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**APPLICATION NUMBER:
22511Orig1s000**

CHEMISTRY REVIEW(S)

NDA 22-511

Vimovo

(naproxen and esomeprazole magnesium) delayed release tablets

375 mg/20 mg* and 500 mg/20 mg*

**Each tablet contains 22.3 mg esomeprazole magnesium, equivalent to 20 mg esomeprazole.*

Pozen Inc.

Rajiv Agarwal

Review Chemist

**Office of New Drug Quality Assessment
Division of Pre-Marketing Assessment II
Branch III**

**CMC REVIEW OF NDA 22-511
For the Division of Gastroenterology Products (HFD-180)**

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Executive Summary Section

CMC Review Data Sheet

1. NDA 22-511
2. REVIEW #: 1
3. REVIEW DATE: 07-APR-2010
4. REVIEWER: Rajiv Agarwal
5. PREVIOUS DOCUMENTS: None
6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original Submission	30-JUN-2009
Amendment	19-NOV-2009
Amendment	30-NOV-2009
Amendment	04-MAR-2010
Amendment	25-MAR-2010

7. NAME & ADDRESS OF APPLICANT:

Name: Pozen Inc.
Address: 1414 Raleigh Road, Suite 400
Chapel Hill, NC 27517
Representative: Paul A. Ossi
Telephone: 919-913-1030

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Vimovo
b) Non-Proprietary Name (USAN): naproxen and esomeprazole magnesium
c) Code Name/# (ONDQA only): PN 400
d) Chem. Type/Submission Priority (ONDQA only):

- Chem. Type: 4
- Submission Priority: S

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