

Cordaro, Debbie

From: Brony, Michael
Sent: Thursday, April 30, 2009 6:58 AM
To: Ko, Hon Sum
Cc: Fisher, Robert; Jain, Nisha; Cordaro, Debbie
Subject: RE: Anascorp name review

Thanks Hon-Sum. I will include the name in the analysis.

Michael

From: Ko, Hon Sum
Sent: Monday, April 27, 2009 7:37 AM
To: Brony, Michael
Cc: Fisher, Robert; Jain, Nisha; Cordaro, Debbie
Subject: RE: Anascorp name review

Michael:

On thinking over the proprietary name during the weekend, I came across "Aranesp" - darbepoietin alfa - and think that their similarity in writing, especially by physicians with poor penmanship, might cause confusion.

Hon-Sum.

From: Brony, Michael
To: Fisher, Robert; Ko, Hon Sum
Cc: Scott, Dorothy
Sent: Fri Apr 24 10:21:13 2009
Subject: RE: Anascorp name review

Thanks Robert. I am not 100% sure of the process or criteria, but from what it looks like from the website, Anascorp could fall under the USAN "jurisdiction", so to speak.

Please keep me posted.

Thanks

Michael

From: Fisher, Robert
Sent: Friday, April 24, 2009 10:15 AM
To: Brony, Michael; Ko, Hon Sum
Cc: Scott, Dorothy
Subject: Re: Anascorp name review

I'll tell the firm to look into it. Their us rep thinks it's done for drugs but maybe not for biologics.
Robert W. Fisher, Ph.D.
Staff Fellow

FDA/CBER/OBRR/DH/LPD
301-496-2579
Robert.Fisher@fda.hhs.gov

From: Brony, Michael
To: Ko, Hon Sum
Cc: Scott, Dorothy; Fisher, Robert
Sent: Fri Apr 24 09:32:03 2009
Subject: RE: Anascorp name review

Good Morning, Hon-Sum,

If I understand the process correctly, the company should have already submitted their name for a USAN review. I don't believe we (FDA) have jurisdiction over the proper name but it does seem peculiar that the route of administration is in the proper name.

Do we know if they did submit the proper name for review? There are some drugs that they would not review but I do not believe this is one of them.

Here is link to the process:

<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/how-apply-a-name.shtml>

Please let me know if we need to do anything else.

Thanks

Michael

From: Ko, Hon Sum
Sent: Thursday, April 23, 2009 10:31 PM
To: Brony, Michael
Cc: Scott, Dorothy; Fisher, Robert
Subject: RE: Anascorp name review

Michael:

The product has "Alacramyn" as a registered trademark in Mexico, but now Bioclon wants to use a new name "Anascorp" in the US. I do not have a problem with the new name itself. However, they have several products named with the -myn suffix. Whether there is an issue with -myn so that they try to change the name is something I don't know. Perhaps Dot is more familiar with that situation.

I am, however, not so sure about the Proper Name, Centruroides (Scorpion) Immune F(ab)2 Intravenous (Equine). For a similar pepsin-digested product, we have Botulism Antitoxin Bivalent (Equine), Types A&B.without mentioning Immune F(ab')2 or route of administration. The Proper Name of Crofab is Crotalidae Polyvalent Immune Fab (Ovine) which mentionjs Fab but also without route of administration. Do we submit this to USAN to determine the Proper Name?

Thanks.

4/30/2009

Hon-Sum.

From: Brony, Michael
Sent: Thursday, April 23, 2009 7:55 AM
To: Ko, Hon Sum
Subject: Anascorp name review

Hi Hon-Sum,

As part of APLB's name review, I wanted to know if you had any problems with the name Anascorp for the scorpion antivenin.

Please let me know.

Thank you,

Michael