

Pooler, Bob

From: Robinson, Barbara -AMS
Sent: Tuesday, August 15, 2006 8:47 AM
To: Bradley, Mark; Nally, Shannon; Pooler, Bob
Cc: Wilson, Demaris; Mathews, Richard
Subject: RE: PBN Nutritionals

Ok. Listen--I think we all need to get on the same page here; my only point in asking this question was the following:

1. QAI wrote in on 7/27 requesting further time, and a meeting, up until 9/11, to discuss the issue and present more material; they also asked if we would be willing to talk to the Int'l Formula Council. Mark acknowledged this incoming with an email that said "fyi" to C&A.
2. Regardless of this letter, QAI was still told to issue a noncompliance to their client and proceed;
3. On 8/8, I received a phone call from the attorney representing the client, who wanted to know why they were being issued a noncompliance without any regard for the letter that had been written asking for consideration for time and a meeting. Whereupon, Mark, you and I had the "Big Discussion" we had all last week over Nutrient Vitamins and Minerals on the National List, and what the National List really says or doesn't say...
4. On Friday, 8/11, I directed that NOP should contact QAI and tell them not to issue any noncompliance for the time being with respect to DHA or ARA. On nucleotides, I believe I told you (Mark) that if you still had reservations, you could tell QAI to ask for further information from the client if they still had reservations. I then asked Shannon for the entire file, which she said she would have faxed to me on Monday, 8/14 (and which I received from Shannon).
5. I also called the attorney for the client on Friday, 8/11 and told him that his client was okay on DHA and ARA but we did not have a decision on nucleotides. He was fine with that, and so are they (I believe).

My concern in all of this is that we appear to have disregarded the incoming request for further consideration by the certifying agent for a meeting, for further information, and simply proceeded with the issuance of a noncompliance. That's all I was asking about. We do need to be vigilant, but we also need to work with these folks. While we certainly are the "keeper of the National List," so to speak, I would not presume to be a scientist, nutritionist, doctor, veterinarian, or any other type of expert required to dismiss out of hand technical information that companies submit, until we do the due diligence (research) with our regs and related regulations that may be required to come to a conclusion about a material. Sometimes it looks easy, but sometimes there's more to the story. That's all...that was my point.

Barbara

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

From: Bradley, Mark
Sent: Mon 8/14/2006 4:55 PM
To: Nally, Shannon; Pooler, Bob
Cc: Robinson, Barbara -AMS
Subject: RE: PBN Nutritionals

I talked to David Abney and he asked for a meeting while he was here in early October, but no mention was made of PBM. I have no problem with giving them an extension. I think we all need to talk.

USDA, AMS, TM, National Organic Program

From: Nally, Shannon
Sent: Monday, August 14, 2006 4:41 PM
To: Bradley, Mark; Pooler, Bob
Subject: PBN Nutritionals

In re to the PBM Nutritionals/Infant Formula complaint, QAI had written a letter dated July 27, 2006, which asked that they be granted until September 11th to respond to the unfavorable determination of product ingredients. Bill Bent had stated that he would grant the extension if NOP did not respond. Have you contacted QAI to discuss this extension and/or meeting?

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