



Branded Pharmaceutical
Products R&D

January 4, 2013

2013 JAN - 7 A 11: 09

Division of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket 2006P-0285/CP1

To Whom it May Concern:

Reference is made to the Citizen's Petition filed on July 14, 2006, and assigned Docket Number 2006P-0285/CP1.

Reference is also made to the December 20, 2012 telephone call between Jane Baluss, Division of Docket Management, and Amy Hummel, Senior Manager of Regulatory Affairs for Teva Women's Health, the successor entity of Duramed Pharmaceuticals following the acquisition of Duramed's parent company, Barr Pharmaceuticals, Inc., by Teva in 2008, and current NDA holder. Ms. Baluss inquired whether the company would still like FDA to rule on the referenced Citizen's Petition, or elect to withdraw it.

This correspondence serves to confirm Ms. Hummel's email of January 2, 2013, confirming Teva's desire to withdraw the petition.

If you have any questions, please contact the undersigned at (610) 727-6322.

Sincerely,

Teva Branded Pharmaceutical Products R&D, Inc.

A handwritten signature in black ink, appearing to read "Amy C. Hummel".

Amy C. Hummel, MS
Senior Manager, Regulatory Affairs

From: (610) 738-6324
RA Operations
Cephalon
41 Moores Road

Frazer, PA 19355

Origin ID: NMZA

FedEx
Express



J12201208200325

SHIP TO: (610) 727-6322

BILL SENDER

Room 1061

FDA, Division of Dockets Management
5630 Fishers Lane

ROCKVILLE, MD 20852

Ship Date: 04JAN13
ActWgt: 0.5 LB
CAD: 101300352/INET3300

Delivery Address Bar Code



Ref # 100004202006p 0285/CPI
Invoice #
PO #
Dept #

MON - 07 JAN A1
STANDARD OVERNIGHT

TRK# 7944 4433 1044
0201

SA NSFA

20852
MD-US
IAD

