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March 19, 2007

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

**CITIZEN PETITION (DOCKET NO. 2006P-0144) AMENDMENT #1**

The undersigned submits an amendment to the originally filed petition (Docket No. 2006P-0144) 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 10.30 to amend the original petition to include clarification on the Orphan Drug Designation of an Approvable Drug Product, Gestiva™, in light of the previously marketed Delalutin® and the potential for Abbreviated New Drug Applications (ANDAs) using Delalutin® as a Reference Listed Drug (RLD).

**A. Action Requested**

According to publicly available reports, Adeza has received Orphan Drug Designation for their Approvable Drug Product Gestiva™ (Hydroxyprogesterone Caproate). Gestiva™'s formulation is the same as Delalutin® (Hydroxyprogesterone Caproate) Injection, a Bristol-Myers Squibb (BMS) product voluntarily withdrawn from sale. The undersigned is seeking clarification from the Commissioner that granting Orphan Drug Status to Gestiva™ meets the intent of Orphan Drug Statutes and its implications on generic competition meet the intentions of the Hatch-Waxman Act.

**B. Statement of Grounds**

On March 27, 2006 the original Citizen Petition 2006P-0144 was filed with the Agency. On September 22, 2006 written correspondence from the Agency detailed that no decision had been made on Citizen Petition 2006P-0144/CP1. According to public record, on October 23, 2006, Adeza Biomedical Corporation ("Adeza") announced that it had received an Approvable letter from the Food and Drug Administration (FDA) for its drug, Gestiva™ (Hydroxyprogesterone Caproate). The advisory committee meeting minutes from the August 29, 2006 meeting to discuss Gestiva™ (See Attachment A for the FDA Reproductive Health Advisory Committee Meeting for Gestiva™) indicate that Gestiva™ has the same formulation as Delalutin® (Hydroxyprogesterone Caproate) Injection, a Bristol-Myers Squibb product. Additionally, Scott Monroe, MD, the Acting Director of Reproductive and Urologic Drug Products with the FDA indicated that Delalutin® was voluntarily withdrawn from sale in September 2000 by BMS and that the withdrawal was not related to safety concerns. On January 25, 2007 Gestiva™ was granted Orphan Drug Designation from the FDA. (See Attachment B)

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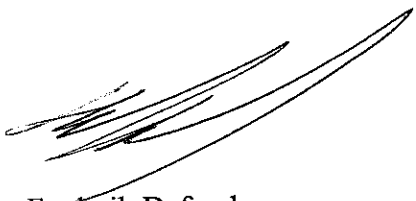
Granting Orphan Drug Status to Gestiva™ will allow a seven (7) year exclusivity period, whereby no generic products can be approved for the indication which Adeza receives approval, deterring generic competition and possibly benefiting Adeza at the expense of public health and consumers.

Orphan Drug Statues exist to promote development of drug products where no treatments or marketed drug products currently exist. Delalutin® was available on the market as a treatment to prevent pre-term births, the same indication as Gestiva™. Delalutin® is listed as a Reference Listed Drug in the Electronic Orange Book, however no clarification on reasons for discontinuation of the product is provided. If the product was not discontinued due to safety or efficacy reasons, the product would be suitable for an ANDA. Designating a product as an Orphan Drug when an ANDA (for the same formulation and indication) could be filed seems to contradict the purpose behind designating products as Orphan Drug and disregarding the intent of the Hatch-Waxman Act.

In view of the above, the petitioner respectfully seeks that the Commissioner clarify the Agency's position with regard to granting Orphan Drug Designations on products with the same formulation (and indications) as discontinued Reference Listed Drugs.

Additionally, we request based on the information provided by Scott Monroe that the Commissioner make a determination that Delalutin® (Hydroxyprogesterone Caproate) Injection was not withdrawn for reasons of safety or efficacy and request the agency annotate the listing for Delalutin® in the Orange Book to indicate that it was not withdrawn for reasons of safety or efficacy.

Respectfully Submitted,



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Attachments