DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-234/S-004

Institut Biochimique SA (IBSA)
8602 Mossford Drive
Huntington Beach, CA 92646

Attention: Clarence E. Jones, Ph.D.
IBSA U.S. Agent

Dear Dr. Jones:

Please refer to your supplemental new drug application dated April 22, 2008, received April 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flector (diclofenac epolamine patch).

This supplemental new drug application provides for revisions to the Flector Patch carton and envelope labels.

Reference is also made to the comments sent to you via email on October 21, 2008, recommending revisions to your proposed carton and envelope labels, and your October 22, 2008, email concurring with the revisions.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below.

Revise #5 of the back panel of the carton and envelope as follows:

Avoid contact of Flector Patch with your eyes, nose or mouth. If contact with your eyes occurs, rinse right away with water or saline. Talk with your doctor if eye irritation continues.

The final printed labeling (FPL) for the carton and envelope must be identical, and include the minor editorial revision indicated, to the immediate container and carton labels submitted April 22, 2008, and revised October 22, 2008. These revisions are terms of the approval of this application.

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 Lisa Basham, Regulatory Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
And Rheumatology Products
Office of Drug Evaluation II
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/

Rigoberto Roca
10/23/2008 04:43:56 PM
for Bob Rappaport, M.D.