

McCaffrey, Paul (USAKEYE)

From: Janaina Nascimento <jn@lionheartsurgical.com>
Sent: Tuesday, February 12, 2019 5:40 PM
To: Randy Ware
Subject: Re: Unacceptable products

Randy,

We have nothing to hide from our side with FDA as you are fully aware we gave you our import registration before starting working with your company.

You are welcome to contact them about this products, they were imported legally as everything we deal with.

Products are FDA approved, Products are legally imported to the USA.

FDA does not rule over product commercialization we already explained about this over my very first email so not going back over that point. (first sale doctrine), on the other hand I hope that all other vendors you work with are following the formal procedure we do follow which I know is not the case on many of them.

Just for your knowledge, the box "not to be re-export" is the factory (Ethicon) trying to protect market, products are Puerto Rico manufactured. We gave you the option to sell by unit, we told you to open the box and see that the products doesn't have any restriction itself but this doesn't looks a solution for you. We were doing a lot of business and in many times I explained to you that the product were being cleared by FDA, you and I are not direct from Ethicon. If your real intention is to return my product you already have a label issued, everything is fully documented for you to proceed with your investigation.

All my respect for you however I will not going back and forward with this anymore, both of us are doing which we assume as right for our own business and as you know these products have depreciation.

Best regards,



Janaina do Nascimento

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Em 12 de fev de 2019, à(s) 14:09, Randy Ware <rware@wareconsultingllc.com> escreveu:

I'll be taking this now to our attorneys and asking for them to get an opinion from the FDA.

I fully intend to return these products, once this is completely resolved.

The bottom line is that these products do not legally belong in the United States, so I want to understand the FDA's thoughts, which is why I asking you to tell me who imported them and sold them to you. Keeps both your company and mine out of the line of fire.

Please provide the contact information for just this specific supplier and we can get this moving.

Randy Ware

Principal | Ware Consulting, LLC

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From: Janaina Nascimento [<mailto:jn@lionheartsurgical.com>]

Sent: Tuesday, February 12, 2019 12:22 PM

To: Randy Ware <rware@wareconsultingllc.com>

Subject: Re: Unacceptable products

Importance: High

Randy

Your disappointed doesn't give you the right to don't return our product and put conditions "if you do this I will do that" both of us know exactly what is this.

Now you are not only asking for my suppliers information which is unacceptable on our trade (you will never give away yours) but also adding to your request for our company to fulfill this order with another product lot... Speechless.

Regarding the treat received do what you think is right Randy, not much sense to challenge what you think is right.

From our side I'm just letting you know that of course we will not abandon our goods and unfortunately we will have to send this collection unless our goods are returned on timely manner which is the normal business way between any client that is not ok with a product.

Our products were received by your company under tracking 483681119513 - Feb 05.

Kind regards

Janaina do Nascimento

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Em 8 de fev de 2019, à(s) 09:03, Ware <rware@wareconsultingllc.com> escreveu:

Janiana,

I am disappointed too.

You sold me goods that are clearly marked as not to be re-exported to the USA, and that's a huge problem. I'd rather it not be for you, therefore I am asking you again for who you bought these items from.

If you continue to refuse, then I will instruct my attorneys to contact the FDA and inform them of this matter, and we can get their opinion. I am sure when they ask you to provide this information you will be more cooperative.

In addition, I do expect you to fill the order I sent you with product I can in fact receive and resell.

Once you do, I will return the product you originally sent.

Sending me to collections, would be completely unacceptable and only initiate further legal costs for both of us.

Have a nice day !

Randy Ware

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From: Janaina Nascimento [<mailto:jn@lionheartsurgical.com>]

Sent: Thursday, February 07, 2019 5:38 PM

To: Randy Ware <rware@wareconsultingllc.com>

Subject: Re: Unacceptable products

Randy,

As said before it's difficult to understand your grounds to proceed this way.

We never agreed to share our suppliers (this is paper trail), would you share with me yours?

It's clear that your decision is neither return or pay for this order unless we are giving away our vendors (we still surprised that you put this in writing) thank you for make it clear avoiding wasting of your and my time over this matter.

We will accept a return on this (here is the label for it over the next days) or payment a per invoice terms if not we will send this to collection, we don't see any other way to deal with this.

Unfortunately this is happening, we were building a nice business relationship, we shipped over 2000 items between Covidien, Bard and Ethicon in less than a year, we are very sorry things get this path!

Best regards,

Nina

Best regards,

Janaina do Nascimento

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Em 6 de fev de 2019, à(s) 17:58, Randy Ware <rware@wareconsultingllc.com> escreveu:

First, I request that you share with me the suppliers information:

- Name of business
 - Your contact name
 - Contact email address
 - Contact physical address
 - Contact direct phone number
 - a copy of the invoice they sent you for the product
- If you know the country of origin, please provide that too.

I will be holding this product until you send me this info.

I will not be paying you for this product.

Randy Ware

Principal | Ware Consulting, LLC

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From: Janaina Nascimento [<mailto:jn@lionheartsurgical.com>]

Sent: Wednesday, February 06, 2019 5:56 PM

To: Randy Ware <rware@wareconsultingllc.com>

Subject: Re: Unacceptable products

Importance: High

Randy,

Very surprised about your email , let's try to keep our good business relationship , where we are doing our best to fulfill your products expectations. As I did mention the very first time I talked with you I do have admiration and respect for you and for your business.

On the other hand I'm answering your email point by point; we are a very small company but we truly know what we do.

First of all we do authorize your company to open the boxes to verify that the product does not have any type of legend or restriction to be sold in the USA.

(Picture attached)

Secondly for sure your legal counsel is fully aware that in the USA there is something called "the first sale doctrine" It simply means that once a tangible copyrighted work (or something with copyright in it) is sold lawfully the first time, the original copyright owner no longer has rights over the physical item. In plain words after that, the buyer can do whatever he or she wants with it — sell it again, donate it, whatever. That's why we can all sell legally anything online as soon we are not exposing trademark., the resale right applies to physical items only.

Furthermore this has been challenged in the supreme court with supreme court's decision reaffirming that owners have resale rights in 2013.

These obviously applies when you are buying surplus from anyone in the USA (not us) you obviously don't have paper trail on that., on the other hand if this was a condition for purchase from your side was never mentioned or attached to your purchase order (PO 1314)

Thirdly these products have not RE EXPORT control by the USA department of commerce , therefore there is not restriction for importing/re selling but FDA which we complied.

I kindly asked to instruct your warehouse to verify what I'm attaching over this email (no legends on the product), Once you do that if still is not acceptable for you please let me know to proceed with the return of this order to us as any normal business transaction between companies.

Best regards,

Best regards,

Janaina do Nascimento

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Em 6 de fev de 2019, à(s) 15:35, Randy Ware
<rware@wareconsultingllc.com> escreveu:

Janaina,

See attached. This is a photo of the 1952 Surgicel you just shipped to me.

I am very disappointed in this shipment, as it is 100% clearly product that does not belong here in the United States, and either you have imported or bought from someone who has.

First, I request that you share with me the suppliers information:

- Name of business

- Your contact name
- Contact email address
- Contact physical address
- Contact direct phone number
- a copy of the invoice they sent you for the product

If you know the country of origin, please provide that too.

I will be holding this product until you send me this info.

I will not be paying you for this product.

I also will not be doing any further business with you, unless you can “in writing” with each future order guarantee me that the products you are selling to me are authorized to be sold in the United States.

Please do not call or text me, there is nothing to discuss until you provide the information requested.

Our legal counsel is informed, and has advised me on this matter.

Thank you.

Randy Ware

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