



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

Bureau of Consumer Protection  
Division of Enforcement

Julia Solomon Ensor  
Attorney

Email: [jensor@ftc.gov](mailto:jensor@ftc.gov)  
Direct Dial: (202) 326-2377

July 18, 2024

**VIA EMAIL**

Caitlyn M. Barnes, Esq.  
Stites & Harbison PLLC  
400 West Market Street  
Suite 1800  
Louisville, KY 40202-3352  
[Cbarnes@stites.com](mailto:Cbarnes@stites.com)

Dear Ms. Barnes:

We received your submissions on behalf of Med-Dyne, Inc. (“Med-Dyne” or the “Company”). During our review, we discussed concerns that marketing materials may have overstated the extent to which certain products, including, but not limited to, pediatric ECG and sleep testing supplies, are made in the United States. Specifically, among other things, Med-Dyne’s website included broad, unqualified “Made in USA” claims when, in fact, certain products featured on the site incorporate significant imported parts.

In most instances, unqualified U.S.-origin claims in marketing materials – including claims products are “Made” or “Built” in the USA – likely suggest to consumers that the advertised products are “all or virtually all” made in the United States.<sup>1</sup> Depending on context, the Commission may analyze a number of different factors to determine whether a product is “all or virtually all” made in the United States, including the proportion of total manufacturing costs attributable to U.S. parts and processing, how far removed any foreign content is from the finished product, and the importance of the foreign content or processing to the product’s overall function. The “all or virtually all” standard is codified in the Made in USA Labeling Rule, 16 C.F.R. § 323 (the “MUSA Labeling Rule”).<sup>2</sup>

---

<sup>1</sup> FTC, *Issuance of Enforcement Policy Statement on “Made in USA” and Other U.S. Origin Claims*, 62 Fed. Reg. 63756, 63768 (Dec. 2, 1997) (the “Policy Statement”).

<sup>2</sup> Effective August 13, 2021, it is a violation of the MUSA Labeling Rule to label any covered product “Made in the United States,” as the MUSA Labeling Rule defines that term, unless the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States. *See* <https://www.federalregister.gov/documents/2021/07/14/2021-14610/made-in-usa-labeling-rule>. Pursuant to 15 U.S.C. § 45(m)(1)(A), the Commission may seek civil penalties of up to \$51,744 per MUSA Labeling Rule violation.

When a product is last substantially transformed in the USA but contains more than *de minimis* imported content, a marketer may be able to make a qualified claim that conveys truthful information about U.S. processes or content without implying the product is “all or virtually all” made in the United States. A marketer may make any qualified claim that is truthful and substantiated, including one that generally alerts consumers to the existence of foreign content in the product (e.g., “Made in USA of Imported Parts”), one that identifies the particular countries from which the parts came (e.g., “Made in USA from French and Korean Parts”), or one that specifies the proportion of the product that comes from the U.S. (e.g., “60% U.S. Content”).<sup>3</sup>

Alternatively, a marketer may advertise a product as “Assembled in USA” if the product is last substantially transformed in the USA, its principal assembly takes place in the USA, and United States assembly operations are substantial.<sup>4</sup> In most cases, marketers need not qualify “Assembled in USA” claims with information about the origin of the parts or materials the product contains. The FTC reminds marketers when a product is last substantially transformed abroad and thus required by Customs and Border Protection (“CBP”) to be marked with a foreign country of origin, “it would be inappropriate, and confusing,” to make a U.S. origin claim.<sup>5</sup>

As discussed, it is appropriate for the Company to promote its commitment to American jobs and highlight U.S. processes. However, marketing materials should not state or imply products are wholly or partially made in the United States unless the Company can substantiate those claims. To avoid deceiving consumers, Med-Dyne has removed unqualified “Made in USA” claims from all marketing materials.

FTC staff members are available to work with companies to craft claims serving the dual purposes of conveying non-deceptive information and highlighting work done in the United States. Based on the Company’s actions and other factors, the staff has decided not to pursue this investigation any further. This action should not be construed as a determination that there was no violation of applicable law. The Commission reserves the right to take such further action as the public interest may require. If you have any questions, please feel free to call.

Sincerely,



Julia Solomon Ensor, Staff Attorney



Lashanda Freeman, Senior Investigator

---

<sup>3</sup> Policy Statement at 63769.

<sup>4</sup> *Id.* at 63770.

<sup>5</sup> *Id.*