



NDA 20-607/S-013

APPROVAL LETTER

G.D. Searle LLC
Attention: Tricia Douglas
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Douglas:

Please refer to your supplemental new drug application dated and received November 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arthrotec® (diclofenac sodium/misoprostol) Oral Tablets.

We acknowledge receipt of your submission dated March 4, 2009 and September 2, 2009, and we reference our emails to you on July 15, 2009, and August 18, 2009.

This “Changes Being Effected” supplemental new drug application provides for changes to the PRECAUTIONS and ADVERSE REACTIONS sections of the Package Insert.

We completed our review of this supplemental new drug application, as amended. 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.

- Please ensure that the revision date states September 2009 (the month in which this label is approved).

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 [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the labeling submitted to us on September 2, 2009, and enclosed with the minor revision above. 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 20-607.”

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send

one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

LETTERS TO HEALTH CARE PROFESSIONALS

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

Please submit one market package of the drug product when it is available.

REPORTING REQUIREMENTS

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D.
Deputy Director, Safety
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-20607	----- SUPPL-13	----- GD SEARLE LLC	----- ARTHROTEC

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

/s/

JOYCE A KORVICK
09/11/2009