

Daniel Fabricant

From: David Seckman [dseckman@nnfa.org]
Sent: Wednesday, October 31, 2007 12:45 PM
To: Daniel Fabricant
Subject: Fw: Follow-up

Sent from my Verizon Wireless BlackBerry

-----Original Message-----

From: "Elder, David K." <david.elder@fda.hhs.gov>

Date: Wed, 31 Oct 2007 11:11:37

To: "David Seckman" <dseckman@naturalproductsassoc.org>

Subject: RE: Follow-up

David - thanks again for this and we've begun looking deeper into the sibutramine issue. We are conducting surveillance and identifying potential targets for sampling and analysis. I can't say what they are at this point but I wonder if any of your industry reps or scientific advisors have any particular brand names or mfr/dist names in mind that we should be sure to consider when identifying our potential targets. If they don't, or if you'd prefer not to identify specific products, I understand and we'll continue our work.

I enjoyed the meeting last week. I'm sorry I had to connect by phone but couldn't avoid it due to other meetings before and after.

Thanks.

David Elder

From: David Seckman [mailto:dseckman@naturalproductsassoc.org]
Sent: Friday, October 05, 2007 10:37 AM
To: Elder, David K.
Subject: Follow-up

David --

I wanted to follow up on our conversation where you asked me if we could provide you with some insights and ideas on areas of possible adulteration and illegal products coming into the country in the form of dietary supplements. Our group meet late last week and I wanted to provide you with the attached paper. We are particularly concerned with illegal products marketed as dietary supplements that were intentionally adulterated with analogues of the active pharmaceutical ingredients sildenafil, tadalafil, vardenafil. This problem was first observed as early as 2001 in Asia (Takako, M., Sutemi, S., Kiyoko, K., Fusako, I., Jyunichi, N., Hisashi, K. and Ichiro, Y. 2001. Identification system for sildenafil in health foods. Yakugaku Zasshi 121: 765-769.; Tseng, M. C. and Lin, J. H. 2002. Determination of sildenafil citrate adulterated in a dietary supplement capsule by LC/MS/MS. J. Food Drug Anal. 10: 112-119.; and Shin, M. H., Hong, M. K., Kim, W. S., Lee, Y. J. and Jeoung, Y. C. 2003. Identification of a new analogue of sildenafil added illegally to a functional food marketed for penile erectile dysfunction. Food Addit. Contam. 20: 793-796.) With that in mind, the

enclosed paper in addition to some informal discussion with some industry representatives who maintain an active presence in Asia have mentioned the potential for the illegal distribution of products marketed as dietary supplements for weight control/ fat loss intentionally adulterated with pharmaceutical analogues, specifically the active pharmaceutical ingredient sibutramine (trade name meridia).

I hope this information is helpful to you and are the type of products/ingredients that the agency will want to focus on. On another topic, I wanted to let you know that I have e-mailed Dr. Bracket requesting a meeting the week of October 22nd - 26th to discuss our testing of raw ingredient program with USP in China. Per your suggestion I asked for all of the individuals you included in your e-mail to me be invited to the meeting. Thanks again and let me know what more we can do for you and your team. And, I look forward to seeing you at the above mentioned meeting soon.

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