

Ingredient Supplier Settles FTC Charges Related to Sponsored Trial

[John E. Villafranco](#)

September 10, 2014

Earlier this week, the FTC [announced](#) a settlement with a company that supplies functional ingredients to food and dietary supplement sellers. According to the FTC, the company sponsored “a seriously flawed human clinical trial” on a green coffee ingredient, advertised the results of the study, and through its advertising, provided its customers with the “the means and instrumentalities to deceive consumers.” The company’s study, which was a weight loss study, was discussed on the Dr. Oz Show, and the company issued a press release about the discussion on the Dr. Oz Show. The FTC attached a copy of the press release to its complaint.

The FTC alleges that the company commissioned the study in Bangalore, India, and that “during and after the trial, the principal investigator repeatedly: (1) altered the weights and other key measurements of the subjects; (2) changed the length of the trial; and (3) confused which subjects took either the placebo or [the green coffee ingredient] at various points during the trial.” The FTC further alleges that “[w]hen the principal investigator failed to find a publisher for his summary of the purported trial, [the company] hired ghost-writers, who – like [those at the company] . . . received numerous, conflicting data sets from the principal investigator.” The FTC contends that “despite the[] discrepancies,” neither the company nor the “ghost writers” checked the revised data sets against the original raw data. In addition to the alleged data issues, the FTC takes issue with the study report failing to provide information on blinding, diet and exercise protocols, or “how randomization occurred.”

The company admitted no wrong-doing and agreed to injunctive relief and a \$3.5 million monetary settlement. The injunctive relief requires at least two “adequate and well-controlled human clinical tests” for any future claims that a drug, dietary supplement, or device causes or helps cause weight or fat loss. The order also imposes record-keeping requirements for certain clinical trials relied upon for claim substantiation and requires the company to provide notice of the settlement to past customers.