NDA 020607/S-033

SUPPLEMENT APPROVAL

G.D. Searle LLC
Attention: Lisa Amatulli, MS
Manager, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-7555

Dear Ms. Amatulli:

Please refer to your supplemental new drug application (sNDA) dated and received April 18, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Arthrotec (diclofenac sodium and misoprostol tablets).

This Prior Approval supplemental new drug application provides for labeling updates to the Prescribing Information (PI) in the Boxed Warning, Use in Specific Populations, Section 8.1 Pregnancy, and the Medication Guide (MG) regarding the risk of uterine rupture with use of misoprostol.

APPROVAL & LABELING

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

- Reformat the section headings in Highlights with a horizontal line over the entire column width and reduce white space to move text up from the second to the first page.

We note that your submission, dated and received on July 21, 2020, includes final printed labeling (FPL) for your PI and MG. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Prescribing Information, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2] The SPL will be accessible from publicly available labeling repositories. Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft (MS) Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Benjamin Vali, Regulatory Project Manager, at 301-796-4261 or Benjamin.vali@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology (DG)
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling:
Prescribing Information (PI)
Medication Guide (MG)

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
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