

**DYNAKOR**  
PHARMACAL™

5742 West Harold Gatty Drive  
Salt Lake City, UT 84116  
phone 1.801.517.7000  
fax 1.801.517.7001  
www.DynakorPharmacial.com

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CTS 91699

May 16, 2005

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**VIA: Certified Mail**

Food and Drug Administration  
200 C Street S.W.  
Washington, DC 20204

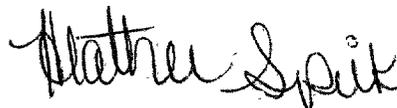
**Re: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93**

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product IsoCrystalin™. This notification is on behalf of Dynakor Pharmacal™, LLC.

Please review the information at your earliest convenience. Please contact me with any questions or if there is any further information I can provide regarding this matter.

Sincerely,



Heather Sprik  
Legal Assistant

Enclosure

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**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR § 101.93**

This notification is being filed on behalf of Dynakor Pharmacal™, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 W Harold Gatty Dr. Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **IsoCrystalin™**.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): "Eliminate Catabolic Protein Deficit"  
(Statement 2): "No Bloating"  
(Statement 3): "No Fat"

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	IsoCrystalin™ – 36gram Packet
2	IsoCrystalin™ – 36gram Packet
3	IsoCrystalin™ – 36gram Packet

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Dynakor Pharmacal™, LLC	both
2	Dynakor Pharmacal™, LLC	both
3	Dynakor Pharmacal™, LLC	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Dynakor Pharmacal™, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that Dynakor Pharmacal™, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 16 day of May, 2005.

By:   
Daniel B. Mowrey, Ph.D.  
Consultant for Dynakor Pharmacal™, LLC