DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022468/S-009/PMC 1547-5

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Allos Therapeutics, Inc.
Attention: Todd Marshall
Director, Regulatory Affairs
11080 CirclePoint Road Suite 200
Westminster, CO 80020

Dear Mr. Marshall:

Please refer to your Supplemental New Drug Application (sNDA) dated August 19, 2011, received August 22, 2011, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Folotyn®, (pralatrexate injection) 20 mg/1 mL and 40 mg/2 mL.

We also refer to your July 27, 2011 Submission containing final study reports for PMC 1547-5 (In vitro studies to determine if transporters are involved in the elimination of pralatrexate).

In addition, we refer to the Agency's August 3, 2011 Supplement Request which requested revised labeling based on the final study reports.

We acknowledge receipt of your amendment to S-009 dated January 31, 2012.

The "Changes Being Effected" supplemental new drug application revises and adds transporter study results to a) Section 12 Clinical Pharmacology: 12.3 Pharmacokinetics – *Distribution* and b) Section 7 Drug Interactions with a cross-reference to the transporter study results in Clinical Pharmacology (12.3). As pralatrexate was found to be a potent inhibitor of MRP3 in this in vitro system, known substrates of MRP3 are included in the Drug Interaction section.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling text for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated July 27, 2011, received July 28, 2011, containing the final report for the following postmarketing commitment listed in the September 24, 2009 approval letter.

PMC 1547-5 Perform in vitro studies to determine if transporters are involved in the elimination of pralatrexate. Description of study: This will be an in vitro study to determine whether pralatrexate is a substrate for the organic anion transporter (OAT) family, including but not limited to OAT1 and OAT3, and whether drugs that interfere with or compete for these transporters (e.g., acyclovir, probenecid, NSAIDS) have an effect on pralatrexate transport.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there are postmarketing requirements listed in the September 24, 2009 approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Amy Tilley, Regulatory Project Manager, at (301) 796-3994.

Sincerely,

{See appended electronic signature page}

Ann Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ANN T FARRELL
02/15/2012