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BY FEDERAL EXPRESS

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

CITIZEN PETITION

The undersigned submits in quadruplicate this Citizen Petition, pursuant to FDA regulations 21 C.F.R. §§ 10.20, 10.30, 314.122 and 314.161.

A. ACTION REQUESTED

That the Food and Drug Administration (FDA) issue a determination that the drug product ELOXATIN (oxaliplatin for injection) lyophilized powder for infusion, 50 mg and 100 mg vials, was not voluntarily withdrawn from sale for safety or effectiveness reasons.

B. STATEMENT OF GROUNDS

1. The above-referenced drug product was initially approved under NDA 21-492 (see approval letter dated August 9, 2002 in annexed Exhibit 1). This product was designated by FDA as the reference listed drug for oxaliplatin for injection lyophilized powder for infusion, 50 mg and 100 mg vials (see Orange Book listing in annexed Exhibit 2).

2. In or about June 2006, this drug product was voluntarily withdrawn from sale (see "Additions/Deletions for Prescription Drug Product List," 25th Edition, Cumulative Supplement No. 6: June, 2006, in annexed Exhibit 2). According to this list, the drug product ELOXATIN (oxaliplatin for injection) lyophilized powder for infusion, 50 mg and 100 mg vials was not withdrawn from sale for safety or effectiveness reasons.

3. An abbreviated new drug application (ANDA) seeking approval of a generic formulation of a discontinued reference listed drug must be accompanied by a Citizen Petition for FDA's determination that the discontinued reference listed drug was not voluntarily

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withdrawn from sale for safety or effectiveness reasons. 21 C.F.R. §§ 314.122, 314.161.

4. The instant Citizen Petition requests such a determination by FDA for ELOXATIN (oxaliplatin for injection) lyophilized powder for infusion, 50 mg and 100 mg vials. It is requested that FDA make this determination as promptly as possible, since a pertinent ANDA including a Paragraph IV certification against Orange Book patents that were listed for this drug is eligible to be submitted on August 9, 2006. 21 U.S.C. § 355 (j)(5)(D)(ii).

For the foregoing reasons, this Citizen Petition should be granted.

C. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 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 their best knowledge and belief, this Citizen Petition includes all information and views upon which the Petition relies, and includes representative data and information known to Petitioner which are unfavorable to the Petition.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: _____



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Enclosures