

Withdrawal of Citizen Petition 2006P-0151

Determination of whether NDA 63-293 was withdrawn for safety or effectiveness reasons

1.2 Cover letters

B|BRAUN

0157 9 JAN 21 AIO 52

January 19, 2009

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 161
Rockville, MD 20862

Petition # 2006P-0151
Withdrawal of Citizen Petition

Dear Sir/Madam:

In accordance with 21 CFR 10.30, B. Braun Medical Inc. (B. Braun) hereby requests withdrawal of the above mentioned Citizen Petition. This petition was originally filed with the Agency for the purpose of determining if listed drug Cefotan[®] (cefotetan injection) manufactured by AstraZeneca approved under NDA 63-293, had been voluntarily withdrawn from sale for safety and efficacy reasons.

In response to a telephone conversation on January 9, 2009 between Nam Kim, Regulatory Counsel of the Office of Regulatory Policy and me, B. Braun submits this request for withdrawal of Citizen Petition number 2006P-0151, Legacy Number 2006P-0404.

If you should have any questions regarding this withdrawal, please do not hesitate to contact me via telephone at (610) 596-2356, facsimile (610) 596-4962 or email at kimberly.ernst@bbraun.com.

Yours truly,



Kimberly Ernst
Director, Regulatory Affairs

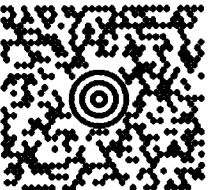

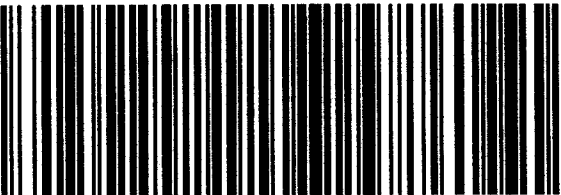

UPS CampusShip: View/Print Label

1. **Print the label(s):** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.
2. **Fold the printed label at the dotted line.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.
3. **GETTING YOUR SHIPMENT TO UPS**
Customers without a Daily Pickup
 - o Schedule a same day or future day Pickup to have a UPS driver pickup all your CampusShip packages.
 - o Hand the package to any UPS driver in your area.
 - o Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return ServicesSM (including via Ground) are also accepted at Drop Boxes.
 - o To find the location nearest you, please visit the Resources area of CampusShip and select UPS Locations.

Customers with a Daily Pickup

- o Your driver will pickup your shipment(s) as usual.

FOLD HERE

DONNA FEIST 610-596-2368 B BRAUN MEDICAL INC 901 MARCON BLVD. ALLENTOWN PA 18109		LTR	1 OF 1
SHIP TO: DEPT. OF HEALTH AND HUMAN SERVICES FDA - DIVISION OF DOCKETS MGMT ROOM 161 5630 FISHERS LANE ROCKVILLE MD 20857-0001			
	MD 207 9-83 		
UPS NEXT DAY AIR		1	
TRACKING #: 1Z 058 38W 01 9503 7159			
			
BILLING: P/P			
Cost Center: 329002206			
CS 11.0.17.		W001E60 84.0A 10/2008	
		 TM	