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APPLICATION NUMBER:
22-311

OTHER REVIEW(S)

MEMORANDUM

To: Susan Jenney
Division of Drug Oncology Products

From: Iris Masucci, PharmD, BCPS
Division of Drug Marketing, Advertising, and Communications
for the Study Endpoints and Label Development (SEALD) Team, OND

Date: November 20, 2008

Re: Comments on draft labeling for Mozobil (plerixafor injection)
NDA 22-311

We have reviewed the proposed label for Mozobil (FDA version dated 11/19/08) and offer the following comments. These comments are based on Title 21 of the Code of Federal Regulations (201.56 and 201.57), the preamble to the Final Rule, labeling Guidances, and FDA recommendations to provide for labeling quality and consistency across review divisions. We recognize that final labeling decisions rest with the review division after a full review of the submitted data.

GENERAL

- Please ensure that all headers and footers are removed from the document when appended to the approval letter. Page numbers are allowed.

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/s/

Iris Masucci
12/2/2008 12:58:26 PM
DDMAC REVIEWER

Laurie Burke
12/5/2008 07:41:06 PM
INTERDISCIPLINARY