NDA 020607/S-036

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Lisa Amatulli, M.S.
Senior 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 on March 22, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Arthrotec (diclofenac sodium and misoprostol delayed-release tablets).

This Prior Approval sNDA revises the established name to "diclofenac sodium and misoprostol delayed-release tablets" and includes an equivalency statement for diclofenac sodium for all labeling, in order to be consistent with the United States Pharmacopeia (USP) monograph title and naming policy for salt drug substances, while additionally revising portions of all affected labeling accordingly (wherever applicable).

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.

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 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.

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

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).

CONTAINER LABELING

Submit final printed container labeling that are identical to the enclosed container labeling submitted on September 9, 2020, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry, *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Container Labeling for approved NDA 020607/S-036**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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.

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
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling:
Prescribing Information
Medication Guide
Container Labeling

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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