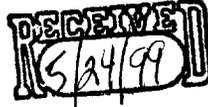




C/ Acero nº 25 -Polígono Industrial Sur  
Apartado de Correos nº 5  
28770 Colmenar Viejo - Madrid - ESPAÑA  
Tel.: 34-91-845 02 00 - Fax: 34-91-845 02 08  
Télex: 47918 COVX E - Cables: COVEX  
E-mail: vinpocetin@covex.es



9 4 7 2 ' 9 9 JUN - 2 P 1 : 2 5

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington D.C. 20204  
United States of America

s/ref.:  
your ref.:

n/ref.:  
our ref.:

TO WHOM IT MAY CONCERN

MTM/pc

RE : INTELECTOL™ . DIETARY SUPPLEMENT POST-MARKET  
NOTIFICATION TO FDA

Colmenar Viejo, May 13<sup>th</sup> 1999

Dear Sir/Madam

Please find here attached our company's post marketing notification according to §101.93, 21 FCR , for the marketing of the dietary supplement Intelectol™ containing the ingredient Vinpocetine.

Please confirm the reception of the whole document.

Thanking your kind attention I remain.

Yours Sincerely

Maria Teresa Manresa  
Technical Director



**DIETARY SUPPLEMENT POST-MARKET NOTIFICATION TO**

**Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration**

Colmenar Viejo May 13<sup>th</sup> 1999

TO WHOM IT MAY CONCERN :

*According to §101.93, 21 CFR Notification Procedures for certain type of statements on dietary supplements.*

*The manufacturer of Intelectol™ hereby notifies the Secretary no later than 30 days after the first marketing of the dietary supplement Intelectol™ containing the statements hereunder described that these statements are being made.*

The undersigner, Maria Teresa Manresa, Ph.D., Technical Director of Covex S.A. hereby DECLARES:

**(1) Covex, S.A., is the MANUFACTURER of the dietary supplement INTELECTOL™**

Address :

C/ Acero, 25.  
Polígono Industrial Sur  
Colmenar Viejo, 28770  
Madrid - Spain - Europe

Tel : +34-91-8044545  
Fax : +34-91-8043030  
email : [vinpocetin@covex.es](mailto:vinpocetin@covex.es)

**(2) The dietary supplement INTELECTOL™ contains the following ingredients :**

"Each tablet contains : Vinpocetine. 5mg.  
Excipients : Lactose, Hydropropylcellulose, Magnesium Stearate and Talc."

Vinpocetine 5mg is the only dietary ingredient present in the product .  
No daily consumption value recommendation has been established by the Secretary.

**(3) The Statements on the label of Intelectol™ are :**

.- "Powerful Memory Enhancer"

.- "Vinpocetine is a derivative of Vincamine, which is extracted from the periwinkle plant (*Vinca Minor, Vinca Pervinca*)."

.- "Research has shown that Vinpocetine helps the body to maintain healthy circulation in the brain. Studies also suggested that Vinpocetine decreases cerebral vascular resistance, improves cerebral blood flow and cerebral oxygen and glucose utilization. Vinpocetine increases the concentration of some neurotransmitters involved in the process of memory formation."

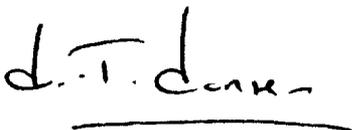
.- "Covex S.A. affirms that the statements presented on this package are supported by well controlled clinical studies."

.- *"The statements presented on this package have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."*

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The undersigner, Maria Teresa Manresa Ph.D. Technical Director of Covex S.A. hereby CERTIFIES that all this information presented and contained in this notice is accurate and complete, and that Covex S.A. has substantiation that the statements made on the label of Intelectol™ are truthful and not misleading.

All for which I sign in Madrid, May 13<sup>th</sup> 1999

Signed : 

Maria Teresa Manresa Ph.D.  
Technical Director of Covex S.A.