Bayer Prevails in FTC Probiotic Supplement Case

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A federal judge on Thursday denied the FTC's request to hold <u>Bayer Corp.</u> in contempt in a case that has been followed closely by the dietary supplement industry.

Jose Linares, a federal judge in New Jersey, filed his opinion under seal until Oct. 8 so the rationale for his decision wasn't clear.

The FTC had no immediate comment on the decision.

Government lawyers accused Bayer of violating a 2007 consent decree that was entered with the FTC, making unfounded claims that a probiotic supplement, Phillips' Colon Health (PCH), helps defend against certain symptoms including bloating, constipation and diarrhea. But representatives for the supplement industry have maintained the government's demand for randomized controlled trials (RTCs) to support Bayer's probiotic claims is unnecessary and would undermine the 1994 Dietary Supplement Health and Education Act (DSHEA).

Bayer said it was pleased with the decision.

"Requiring a drug-level randomized controlled clinical trial for a dietary supplement is not and has never been the standard for dietary supplement claims," the company said in an emailed statement.

"Based on the Order, it is safe to say that the Government did not meet its burden of proving that Bayer disobeyed the prior consent order—that all supplement claims would be supported by 'competent and reliable' scientific evidence—by clear and convincing evidence," said Richard J. Oparil, a principal in Washington with the law firm Porzio, Bromberg & Newman, P.C.

Oparil's firm represented the <u>Natural Products Association</u> (NPA), which filed an amicus brief in the case.

"Probiotic bacteria, including the three species used in PCH, have substantial science supporting their digestive benefits," Bayer said in its statement. "Claims about PCH are fully substantiated by numerous clinical, animal and genetic studies, among other things, and satisfy all applicable legal standards."