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FDA Drug Preclusion, Enforcement and Reorganization: Implications for industry

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- The Expo Hall is open today from 10am – 5:00pm.
- What's Up With Supps is tonight from 5-11pm at the House of Blues at Mandalay Bay.
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FDA Drug Preclusion, Enforcement and Reorganization: Implications for industry

Bob Durkin

Arnall Golden Gregory LLP

Daniel Fabricant

Natural Products Association

Josh Long

Natural Products Insider

Drug Preclusion: "Marketed as a Dietary Supplement"

"We are aware that 25-hydroxyvitamin D3 was a component of marketed food; however, this is not enough to show that 25-hydroxyvitamin D3 was 'marketed' as food within the meaning of section 201(ff)(3)(B) of the FD&C Act (as the district court noted about lovastatin on remand in *Pharmanex v. Shalala*). Likewise, the body producing a substance from sun exposure would not make that substance 'marketed as a dietary supplement or as a food' for purposes of section 201(ff)(3)(B) of the FD&C Act. Without information that 25-hydroxyvitamin D3 was 'marketed as a dietary supplement or as a food' for purposes of section 201(ff)(3)(B) of the FD&C Act before the relevant date, we currently do not have reason to question that 25-hydroxyvitamin D3 products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act."

Oct. 13, 2023 email from Food and Drug Administration to Dan Fabricant, Natural Products Association

Drug Preclusion: IND Authorization

We realize the relevant date is not necessarily public information, but would point out that substantial clinical investigations include investigations by Alan R. Fleischman et al.
(see https://jamanetwork.com/journals/jamapediatrics/fullarticle/508138, published in October 1978) and by Laura S. Hillman et al.
(see https://www.sciencedirect.com/science/article/pii/S0022347685802559?via%3Dihub, published in June 1985)."

Continuation of previous Oct. 13, 2023 email from Food and Drug Administration to Dan Fabricant, Natural Products Association

End –
Thank You

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