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

Citizen Petition

Dear Sir or Madam,

The undersigned submits this petition in quadruplicate pursuant to 21 CFR 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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness for the reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Eloxatin® (Oxaliplatin for Injection) 50 mg and 100 mg sterile lyophilized powder vials (NDA #21-492; Sanofi Aventis US) has been voluntarily withdrawn from sale for safety or efficacy reasons.

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). This List, referred to as the Orange Book, contains all FDA-approved drug products. Eloxatin® (Oxaliplatin for Injection) 50 mg and 100 mg sterile lyophilized powder vials (Sanofi Aventis US), NDA 21-492, was approved by the FDA in August 2002 and is considered to be a "listed drug product". The current listing in the electronic Orange Book, accessed July 17, 2006, does not list Eloxatin (NDA 21-492) in the active section of the Orange Book. Rather, the product appears in the "Discontinued" section of the Orange Book. It is believed that the innovator has discontinued

marketing the product for commercial reasons. It is noted that the recent discontinuance of the drug corresponds closely to the August 9, 2006 first date that an ANDA referring to Eloxatin (NDA 21-492) may be filed. Further, Sanofi Aventis US has not withdrawn its Eloxatin 50 mg and 100 mg injection sterile aqueous solution products (NDA 21-759), which contain the same active ingredient and dosage as the discontinued product.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or discontinued from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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, there is no evidence that the innovator is currently marketing its product Eloxatin Sterile Lyophilized Powder. Therefore, because the product has been discontinued from marketing, it is requested that the FDA determine whether the applicant holder's decision to discontinue marketing of Eloxatin, as approved under NDA 21-492, was for reasons of safety or effectiveness. Such a determination will permit the FDA to approve ANDAs for that drug product.

Should the NDA holder reintroduce Eloxatin to the market after the submission of this petition and prior to FDA response, and there is evidence that the product is available in the marketplace, we will consider the petition moot, and 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(b), 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 knowledge and belief of the undersigned, 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 are unfavorable to the petition.

Please contact the undersigned (Tel: 202-783-6040 or Fax: 202-783-6031), if you have any questions concerning this submission.

Respectfully submitted,

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