

LAW OFFICES
HYMAN, PHELPS & McNAMARA, P.C.

700 THIRTEENTH STREET, N.W.

SUITE 1200

WASHINGTON, D.C. 20005-1129

2013 NOV 8 10:02
37-6600

FACSIMILE
(202) 737-9329

www.hpm.com

KURT R. KARST

Direct Dial (202) 737-7544
KKarst@hpm.com

November 7, 2013

BY FEDERAL EXPRESS

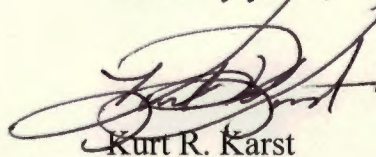
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061 (HFA-305)
Rockville, Maryland 20852

Re: Docket No. FDA-2013-P-0769; Bendamustine HCl, 200 mg/vial

Dear Sir or Madam:

I am writing with respect to the above-referenced Citizen Petition requesting that FDA declare the drug product Bendamustine Hydrochloride, 200 mg/vial, is suitable for consideration in an Abbreviated New Drug Application. FDA has not yet substantively responded to the Citizen Petition. I request that at the time FDA issues a decision on the Citizen Petition and transmits that response to the Petitioner, a copy of FDA's response be sent to me at the address above.

Sincerely yours,



Kurt R. Karst

KRK/eam

cc: Johnny L. Young
Office of Generic Drugs

<https://www.fedex.com/shipping/ht...>

Page 1 of 1

From: (202) 737-5800
Kurt Karst
Hymari, Phelps & McNamara, P.C.
700 13th St NW
Suite 1200
Washington, DC 20005

Origin ID: BZSA

FedEx
Express



J13201306280326

Ship Date: 07NOV13
ActWgt: 1.0 LB
CAD: 2822206/INET3430

Delivery Address Bar Code



SHIP TO: (301) 827-6860

BILL SENDER

Dockets Management, HFA-305
Food and Drug Administration
5630 FISHERS LN RM 1061
Dept. of Health and Human Serv.
ROCKVILLE, MD 20852

Ref # 5519.030 and 5519.031
Invoice #
PO #
Dept #

FRI - 08 NOV 10:30A
PRIORITY OVERNIGHT

TRK# 7971 0116 2918

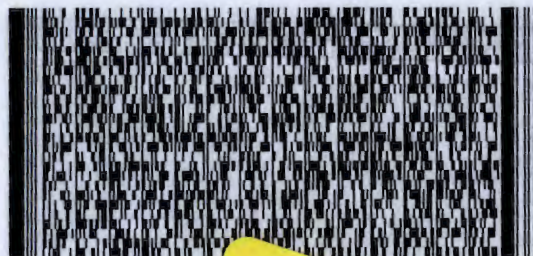
0201

19 NSFA

20852

MD-US

IAD



51AG1/D5E8/1A9E

After printing this label:

