

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-042

CHEMISTRY REVIEW(S)

Official Memorandum

To: NDA 22-042
Through: Ravi Harapanhalli, Ph.D.
From: Sarah C. Pope, Ph.D.
Date: 8/30/2007
Re: CMC Recommending Approval for Type 6 NDA

Reference is made to the Applicant's Type 6 NDA submission dated 13-NOV-2006. The submission contained no new Chemistry, Manufacturing and Controls information with the exception of an updated request for a categorical exclusion. Based on the Applicant's updated request and 21 CFR 25.21, this request is granted.

The current Type 6 NDA will utilize the previously-approved (60 mg) tablet formulation. Internal discussion with the Medical Officer (Dr. B. Mann) confirmed that there are no proposed revisions in dosing that necessitate re-examination of the corresponding drug substance impurity profiles.

All previously-approved CMC information remains satisfactory. The Applicant's request for a categorical exclusion is granted, and there are no outstanding CMC issues with this Type 6 NDA.

From a CMC standpoint, this Type 6 NDA is recommended for approval.

Appears This Way
On Original

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Sarah Pope
8/30/2007 02:27:40 PM
CHEMIST

Ravi Harapanhalli
8/30/2007 02:40:39 PM
CHEMIST

Appears This Way
On Original