DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-793/S-009 **SUPPLEMENT APPROVAL**

Bedford Laboratories
300 Northfield Road
Bedford, Ohio 44146

Attention: Amy Schutte
Manager, Regulatory Affairs

Dear Ms. Schutte:

Please refer to your Supplemental New Drug Application (sNDA) dated, December 11, 2009, received December 11, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cafcit (caffeine citrate) Injection and Oral Solution.

We acknowledge your June 7, 2010, submission containing final printed carton and container labels.

This Prior Approval supplemental new drug application provides for more clearly differentiated carton and container labeling for Cafcit injection and oral solutions.

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 carton and container labeling.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on June 7, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA20-793/S-009.**" Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Angela Robinson, Senior Regulatory Project Manager, at (301) 796-2284.

Sincerely,

{See appended electronic signature page}
Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20793	SUPPL-9	MEAD JOHNSON AND CO	CAFCIT

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/s/

BADRUL A CHOWDHURY
06/11/2010