



Bureau of Consumer Protection
Division of Enforcement
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VIA EMAIL

Mr. Arthur Lih, Chief Executive Officer
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Mr. Lih and Mr. Plunkett,

We received your submissions on behalf of Life Vac LLC d/b/a LifeVac (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, certain medical devices, are made in the United States. Specifically, among other things, LifeVac marketed products “Made in the USA,” when those products contained significant imported content.

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.¹ 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”).²

The Commission has explained that, unless marketers either specify which products are covered or directly link claims to particular products, consumers generally interpret U.S.-origin claims in marketing materials to cover *all* products advertised in those materials. Accordingly, the Policy Statement provides, “marketers should not represent, either expressly or by

¹ 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”).

² 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 \$53,088 per MUSA Labeling Rule

implication, that a whole product line is of U.S. origin (*e.g.*, ‘Our products are Made in USA’) when only some products in the product line are, in fact, made in the United States.’³

Additionally, marketers should recall representations may be either express or implied, and ensure they can substantiate reasonable takeaways. “In identifying implied claims, the Commission focuses on the overall net impression of an advertisement, label, or other promotional material. This requires an examination of both the representation and the overall context, including the juxtaposition of phrases and images, and the nature of the transaction.”⁴ If, in context, an ad implies to a reasonable consumer that a product is of U.S. origin, the marketer must have appropriate substantiation for that claim. If no such substantiation exists, the marketer should update or qualify the claim to avoid deception.

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,