Message

From: Diane Miranda/Morristown/Watson [Diane Miranda/Morristown/Watson]

Sent: 7/17/2007 9:00:32 AM

To: Tracey Hernandez/Morristown/Watson%Watson

CC: Al Paonessa III/Anda/Andrx%Andrx

Subject: Re: DEA Contact History

Hi Tracey.

The summary is consistent with my notes. As it relates to the meeting, I would like to attend from this end. Please keep us posted as you obtain more information regarding timing.

Thanks.

Oiane Hiranda

Vice President, Sales Operations,
Distribution & Commercial Headquarters
P 973-355-8388
F 973-355-8596
dmiranda@watsonpharm.com

置Tracey Hernandez/Morristown/Watson

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07/17/2007 11:41 AM

ToAl Paonessa III/Anda/Andrx@Andrx, Diane Miranda/Morristown/Watson@Watson

CC

SubjectDEA Contact History

Diane/Al-

Just wanted to document for history's sake the contact from DEA yesterday and our response. Once you are both okay with this, I will forward it to Brett Hagadorn, Gordon Munro and anyone else you suggest. I will also maintain a copy for our DEA history file.

Please also convey who you would suggest attend the meeting with DEA - My recommendation would be to keep the attendance minimal.....

Parking lot notes for the future meeting with DEA (per our internal conversations): Anda distributes hydrocodone for multiple manufacturers and we are a leader in CSOS (electronic 222 form) technology - which tends to lead to increased controlled substance orders.

On 7/16/07, I received a telephone call from Michael Mapes, DEA HQ. Mr. Mapes inquired as to whether or not Watson owned Anda and was told that we did. He then indicated he had concerns about Anda that he would like to discuss. He referenced a meeting DEA had had in September 2005 involving Michael Cochrane and Hirshell Sparks to discuss internet pharmacies. Mr. Mapes said that after that meeting it became apparent to them that Anda had stopped shipping to about 100 retail pharmacies. They were pleased to see that at the time.

Mr. Mapes then went on to say that since then, they have seen a steady increase in Anda's sales of hydrocodone, to the



point of these sales being extremely questionable. He stated that many of the retail pharmacies we are selling to are feeding illegal internet pharmacies. He also asked about the effectiveness of Anda's suspicious order monitoring system; quoting orders of 279,000 hydrocodone dosage units sold to a single customer in a 30 day period and another for 174,000. He referenced recent regulatory actions DEA has taken against Southwood, Bellco, Richie Pharmacal and Amerisource Bergen (these actions include suspension/revocation of licensure). Mr. Mapes expressed concern that if Anda did not make immediate changes they would be forced to take similar regulatory action against us. He indicated that a change at this point does not mean DEA won't still take some sort of action, but an immediate change might limit the severity. I assured him that we did not want our license to be revoked/suspended and inquired as to what action he would like us to take.

Mr. Mapes immediately responded with, "Do not ship more than 5000 dosage units in a 30 day period to any retail pharmacy". He then clarified, "That does not mean 5000 from Ohio and 5000 from Florida, that means 5000 total, and in the long run, you should take a serious look at allowable quantities in your suspicious order monitoring system...and getting notified that an order is suspicious AFTER it ships, does not meet the regulation." Mr. Mapes also offered to meet with us to discuss the issue and internet pharmacies in general in more detail. I conveyed to Mr. Mapes that I would communicate this information to the right people internally and would get back to him within a couple of days at the most.

Discussions later that day with Al Paonessa and Diane Miranda, resulted in the following decisions:

- All large size bottles (over 100 count) of any Schedule II or III product and any frequently abused/diverted products (such as alprazolam, soma/carisoprodol or phentermine) will be removed from the system (unable to purchase) immediate implementation
- A daily limit will be set of one bottle per day of an SKU immediate implementation
- Any customer who has already ordered 5000 dosage units in July, will be immediately cut-off immediate implementation
- By Friday morning, a program will be put into effect preventing orders greater than 5000 dosage units per month from occurring

This commitment was conveyed to Mr. Mapes by telephone on 7/16/07. He seemed pleased, but not 100% confident that we would follow through (he did not state this verbatim, rather it was read in the tone of his voice). I also inquired about meeting with him and he indicated that he would want to meet at the HQ Office in Washington, D.C. and that the earliest he could meet would be the week of August 20th. I informed him that I would determine who from Watson/Anda would be in attendance and would contact him with possible dates/times.

Tracey L. Hernandez
Director, Corporate CS Compliance
360 Mt. Kemble Avenue
Morristown, NJ 07963
973-355-8479 (office)
973-953-6294 (cell)
973-355-8184 (fax)