Prepared for Demo brand, Inc. under terms version 2026-10-15. Show it to a platform, processor or buyer as evidence that every claim was reviewed. Anyone else relying on it for their own decisions needs our written reliance letter.

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

> **Sample report. The brand, products and copy are invented. The reviewer's name is withheld on samples and printed on every client file.**

Prepared for: Demo brand, Inc. · Demo Counsel
Letter: Unapproved New Drugs/Misbranded · dated October 8, 2026
Source: the letter as supplied by the company
Ruled against: Claims Verified standards v1.4.1 · 109 standards
Date: October 15, 2026

> **Signed claims analysis and draft language for counsel. 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 (October 8, 2026), the window closes on **October 29, 2026**: 10 working days after the date of this section. If the letter arrived later, count from the day it arrived. Confirm the receipt date with counsel.

2. The claims the letter quotes

The letter quotes 8 statements from the company's own marketing. Each is ruled below with the corrective action: remove, or replace with wording the standard allows.

1. “DemoNerve Nerve Support, 60 capsules: delivers key nutrients to damaged and inflamed nerves.”

Our ruling: [Critical] Product name implying treatment. The product title itself promises help for damaged and inflamed nerves, so every place the title runs carries a treatment claim.
Corrective action: Rename the product title, since the title itself makes the treatment claim.

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. "Formulated for damaged and inflamed nerves."

Our ruling: [Critical] Disease keyword in Amazon title/bullets. Describing nerves as damaged and inflamed names a disease state in a bullet, which can trigger Amazon suppression and treatment as a drug claim.
Corrective action: Remove.

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

3. "Users felt the difference within 7 days."

Our ruling: [High] works in a set number of days. A time-to-result claim needs 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

4. “In a study, DemoNerve users reported a significant drop in pain scores after 7 days.”

Our ruling: [High] Ingredient study on a disease population. A study reporting lower pain scores reads as a treatment result, the kind of study run in people with neuropathy.
Corrective action: Cite studies in healthy populations, or remove the citation.

Rules applied

- 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.

- 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

5. “DemoNerve goes after the root cause of nerve pain in the feet, hands, arms, legs, head and neck.”

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: “Provides B vitamins that support normal 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

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. “Relief support for burning, tingling and numbness.”

Our ruling: [Critical] relieves symptoms of. Burning, tingling and numbness are symptoms of neuropathy, and 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

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

- 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.

7. “Nourishes damaged, struggling 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

8. “Alpha lipoic acid shields your nerves from damage.”

Our ruling: [Critical] prevents. Shielding nerves from damage is a disease prevention claim.
Corrective action: Replace with: “Alpha lipoic acid is an antioxidant that supports healthy nerve cells.”

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

- 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.

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

1 further finding 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 this exposed.

SEVERITY	CLAIM	WHERE	CORRECTIVE ACTION
Critical	“Relief for damaged nerves, backed by science.”	website	Remove.

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4. Corrective-action schedule

Each statement, the action taken, the date it was completed and the dated capture of the page after the change. Counsel will want the dates, and FDA closes a letter only on corrections it can verify.

#	STATEMENT	ACTION	WHERE CHANGED	DATE COMPLETED	CAPTURE AFTER THE CHANGE
1	“DemoNerve Nerve Support, 60 capsules: delivers key nutrients to damaged and inflamed nerve”	Retitled	Amazon listing, website	October 15	Pages as read on October 15, text held on file
2	“Formulated for damaged and inflamed nerves.”	Removed	Amazon listing, website	October 15	Pages as read on October 15, text held on file
3	“Users felt the difference within 7 days.”	Removed	Amazon listing, website	October 15	Pages as read on October 15, text held on file
4	“In a study, DemoNerve users reported a significant drop in pain scores after 7 days.”	Removed	Amazon listing, website	October 15	Pages as read on October 15, text held on file
5	“DemoNerve goes after the root cause of nerve pain in the feet, hands, arms, legs, head and”	Replaced	Amazon listing, website	October 15	Pages as read on October 15, text held on file
6	“Relief support for burning, tingling and numbness.”	Removed	Amazon listing, website	October 15	Pages as read on October 15, text held on file
7	“Nourishes damaged, struggling nerves.”	Replaced	Amazon listing, website	October 15	Pages as read on October 15, text held on file
8	“Alpha lipoic acid shields your nerves from damage.”	Replaced	Amazon listing, website	October 15	Pages as read on October 15, text held on file
9	“Relief for damaged nerves, backed by science.” (not quoted)	Removed	website	October 15	Page as read on October 15, text held on file

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: one further statement of the same kind, on the company website, was also removed. 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 a licensed pharmacist, independent review of marketing-claims findings against the published Claims Verified standards. Licence on file, verifiable on the public register.

Sign-off

Claims Review Report · Form CV-AR

Independent review of the marketing-claims findings in this report under the published Claims Verified standards, version **v1.4.1**. Findings reflect copy as captured on **the capture dates listed under Sources reviewed**.

Signature

Date signed

15 October 2026

Licensed pharmacist

Licence on file

Sample report. The reviewer's name, licence number and signature are printed on every client file and withheld on samples.

Sample file. A client file carries its report ID here.

Review of marketing language only. Not product testing, formulation or facility compliance. Findings are the reviewer's professional opinion under the published Claims Verified standards.