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November 8, 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:

Ebewe Parenta Pharmaceuticals, Inc., hereby submits a petition in quadruplicate pursuant to 21 CFR §§ 10.20, 10.30 and 314.92(a)(1), requesting the Commissioner of the Food and Drug Administration to provide a determination whether a 200 mg/vial presentation of Oxaliplatin for Injection (lyophilized powder for infusion) may be filed as an Abbreviated New Drug Application.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration (FDA) determine whether a 200 mg/vial presentation of Oxaliplatin for Injection (lyophilized powder for infusion) may be filed as an Abbreviated New Drug Application based on the reference listed drug Eloxatin® (Oxaliplatin for Injection) lyophilized powder for infusion, 50 mg/vial and 100 mg/vial (NDA 021429), which has been discontinued.

Reference is made to Docket 2007P-0062/CP1 in which a petition was submitted to the FDA on behalf of Ebewe Parenta Pharmaceuticals (Ebewe Parenta) to determine whether NDA 021429 for Eloxatin® (Oxaliplatin for Injection) was withdrawn for safety or efficacy reasons.

B. Statement of Grounds

In accordance with 21 CFR 314.92(a)(1), the 200mg/vial presentation is identical in active ingredient, dosage form, strength, route of administration, and conditions of use as the withdrawn product Eloxatin® (Oxaliplatin for Injection) lyophilized powder for infusion, 50 mg/vial and 100 mg/vial. Additionally, a 200 mg/40 mL (5 mg/mL) ready-to-use presentation of Eloxatin® Injection (NDA 021759) was approved on November 17, 2006, and is currently marketed by Sanofi Aventis. The lyophilized product and the ready-to-use product contain the same active ingredient and dosage form. Eloxatin® for Injection and Eloxatin® Injection information from the Approved Drug Products with

2007P.0450

CP1

Therapeutic Equivalents Evaluations, also known as the Orange Book, is provided as reference in Attachments I and II.

The labeling for Ebewe Parenta's Oxaliplatin for Injection will be identical to that of the reference listed drug, Eloxatin® for Injection, with the exception of the addition of the 200 mg information.

As the active ingredient, dosage form, strength, route of administration, conditions of use and labeling of Ebewe Parenta's Oxaliplatin for Injection are identical to that of Eloxatin® (Oxaliplatin for Injection); the safety and effectiveness of the 200 mg presentation is demonstrated by the reference listed drug.

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.

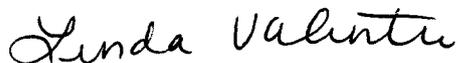
D. Economic Impact

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.

Sincerely,



Linda Valentine
RA Manager

Active Ingredient Search Results from "OB_Diac" table for query on "oxaliplatin."

Appr No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Applicant Name
<u>021492</u>	OXALIPLATIN	INJECTABLE; IV (INFUSION)	100MG/VIAL	ELOXATIN SANOFI AVENTIS US
<u>021492</u>	OXALIPLATIN	INJECTABLE; IV (INFUSION)	50MG/VIAL	ELOXATIN SANOFI AVENTIS US

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Office of Generic Drugs

Division of Labeling and Program Support

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Generic Drug Product Information & Patent Information - Daily

Orange Book Data Updated Through September, 2007

Patent and Generic Drug Product Data Last Updated: November 08, 2007

Search results from the "OB_Disc" table for query on "021492."

Active Ingredient: OXALIPLATIN
Dosage Form/Route: INJECTABLE; IV (INFUSION)
Proprietary Name: ELOXATIN
Applicant: SANOFI AVENTIS US
Strength: 50MG/VIAL
Application Number: 021492
Product Number: 001
Approval Date: Aug 9, 2002
RX/OTC/DISCN: DISCN
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: OXALIPLATIN
Dosage Form/Route: INJECTABLE; IV (INFUSION)
Proprietary Name: ELOXATIN
Applicant: SANOFI AVENTIS US
Strength: 100MG/VIAL
Application Number: 021492
Product Number: 002
Approval Date: Aug 9, 2002
RX/OTC/DISCN: DISCN
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient Search Results from "OB_Rx" table for query on "oxaliplatin."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Applicant Name
021759		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	100MG/20ML (5MG/ML)	ELOXATIN SANOFI AVENTIS US
021759		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	200MG/40ML (5MG/ML)	ELOXATIN SANOFI AVENTIS US
021759		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	50MG/10ML (5MG/ML)	ELOXATIN SANOFI AVENTIS US

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Search results from the "OB_Rx" table for query on "021759."

Active Ingredient: OXALIPLATIN
Dosage Form;Route: INJECTABLE; IV (INFUSION)
Proprietary Name: ELOXATIN
Applicant: SANOFI AVENTIS US
Strength: 50MG/10ML (5MG/ML)
Application Number: 021759
Product Number: 001
Approval Date: Jan 31, 2005
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: OXALIPLATIN
Dosage Form;Route: INJECTABLE; IV (INFUSION)
Proprietary Name: ELOXATIN
Applicant: SANOFI AVENTIS US
Strength: 100MG/20ML (5MG/ML)
Application Number: 021759
Product Number: 002
Approval Date: Jan 31, 2005
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: OXALIPLATIN
Dosage Form;Route: INJECTABLE; IV (INFUSION)
Proprietary Name: ELOXATIN
Applicant: SANOFI AVENTIS US
Strength: 200MG/40ML (5MG/ML)
Application Number: 021759
Product Number: 003
Approval Date: Nov 17, 2006
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

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