



October 23, 2023

VIA EMAIL

Attention: Allegations of Regulatory Misconduct Branch
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
WO Bldg. 66 RM 3523
10903 New Hampshire Ave.
Silver Spring, MD 20993
CDRHDeviceAllegations@fda.hhs.gov

Re: Improper Use of FDA Logo to Advertise BeActive Plus products

Dear Sir or Madam:

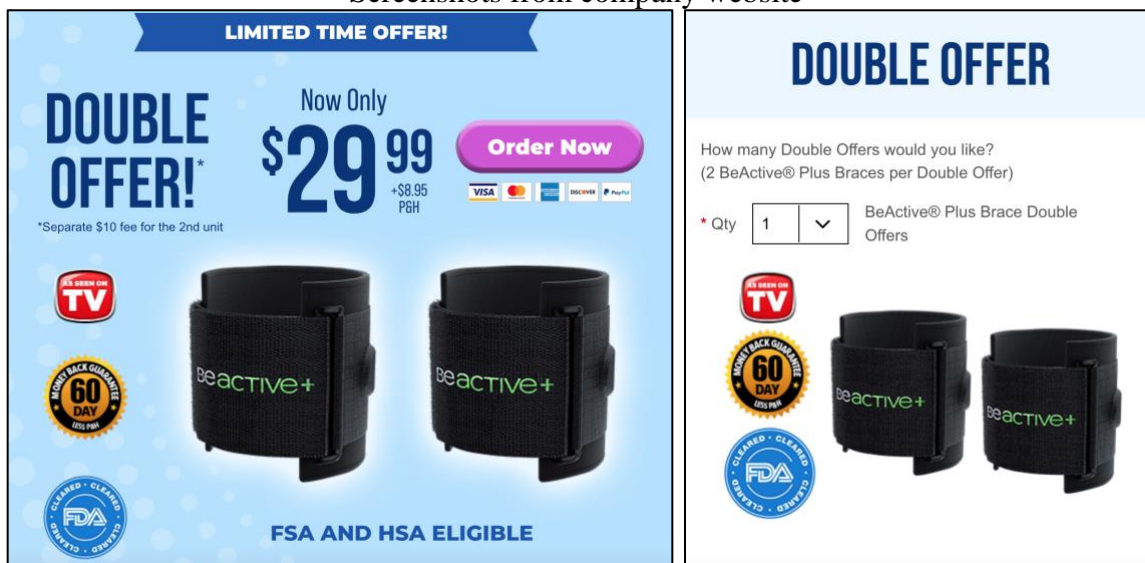
We write on behalf of Truth in Advertising, Inc. (“TINA.org”) to inform you of Top Dog Direct’s improper use of FDA logos to promote its BeActive Plus brace in violation of the FDA’s Logo Policy.¹ Specifically, the Pennsylvania-based company prominently features FDA logos in marketing materials for the brace, including in a BeActive Plus television commercial and on the BeActive Plus website, despite the FDA’s ban against the use of its logos in private sector materials, sending the false and misleading message that the FDA “favors or endorses” BeActive Plus products.

Screenshots from television commercial²





Screenshots from company website³



In addition, while an earlier version of the product was FDA cleared in 2016,⁴ the company is stretching the meaning of such agency clearance in marketing materials. For example, in a television commercial, the company states, “It works so well, the FDA cleared BeActive Plus as a medical device,” and on the Walmart website, the BeActive Plus brace is marketed as “FDA cleared as a breakthrough medical device,”⁵ deceptively implying the product is superior to other similar devices when that is not what FDA clearance means.⁶ Further, the claim that the BeActive Plus brace is “FDA cleared as a breakthrough medical device” is false. (As you know, the FDA has a separate Breakthrough Devices Program,⁷ which this company did not appear to use for the BeActive Plus brace.)

Finally, while the BeActive brace was FDA cleared for “temporarily reducing lower back pain that radiates down the leg associated with normal household or work activities,”⁸ the company claims the BeActive Plus brace can provide “instant relief” for and can “turn off” “excruciating” sciatic nerve pain, as well as hip pain, among other things, thereby going beyond the bounds of the FDA’s 2016 clearance.

Accordingly, TINA.org urges the FDA to commence an investigation into Top Dog Direct's improper use of its FDA logo in marketing materials for the BeActive Plus brace, as well as its use of misleading statements regarding the agency's clearance, and take appropriate enforcement action. If you have any questions, please do not hesitate to contact us.

Sincerely,



Laura Smith, Esq.
Legal Director
Truth in Advertising, Inc.



Bonnie Patten, Esq.
Executive Director
Truth in Advertising, Inc.

Cc via email: Jacklyn Bloemker
Director of Marketing
Top Dog Direct
jacklyn@npiandmei.com

¹ FDA Name and Logo Policy, <https://www.fda.gov/about-fda/website-policies/fda-name-and-logo-policy>.

² BeActive Brace TV Spot, ‘Sciatic Nerve Pain,’ <https://www.ispot.tv/ad/2211/beactive-brace-sciatic-nerve-pain>. The commercial is also published on Amazon. *See* BeActive Plus Acupressure System, Amazon, https://www.amazon.com/dp/B0B5P12FQ3?maas=maas_adg_29D5A6FC75A03A8C09B92D15B9C88E95_afap_abs&ref_=aa_maas&tag=maas&th=1.

³ BeActive Plus Homepage, <https://www.buybeactiveplus.com/>; BeActive Plus Order Page, <https://www.buybeactiveplus.com/BEACTIVEPLUS/15.0000/Index.dtm?sotsid=26116#order>.

⁴ Feb. 26, 2016 Letter to Natures Pillows, Inc. re FDA clearance for Beactive Brace, https://www.accessdata.fda.gov/cdrh_docs/pdf15/K151476.pdf.

⁵ BeActive Plus Instant Relief Acupressure Calf Brace for Sciatic Nerve Pain, Black, Walmart, <https://www.walmart.com/ip/BeActive-Plus-Instant-Relief-Acupressure-Calf-Brace-for-Sciatic-Nerve-Pain-Black/949373881>.

⁶ FDA 510(k) Clearances, <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances>.

⁷ FDA Breakthrough Devices Program, <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>.

⁸ Feb. 26, 2016 Letter to Natures Pillows, Inc. re FDA clearance for Beactive Brace, https://www.accessdata.fda.gov/cdrh_docs/pdf15/K151476.pdf.