DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201699/S-009

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Cubist Pharmaceuticals, Inc.
Attention: Shruta Rege, PhD
Manager, Regulatory Affairs
65 Hayden Avenue
Lexington, MA 02421

Dear Dr. Rege:

Please refer to your Supplemental New Drug Application (sNDA) dated November 13, 2014, received November 13, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DIFICID (fidaxomicin) Tablets.

This "Prior Approval" supplemental new drug application provides for information regarding the postmarketing requirement (PMR) 1757-001 (to conduct a prospective clinical trial of 10 days of DIFICID (fidaxomicin) in at least 32 pediatric patients aged 6 months to less than 18 years of age with *C. difficile*-associated diarrhea to evaluate the safety and pharmacokinetics of fidaxomicin) as listed in the May 27, 2011 approval letter.

APPROVAL & LABELING

We have completed our review of this supplemental application and have determined that your study report is acceptable. This supplemental application is approved. There are no labeling changes warranted at this time.

We also conclude that the above post marketing requirement (1757-001) is fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the May 27, 2011 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 Fariba Izadi, PharmD, Regulatory Project Manager, at (301) 796-0563.

Sincerely,
{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

SUMATHI NAMBIAR
02/24/2015