NDA 21920/S-025

SUPPLEMENT APPROVAL

Biopharma Inc.
Attention: Usha Sankaran
Associate Vice President, Regulatory Affairs
600 Alexander Road,
Suite 2-4B
Princeton, NJ 08540

Dear Ms. Sankaran:

Please refer to your supplemental new drug application (sNDA) received April 26, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for naproxen sodium capsule, 220 mg.

This prior approval supplemental new drug application provides for the following two product line extensions:

- back and muscle pain relief
- menstrual pain relief

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 labeling, with the minor editorial revision listed below:

Revise the proposed 100-count immediate container (stand-alone bottle) Drug Facts label (DFL) (i.e., labels with and without the "compare to" statement), and submit revised labels as final printed labeling (FPL):

Revise the proposed warning according to 21 CFR 201.66(d)(6) from:

(b) (4)

to

"***Warnings***
Allergy alert: Naproxen sodium may cause …"

LABELING

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described in the table below, except for the revision listed above, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling for Approval	Date Submitted
50-Count Outer Carton with "12 Hour Back & Muscle Pain Relief" Descriptor and "Compare To" Statement	October 9, 2019
50-Count Outer Carton with "12 Hour Back & Muscle Pain Relief" Descriptor	October 9, 2019
50-Count Immediate Container (bottle) with "12 Hour Back & Muscle Pain Relief" Descriptor	October 9, 2019
100-Count Immediate Container (stand-alone bottle) with "12 Hour Back & Muscle Pain Relief" Descriptor and "Compare To" Statement	October 9, 2019
100-Count Immediate Container (stand-alone bottle) with "12 Hour Back & Muscle Pain Relief" Descriptor	October 9, 2019
20-Count Outer Carton with "12 Hour Menstrual Pain Relief" Descriptor and "Compare To" Statement	October 9, 2019
40-Count Outer Carton with "12 Hour Menstrual Pain Relief" Descriptor and "Compare To" Statement	October 9, 2019
80-Count Outer Carton with "12 Hour Menstrual Pain Relief" Descriptor and "Compare To" Statement	October 9, 2019
20-Count Outer Carton with "12 Hour Menstrual Pain Relief" Descriptor	October 9, 2019
40-Count Outer Carton with "12 Hour Menstrual Pain Relief" Descriptor	October 9, 2019
80-Count Outer Carton with "12 Hour Menstrual Pain Relief" Descriptor	October 9, 2019
20-Count Immediate Container (bottle) with "12 Hour Menstrual Pain Relief" Descriptor	October 9, 2019
40-Count Immediate Container (bottle) with "12 Hour Menstrual Pain Relief" Descriptor	October 9, 2019
80-Count Immediate Container (bottle) with "12 Hour Menstrual Pain Relief" Descriptor	October 9, 2019

The FPL should be submitted 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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21920/S-025**." Approval of this submission by FDA is not required before the labeling is used.

[1] 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.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] 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*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 LT Sally Doan, Regulatory Project Manager, at 301-796-8025.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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

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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/

KAREN M MAHONEY
10/26/2019 09:21:31 PM