



NDA 219029

**COMPLETE RESPONSE**

Chemo Research, S.L.  
c/o Exeltis USA, Inc.  
Attention: John Kim  
Senior Vice President, Regulatory Affairs  
180 Park Ave, Suite 101  
Florham Park, NJ 07932

Dear John Kim:

Please refer to your new drug application (b) (4)

for dienogest and ethinyl estradiol tablets.

We have completed our review of this application, as amended, and have determined that we cannot approve this application. We have described our reasons for this action below.

1. Review of the safety database from Study LPRI-424/303 clearly demonstrates a markedly increased risk of venous thromboembolism (VTE) rate. A higher VTE rate associated with the same dienogest and ethinyl estradiol (DNG/EE) combination as your proposed product as compared to other combination oral contraceptives (COCs) in the European postmarketing database further substantiates an increased risk of your proposed fixed dose combination product. The benefit/risk profile for this COC product is unacceptable for an indication of prevention of pregnancy.

(b) (4)

We are unable to recommend any further actions that would result in approval of this application. If you choose to submit a new original NDA for a different COC product that would have a more favorable benefit/risk profile, we would consider that product on its own merits.

### **PRESCRIBING INFORMATION**

We reserve comment on the proposed labeling because the application is otherwise inadequate.

### **CARTON AND CONTAINER LABELING**

We reserve comment on the proposed labeling because the application is otherwise inadequate.

Within one year after the date of this letter, you are required to take an action available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65.

The product may not be legally marketed.

If you have any questions, contact

(b) (4)

Sincerely,

*{See appended electronic signature page}*

(b) (4)

Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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(b) (4)

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