**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-193/S-013

Methapharm, Inc.
81 Sinclair Blvd.
Brantford, Ontario N3S 7X6
Canada

Attention: Dr. Rahman Rousta
Director of Regulatory Affairs and Quality Assurance

Dear Dr. Rousta:

Please refer to your supplemental new drug application dated January 28, 2008, received January 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Provocholine ® powder for inhalation.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the additional of 0.9% saline injection as an alternative diluent.

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

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl/html that is identical to the enclosed labeling text for the package insert submitted January 29, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-395.".

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Miranda Raggio, Regulatory Project Manager, at (301) 796-2109.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II/Office of New Drugs
Center for Drug Evaluation and Research

Enclosure: Package Insert of January 28, 2008

---

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

---

/s/

---

Badrul Chowdhury
7/28/2008 09:34:27 AM