



SUPPLEMENT SHERIFF

REGULATORY COMPLIANCE DIVISION

ASIN: N/A

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SUPPLEMENT SHERIFF: REGULATORY AUDIT

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CRITICAL VIOLATIONS

Mismatched Botanical Plant Part (Ashwagandha)

Issue: The Supplement Facts Panel (SFP) declares "Ashwagandha herb extract", which botanically refers to the aerial parts (leaves, stems, flowers) of the plant. However, the product's marketing claims

explicitly

state it is formulated with "Ashwagandha root extract". This is a direct contradiction. Ashwagandha's primary active compounds

(withanolides)

differ significantly between the root and aerial parts.

Logic: "Herb" equals Aerial Parts. "Root" equals Underground Parts. The SFP and marketing claims cannot claim two different parts of the plant for the exact same ingredient.

Regulation: 21 CFR 101.4(h)(1) (Botanical ingredient plant part declaration); FTC Act Section 5 (Deceptive Advertising); Amazon 2026 Deception Policy.

Incorrect Botanical Plant Part (BioPerine)

Issue: The SFP lists BioPerine as a "Black pepper seed extract".

BioPerine

is a patented, standardized extract derived from the dried fruits (peppercorns) of *Piper nigrum*, not the seeds.

Logic: *Piper nigrum* peppercorns are botanically classified as

fruits

(drupes). Sabinsa Corporation (the patent holder) explicitly define BioPerine as a fruit extract.

Regulation: 21 CFR 101.4(h)(1) (Botanical ingredient plant part declaration).

PASSED CHECKS

Extraction Ratio Math: The marketing claims state a "20:1 extract" yielding 150 mg per serving. 150 mg multiplied by a 20 extraction ratio equals a 3000 mg raw herb equivalent. This mathematically substantiates the "Extra Strength" claim on the principal display panel.

Disease Claims: No prohibited disease claims ("cure", "treat", "prevent") were found in the marketing copy. "Stress & Mood Support" is a compliant structure/function claim.

FDA Disclaimer: The mandatory FDA disclaimer is present and properly boxed on the label.

BioPerine Trademark: The trademark symbol and attribution to Sabinsa Corporation are correctly displayed on the label.

SFP Formatting: The Supplement Facts Panel correctly utilizes heavy and light bars, proper footnote placement for the Daily Value, and correctly places the "Other Ingredients" list outside the SFP box.

REMEDIATION PLAN

DELETE: "Ashwagandha herb extract (*Withania somnifera*)" from the SFP.

REPLACE WITH: "Ashwagandha root extract (*Withania somnifera*)"
(Assuming the product actually contains root extract as claimed in marketing).

DELETE: "BioPerine® Black pepper seed extract (*Piper nigrum*)" from the SFP.

REPLACE WITH: "BioPerine® Black pepper fruit extract (*Piper nigrum*)"

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