

# Weight-Loss Claims: How Many Studies Does the FTC Really Think It Takes?

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On Tuesday, the FTC announced that it has sent [warning letters](#) to 20 marketers of weight-loss dietary



supplements. The letters question whether the companies possess adequate support for claims and describe the scientific evidence required to support such claims. The Commission is asking the companies to review all product claims, including endorsements and testimonials, to ensure they are adequately supported, and to revise the claims as necessary.

The letters state that weight-loss claims must be supported by “well-controlled human clinical studies of the product, or a substantially similar product” and that such studies “must be randomized, double-blind, and placebo-controlled and conducted by researchers who are qualified by training and experience to conduct such studies.” The Commission does not, however, specify how many studies are needed. In *POM v. FTC*, the D.C. Circuit rejected an FTC order provision requiring “at least two randomized and controlled human clinical trials” for future claims to treat or prevent prostate cancer and other diseases. The court found, instead, that one clinical study may be adequate and revised the order accordingly. Since that decision, FTC orders on health-related claims have generally required only one, rather than two studies. The only exception has been in the realm of weight loss. An open question has been whether the FTC might still revise its position and expect only one study, rather than two, for weight loss claims. The warning letters do not provide much clarity other than using the plural, “studies.”

As these warning letters indicate, weight-loss and dietary supplement advertising remain a priority for the FTC, and it is important to be prepared to defend your product claims with adequate substantiation [should the FTC come calling](#).