Pam Peinado

From: Denise Strasser
Sent: Thursday, October 30, 2008 1:46 PM
To: Christy Gorey; StartupGroup
Cc: Susan Wampler
Subject: RE: DR. DODD AND MS. CORTES REDLINE/SPONSOR QUESTIONS === FW: DMS ICF(a) Device Med-Systems- P-D015 10.30.08

Hello back!!!

ICF - I have sent the request for change of the icf to the sponsor with explanation. I gave him the deadline of 4:00 pm to return the icf to me and if not possible by 4:00 then we would have to "conditionally approve" the form and send back for review at a later date.

The 510k information – The FDA has registered this device as a 510k (registration # K073692). Under a 510k, the device does not have to be exactly the same as another product on the market but it does have to have similarities to something on the market. I am unable to quote what qualifies as a 510k but this product does have a registration # under a 510k. I think this information should be sufficient but if it is not, let me know and I will get other specifics from the sponsor.

Thanks for facilitating! I will forward the icf if I get it back today!!!

Denise Strasser
New Studies Service Lead

Coast IRB, LLC | **www.coastirb.com**
5475 Mark Dabling Blvd, Suite 351
Colorado Springs, CO 80918
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[redacted]

Please visit www.coastirb.com/service and let us know how we are doing!

From: Christy Gorey
Sent: Thursday, October 30, 2008 10:14 AM
To: StartupGroup
Cc: Christy Gorey; Susan Wampler
Subject: DR. DODD AND MS. CORTES REDLINE/SPONSOR QUESTIONS === FW: DMS ICF(a) Device Med-Systems- P-D015 10.30.08
Importance: High

Hello ~
Please see Dr. Dodd and Ms. Cortes emails below regarding the Consent (attached) and 510K rating for the Device Med-Systems P-D015. Please provide me with the information and I will submit to both Board Members.

With thanks,

Christy Gorey
Senior IRB Administrator

Coast IRB has moved! Please note our new address:

Coast IRB, LLC | **www.coastirb.com**
5475 Mark Dabling Blvd, Suite 351
Colorado Springs, CO 80918
P[redacted]
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[redacted]

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From: Adam and Laura Dodd [redacted]
Sent: Thursday, October 30, 2008 9:01 AM
To: M. Cortes; Christy Gorey
Subject: Re: DMS ICF

M ~

I would favor sending back to sponsor for definitions. This is a good study, so I'm planning to recommend conditional with expedited of ICF back to you and I. If the sponsor was willing to do that before the meeting, I'd be happy to look at it and remove the conditional.

I would also like to know on what basis this is a 510K?.

My understanding of 510Ks and risk assessment is that it's premarketing and that there has to be a clinically identical product already on the market which has a safe risk assessment by the FDA, and I'm not aware of any gels already approved for these indications. Just checking for my info and education. It won't affect my recommendation.

Also, the email address [redacted] pops into my phone. I'm on the run today, but if you need me to look at something feel free to use that one, too.

AD

---- Original Message -----
From: M. Cortes
To: Christy Gorey ; Adam Dodd ; Adam Dodd
Sent: Wednesday, October 29, 2008 7:08 PM
Subject: DMS ICF

Hello,
For whatever reason, I was unable to save my ICF changes for the DMS study on the board website. This ICF, IMO, is atrocious! It is riddled with medical speak that will either have to be re-written in lay terminology, or at the very least, have parenthetical definitions inserted throughout. At many points, it looks like a cut and paste from the protocol. It is just too sophisticated and difficult to understand. Adam, I don't know if you are up to the challenge of rewriting this ICF (transforming medical language to lay language) or if we should send it back to the sponsor for revisions...
Melissa