Subject: RE: Summary Judgement
Date: Fri, 14 May 2010 09:27:10 -0400
From: evan.rae@oci.fda.gov
To: paige@[redacted]

Heather, you are correct, not enough has been done to REVECOMED/AAC at this point. I have re-contacted our Headquarters (Office of Criminal Investigations), the Dallas District Office (Regulatory), the Center for Devices and Radiological Health, Office of Device Evaluation, and everyone else I have had contact with and advised them of the latest developments and the lack of action on our side. A conference call between all concerned is scheduled, which should speed things up when compared to email. I will do everything I can to get things moving. We will likely focus on AAC and other appropriate Texas entities, for ease of logistics. Thank you for your patience. Evan

Evan J. Rae
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Austin Resident Office
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Fax: 512-349-2986
evan.rae@oci.fda.gov

From: [redacted] **On Behalf Of** Paige Peterson
Sent: Wednesday, May 12, 2010 12:06 PM
To: Rae, Evan
Subject: Summary Judgement

Evan,

Last Friday the Judge found in favor of AAC on the summary judgment.
AAC does not believe that there is an investigation of them or RevecoMED, their attorney submitted an affidavit stating that there is no investigation of AAC.
They also said that P2 has made all of this up.

Thought you might find that interesting. Would you like a copy of all of Mark's affidavits and filings with the court?

Any news from your talk with the Justice Department?

It appears that AAC and Reveco get to continue unscathed, and P2 gets to pay the price for doing the right thing.

Paige

Subject: RE: touching base
Date: Thu, 17 Mar 2011 09:39:33 -0400
From: evan.rae@oci.fda.gov
To: [redacted]

Paige, yes, I'm working on it almost every day. Reviewing the 700+ page filing is taking a while, but I may have some specific questions soon. The communications from FDA could not be clearer. They prohibit any marketing of the device and so state in clear language. They are aware of everything I am, so I would anticipate that the extended period will expire without the deficiencies being corrected. Then, we will decide what action is called for. Thanks, Evan

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From: Paige Peterson [redacted]
Sent: Wednesday, March 16, 2011 10:32 PM
To: Rae, Evan
Subject: touching base

Hello Evan,
Wanted to touch base and see if there are any developments since we spoke a couple of weeks ago.
Are things still moving forward with the case?
Best,
Paige

P2 LLC
Paige Peterson

Subject: RE: Lipo Ex - Advanced Aesthetic Concepts - Fort Worth
Date: Tue, 10 Apr 2012 14:41:32 -0400
From: evan.rae@oci.fda.gov
To: Jonnetta.Wheaton@dshs.state.tx.us; [redacted]
CC: Lori.Woznicki@dshs.state.tx.us; Tom.Brinck@dshs.state.tx.us

All,

I won't be available this afternoon for the discussion, but I will add that I have noted the devices to be readily available for purchase and advertised (marketed). The fact that training and "informational seminars" are conducted also speaks to overtly having the device for purchase. I have again contacted the Center for Devices and Radiological Health regarding their opinion, since they (as well as the State) have advised REVECOMED, if not AAC itself, in no uncertain terms that the device may not be marketed. FDA put that paragraph in all caps on both denials of approval. Please let me know what is decided this afternoon, thank you, Evan

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From: Jonnetta.Wheaton@dshs.state.tx.us [mailto:Jonnetta.Wheaton@dshs.state.tx.us]
Sent: Tuesday, April 10, 2012 11:37 AM
To: [redacted]
Cc: Lori.Woznicki@dshs.state.tx.us; Tom.Brinck@dshs.state.tx.us; Rae, Evan
Subject: RE: Lipo Ex - Advanced Aesthetic Concepts - Fort Worth

Hello Paige,
I apologize for the delay in getting back to you with the complaint status. I need some clarification regarding the status of the spa you mentioned as well as information regarding the firm's marketing of the devices for unapproved uses (via the website and the letter you state your friend has received this month). Do you have some time today to discuss this with me? I can give you a call when you are available or you can call me (see contact information below).

Jonnetta Wheaton, Compliance Officer
Drugs and Medical Devices Group
Policy Standards and Quality Assurance Unit
Environmental and Consumer Safety Section
Division of Regulatory Services
Texas Department of State Health Services
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E-mail: jonnetta.wheaton@dshs.state.tx.us

From: revecomed@usa.com
To: paige[redacted]
Date: Wed, 22 Aug 2007 13:06:22 -0500
Subject: Re: US market & others

Paige,
Any territory that tom and his reps do not cover is O.K. Please do not overlap the territories that they already in motion as I like to protect Tom's Reps who have been working hard for Lipotron. I want to keep basic business moral. They are Innocent business person ells. So far I keep quite anything between you and myself in this office including Jim who is a close friend with Roger. It is premature to let them know and as far as business is concerned you don't want to make enemies.

I sent the following instruction to Jim to slow down their activities this morning. This will be part of your duties,too.

Q U O T E
Jim, I was scared in Mexico where one of customer's staffs burned breast. It reminds me that when we sold U/S liposuction to couple of doctors before FDA one of patients had a burn damage. Patient sued the clinic and we came up with 100 K on behalf of the clinic. From that point we never attempt to sell the liposuction in USA even for clinical study.

Roger sold one set to customer in New Jersey month ago where I was there with Roger. Because of short trip I was not able to train them sufficiently. Eventually the device has to be replaced as the customer keeps creating problem after problem. They mentioned about burn damage and FDA while they were complaining the problem. If they report to FDA what will happen is that FDA will order us to withdraw all the devices that we illegally sold, which is mandatory and if we don't come up with the order in time we go in treble right away, going to not civil court but crime court.

So to avoid or minimize the disaster here is my suggestions until 510K
1. Sell the device to the doctors to make sure that they are good friends with Reps.
2. Sell the device only their backyard where they can reach maximum 5 hours by car to their customer.
3. Minimum one full day training before use.
4. No sell through sub-reps if you don't take a full responsibility of any accident or problem in sub-reps territory.
5. No Ad, publication, release of information. Use only manufacturer supplied printed material.
6. No Lipotron or RevecoMED's products, information in Rep's Website.

In the mealtime what we are going to do is :
1. FDA preparation
2. R&D for more secure device
3. Clinical Study in several applications with doctors who you trust.
4. Prepare all necessary documents which you are working on
5. Sell the device in our community

Michael

U N Q U O T E

To place a new order direct it's up to you if they are not ware of it and not in their Reps teritorries.