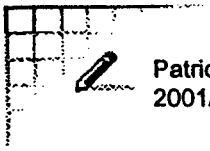
Postnikoff)
...Tony Halisky

Patricia Maynard



Patricia Maynard
2001/03/22 11:56 AM

To: Joan Korol@HWC
cc: Tony Halisky@HWC, Bruce Wozny@HWC

Subject: Re: Bonnie Kaplan, Phd - Importation

Before, we investigate the clinical trial aspect, we need clarification from Daniele about who is to do this. There is no sub-activity in investigations for GCPs. Does anyone have any history of our previous involvement in clinical trial issues? or is this a recent issue? Where is BPA's involvment? This is a pre-market issue.

Joan Korol on 2001/03/22 10:18:17 AM

Joan Korol on 2001/03/22 10:18:17 AM

To: Tony Halisky@HWC
cc: Patricia Maynard@HWC, Bruce Wozny@HWC

Subject: Re: Bonnie Kaplan, Phd - Importation

I agree
Thank you for your comments
Tony Halisky

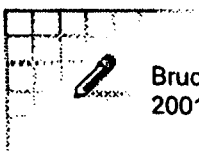
Tony Halisky
2001/03/22 10:02 AM

To: Joan Korol@HWC
cc: Patricia Maynard@HWC, Bruce Wozny@HWC

Subject: Re: Bonnie Kaplan, Phd - Importation

Further to your observation that the product may be PSSM, even if it is, the Interim DIN Directive states that we will not take stringent enforcement action (stoppage of sale) if the legal agent does not obtain a DIN. The Interim DIN and PSSM status has nothing to do with Division 8 and IND requirements, etc. We can still enforce any violations of that Division, including refusal of entry of products destined for clinical studies which have not been approved by TPP.
...Tony Halisky

---------- Forwarded by Tony Halisky on 2001/03/22 09:57 AM ----------



Bruce Wozny
2001/03/22 09:19 AM

To: Joan Korol@HWC
cc: Patricia Maynard@HWC, Tony Halisky@HWC

Subject: Re: Bonnie Kaplan, Phd - Importation

Some observations:

The product is a drug, as its intended use is obvious.
Contact should be made with Bonnie Kaplan to inform her that she is importing a noncompliant product for sale
Regardless of direct links between Synergy and Bonnie Kaplan, or until links are revealed, WR can proceed with independent investigations, as each party appears to be in violation of the regulations.

Bruce

Joan Korol on 03/22/2001 08:46:26 AM

Joan Korol on 03/22/2001 08:46:26 AM

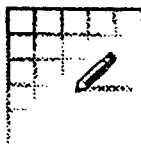
To: Patricia Maynard@HWC
cc: Bruce Wozny@HWC, Tony Halisky@HWC

Subject: Bonnie Kaplan, Phd - Importation

Trish ,
Could we meet to discuss ASAP
My thought is that Bonnie Kaplan is in contravention of the IND requirements with or without the sponsorship of Synergy.
I think she should be asked for the "No Objection" Perhaps Sadhika could provide comment.
In terms of the product EM Power , if it does not make claims for depression on the label, it may very well be a PSSM .

Any suggestions on how to proceed?

---------- Forwarded by Joan Korol on 2001/03/22 08:40 AM ----------



Miles Brosseau
2001/03/21 06:10 PM

To: Joan Korol@HWC
cc: Donna Pura@HWC

Subject: Bonnie Kaplan, Phd - Importation

Donna was advised by the U of C, Materials Management Department, that there are two shipments held at Fedex by CCRA and are awaiting clearance from us before they are released.

The **two shipments (TRK # 791502290769 and TRK # 791502294043)** are both **consigned to:**

Bonnie J. Kaplan, PhD (403) 229-7365
University of Calgary

Alberta Children's Hospital
1820 Richmond Dr. S.W., Calgary T2T 5C7

The **exporter** is listed as :

Telegistics (801) 952-4400
3050 W. California Ave.
Salt Lake, UT-84104

The shipments are described as **nutritional food supplements**. The commercial invoices indicate the Country of Manufacture as the United Stated and **declare the products to be multi-vitamins for clinical trials**. The Invoice value of each shipment is $707.76. Each shipment was said to contain 12 pieces with a unit value of $58.98.

Believing this may be Synergy Product, Donna Pura examined the two shipments at Fedex. **Each shipment consists of a box containing 12 white bottles labeled as "For Experimental Use, Not for Resale, Capsule Dosage 8". The outside of each box carried a label which reads, "E M Power, Schedule 4, 448 CT, Qty. 12, Lot# 01283201, Exp. 06/02"**

Neither Donna or I are familiar with Telegistics but E M Power is the name of the product that has been advertised by the Synergy Group of Canada. This is the first real evidence that Bonnie Kaplan is actually using E M Power but nothing really to indicate that the Synergy Group of Canada is directly promoting the clinical trial usage.

In light of the current investigation involving the Synergy Group of Canada, Donna and I are asking if this shipment should allowed entry or recommended for refusal? If recommended for refusal, under which section of the FDAR do you believe we should recommend refusal?

Please advise both Donna and I asap.

Thank you Joan.