

Ellwood, Kathy

From: Hahn, Martin J. [MJHahn@HHLAW.com]
Sent: Thursday, February 05, 2004 9:57 AM
To: Ellwood, Kathy
Subject: RE: Rotta Extension

Many thanks. We will submit a letter within the next day requesting the agency for the use of a truncated version of the health claim petition. You can advise the lawyers in OCC that the issue will not be pressed by this particular company and that they can focus their attention on other matters.

Martin J. Hahn
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202/637-5926 (direct)
202/637-5910 (fax)

-----Original Message-----

From: Ellwood, Kathy [mailto:Kathy.Ellwood@cfsan.fda.gov]
Sent: Thursday, February 05, 2004 9:50 AM
To: Hahn, Martin J.
Subject: RE: Rotta Extension

Martin,

You're correct.

Kathy

-----Original Message-----

From: Hahn, Martin J. [mailto:MJHahn@HHLAW.com]
Sent: Thursday, February 05, 2004 9:19 AM
To: Ellwood, Kathy
Subject: RE: Rotta Extension

Kathy:

Many thanks for the response. Please forgive my persistence on this issue, but I want to make certain that you are saying that FDA will focus on whether the data supports the "reduces the risk of OA," regardless of the model claim proposed in our petition. I have advised the client that FDA likely would take that position, but I just want to make certain that my understanding is correct.

Many thanks.

Martin J. Hahn
Hogan & Hartson L.L.P.

2004P-0060

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-----Original Message-----

From: Ellwood, Kathy [mailto:Kathy.Ellwood@cfsan.fda.gov]
Sent: Thursday, February 05, 2004 9:15 AM
To: Hahn, Martin J.
Subject: RE: Rotta Extension

Martin,

We will see whether the data supports the claim "...reduces the risk of OA", not any other claim, under the SSA standard.

Kathy

-----Original Message-----

From: Hahn, Martin J. [mailto:MJHahn@HHLAW.com]
Sent: Wednesday, February 04, 2004 10:00 AM
To: Ellwood, Kathy
Subject: RE: Rotta Extension

Kathy:

You asked whether our client would be willing to amend the language of our proposed model health claim. The client is willing to amend the language, provided the agency treats similarly the truncated model health claim and the original language for purposes of its assessment of whether there is significant scientific agreement (SSA) in support of the claim.

By way of brief background, we had proposed a model claim that we believe accurately characterized the science and for which there is significant scientific agreement. Unlike other diseases, the etiology for osteoarthritis is less defined and we considered it important to characterize the manner in which glucosamine sulfate has been shown to prevent osteoarthritis. We believe there is SSA supporting the ability of glucosamine sulfate to reduce the risk of osteoarthritis joint structure and related joint pain and limitation of function. While we also believe there is SSA supporting the ability of glucosamine sulfate to reduce the risk of osteoarthritis, the studies have primarily focused on the effect of glucosamine sulfate on joint structure, joint pain and limitation of function.

To the extent that FDA is willing to treat similarly the truncated claim (i.e., dietary supplementation with glucosamine sulfate reduces the risk of osteoarthritis) and the original proposed claim for purposes of its SSA analysis, Rotta would be willing to amend its proposed health claim.

Please feel free to contact me via phone or e-mail. In the event that the agency will treat similarly the truncated and original claim for purposes of its SSA analysis, we will submit a letter requesting an amendment of the model health claim. We also assume that such a letter would not be treated as a "substantive amendment" that would restart the clock for purposes of our original filing date.

If you have any questions or comments, please contact us.

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-----Original Message-----

From: Ellwood, Kathy [mailto:Kathy.Ellwood@cfsan.fda.gov]
Sent: Monday, February 02, 2004 3:16 PM
To: Hahn, Martin J.; Ellwood, Kathy
Cc: Gibson, Jillian Clark
Subject: RE: Rotta Extension

Martin,

I got the e-mail with the letter attached granting the extension on Friday. Thank you. Is your client going to offer any new claim language as we had discussed?

Kathy

-----Original Message-----

From: Hahn, Martin J. [mailto:MJHahn@HHLAW.com]
Sent: Monday, February 02, 2004 8:20 AM
To: 'kathy.ellwood@fda.hhs.gov'
Cc: Gibson, Jillian Clark
Subject: Rotta Extension
Importance: High

Kathy:

You should have received an e-mail on Friday with the signed letter that grants a 3-week extension to review the Rotta health claim petition. My assistant is of the office until noon and I do not see a copy of the transmittal e-mail in my inbox. In the event that you did

not receive the letter, please accept my apologies because I did intend for you to get it on Friday. If you did not receive the letter, I will see that you get a copy of it when my assistant returns to the office this afternoon.

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