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February 20, 2007

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

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client in quadruplicate pursuant to 21 CFR §§ 10.20, 10.30, 314.122 and 314.161, requesting the commissioner of the Food and Drug Administration to provide a determination whether a previously listed drug Eloxatin[®] (oxaliplatin for injection) lyophilized powder for infusion, 50 and 100 mg vials has been withdrawn for safety or effectiveness for the reasons as outlined below. If not, it is requested that the FDA accept an ANDA for a generic version of the drug.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration (FDA) determine whether Eloxatin[®] (oxaliplatin for injection) lyophilized powder for infusion, 50 and 100 mg (NDA 21-492 held by Sanofi Aventis US) has been voluntarily withdrawn from sale for safety or efficacy reasons. If not, it is requested of the FDA to accept an ANDA for a generic version of the drug.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). The list, referred to as the *Orange Book*, contains all FDA-approved drug products. Eloxatin[®] (oxaliplatin for injection) 50 and 100 mg sterile lyophilized powder vials NDA 21-492 (Sanofi- Aventis US) was approved by the FDA in August 2002 and is considered to be a "listed drug product" in the *Orange Book*.

An electronic query of the *Orange Book* made on February 15, 2007, does not show a listing for the Eloxatin[®] lyophilized powder product, but does show listings for the solution product approved under NDA 21-759 in January 2005 (50 mg/10 mL and 100 mg/20 mL vials) and November 2006 (200 mg/40 mL vial). However, a query of discontinued drugs lists the lyophilized version of the product. It is believed that the NDA holder has discontinued marketing of the product for commercial reasons. It is noted that the discontinuation of the lyophilized product corresponds closely to the first date an ANDA referring to NDA 21-492 may be filed (August 9, 2006). It is further noted that Sanofi Aventis US has not withdrawn its sterile solution products (NDA 21-759), which contains the same active ingredient and dosage as the discontinued product.

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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 the 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)).

As stated above, at the time of submission of this petition, the Eloxatin[®] lyophilized powder products appear in the discontinued section of the *Orange Book* and, therefore, either have been discontinued from sale or never marketed. Therefore, it is requested that the FDA determine whether the appearance of the Eloxatin lyophilized powder products in the discontinued section of the *Orange Book* represents a discontinuation for marketing reasons or safety or effectiveness reasons.

If the Eloxatin[®] lyophilized powder products are withdrawn for marketing reasons, it is requested that the FDA accept applications for generic versions of the drug using Eloxatin[®] lyophilized powder products as the RLD via a reference to NDA 21-492. This petition will be considered moot should Eloxatin[®] lyophilized powder product, or a generic version of the drug, become available on the market, and listed in the *Orange Book*, after the submission of this petition and prior to FDA response. Regulus will at that time take appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

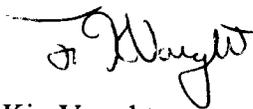
D. Economic impact

Pursuant to 21 CFR 10.30(p), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

The undersigned certifies that to the best of his 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 petitioner, which are unfavorable to the petition.

Respectfully submitted,



Kip Vought
Director, Regulatory Affairs