March 27, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition under section 505 (j)(2)(c) of the Federal Food, Drug and Cosmetic Act and in accordance with the procedural requirements set forth in 21 CFR's 10.30 to request the Commissioner of Food and Drugs to make a determination that the discontinued Reference Listed Drug, Delalutin® (Hydroxyprogesterone Caproate) Injection, the subject of NDAs 10-347 and 16-911, held by Bristol-Myers Squibb Co, was not withdrawn for safety or effectiveness reasons and therefore is suitable for submission in an Abbreviated New Drug Application (ANDA).

A. Action Requested

According to publicly available reports, Bristol-Myers Squibb Co. voluntarily withdrew its drug Delalutin® (Hydroxyprogesterone Caproate) Injection from sale. The undersigned is seeking a determination by the Commissioner that Bristol-Myer's voluntary withdrawal of Delalutin® from sale was for reasons other than safety or effectiveness.

B. Statement of Grounds

On September 30, 2000, FDA announced withdrawal of approval of 28 new drug applications, including NDAs 10-347 and 16-911, for Delalutin® (Hydroxyprogesterone Caproate) Injection. According to the Federal Register notice, the holder of the NDA, Bristol-Myers Squibb Company, had notified FDA in writing that the product was no longer marketed. (65 Fed Reg. 55264 (September 30, 2000)). The Federal Register notice does not explain the reason why the product is no longer marketed. A copy of the Federal Register notice is included as Attachment A.

Delalutin® is now listed in the "Discontinued Section" of the electronic Orange Book on the FDA's web site. According to section 1.11 of the Preface to the Orange Book, a drug product in the Discontinued Section as to which a determination has already been made that withdrawal was not for safety or effectiveness reasons will have the following statement after its product strength: "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons." There is no such annotation next to the product strength for Delalutin®. A copy of the electronic Orange Book is provided as Attachment B.

2006P-0144 CP1

NDA 010-347 and 016-911 for the reference listed drug Delalutin® (Hydroxyprogesterone Caproate) Injection was approved as 125mg/mL and 250 mg/mL solutions. After an extensive search of the literature and other public data sources we were unable to locate any direct information regarding reason for withdrawal.

There have been several publications discussing the potential teratogenic properties of Delalutin® (Hydroxyprogesterone Caproate) Injection over the years. The FDA had labeled Delalutin® as a Category D drug product. However recent studies indicate that with proper administration (beginning in the second trimester) in high risk patients that these risks are minimal or not evident.

The Blue Cross of California has an established policy that addresses the use of intramuscular injections of 17-alpha hydroxyprogesterone caproate or progesterone vaginal suppositories for the prevention of preterm birth in patients in high-risk women. This policy is based on the fact that there are no suitable treatments that impact the incidence of preterm labor since the withdrawal of Delalutin® from the market. Currently the drug is only being supplied by compounding pharmacies. A copy of the Blue Cross of California's policy is included as Attachment C

Recent studies documented in the New England Journal of Medicine, attached as Attachment D, and in Obstetrics & Gynecology, attached as Attachment E, indicated the benefits of hydroxyprogesterone in reducing the incidence of preterm labor.

In view of the above, the petitioner respectfully seeks that the Commissioner makes a determination that Delalutin® (Hydroxyprogesterone Caproate) Injection was not withdrawn for reasons of safety or efficacy and requests that Hydroxyprogesterone Caproate Injection is suitable for submission as an Abbreviated New Drug Application (ANDA).

I request that, if the Commissioner determines that Delalutin® was not withdrawn for safety or efficacy, the agency annotate the listing for Delalutin® in the Orange Book to indicate that it was not withdrawn for reasons of safety or efficacy. If instead the Commissioner determines that Delalutin® was withdrawn from sale for safety or efficacy reasons, I request that the agency publish a notice of this determination in the *Federal Register* and delineate the specific safety and efficacy concerns.

C. Environmental Impact Statement

A claim for categorical exclusion from the requirement of submission of an environmental assessment is made pursuant to 21 C.F.R. 25.31.

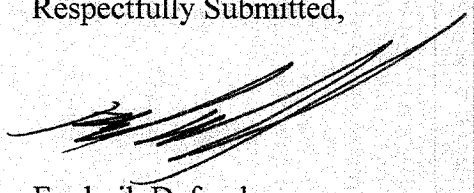
D. Economic Impact

Information on the economic impact of this request will be provided on request.

E. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Respectfully Submitted,



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Attachments

Table of Contents