



NDA 021234/S-006

**SUPPLEMENTAL APPROVAL**

Institut Biochimique SA (IBSA)  
4249 Via Encanto  
Thousand Oaks, CA 91320

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

Dear Dr. Jones:

Please refer to your supplemental new drug application (NDA) application dated August 3, 2009 and received August 4, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flector (diclofenac epolamine) Patch.

We acknowledge receipt of your submission dated August 3, 2009, received August 7, 2009, which contained the SPL version of the package insert.

Reference is also made to our letter dated July 8, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for diclofenac-containing products. This information pertains to the risk of elevations in liver enzymes.

This supplemental new drug application provides for revisions to the labeling for Flector Patch consistent with our July 8, 2009 letter.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format submitted on August 7, 2009.

**CONTENT OF LABELING**

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 021234/S-006.**"

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

## **PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
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 Jessica Benjamin, Regulatory Project Manager, at (301) 796-3924.

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

Enclosures -  
Content of Labeling  
Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21234	SUPPL-6	INSTITUT BIOCHEMIQUE SA	DICLOFENAC EPOLAMINE PATCH (DICLOFENAC E
NDA-21234	SUPPL-7	INSTITUT BIOCHEMIQUE SA	DICLOFENAC EPOLAMINE PATCH (DICLOFENAC E

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

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BOB A RAPPAPORT  
09/03/2009