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Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

AMENDMENT TO A CITIZEN PETITION
DOCKET # 2006P-0496/CP1

The undersigned submits this amendment to docket # 2006P-0496/CP1 in quadruplicate, pursuant to 21 CFR 10.25 and 10.30, and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether certain listed drugs have been withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests to withdraw the reference to Sulfamethoxazole, Trimethoprim, and Phenazopyridine HCl, manufactured by Able. The remainder of the petition that the Commissioner of the Food and Drug Administration determine whether the following drugs have been voluntarily withdrawn or withheld for safety or efficacy reasons remains the same:

Azo Gantanol manufactured by Roche
Azo Gantrisin manufactured by Roche

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products (the Orange Book) that are eligible for submission as abbreviated new drug applications (ANDA). The Orange Book contains all FDA-approved drug products. Azo Gantanol was approved by FDA on September 10, 1987, and Azo Gantrisin was approved by FDA on August 31, 1990. At the time of approval, these drug products were considered to be the "listed drug products" in the Orange Book. Currently, these drug products appear in the discontinued section of the Orange Book.

2006P-0496

AMD 1

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a)(1)).

C. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of preparing an environmental assessment or environmental impact statement, pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner following review of this petition.

E. Certification

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

Respectfully submitted,
VINTAGE PHARMACEUTICALS, LLC

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Regulatory Affairs