listing, label, ads, email]	[DATE]

5. Draft language for the claims section

> Upon receipt of the Warning Letter, Demo brand, Inc. reviewed all product labeling and marketing materials for statements of the kind identified by the Agency. Each statement quoted in the letter has been removed or revised as set out in the attached schedule, which lists the statement, the corrective action and the date it was completed. The review was not limited to the statements quoted: [N] further statements of the same kind across [surfaces] were also corrected. Demo brand, Inc. has put in place a recurring review of new marketing copy before it is published. [Counsel to adapt; not legal advice.]

Independent pharmacist review: Reviewed by [NAME], PharmD, licensed pharmacist, independent review of marketing-claims findings against the published Claims Verified standards. Licence [NUMBER] on file, verifiable on the public register.

Signature pending

`This draft has not been reviewed by the reviewer of record. It is not a deliverable and must not be sent to a client in this state.`

This document is a draft. It carries no professional signature and no part of it should be relied upon until it does.