NDA 21920/S-036

SUPPLEMENT APPROVAL

Bionpharma 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) dated and received June 23, 2021, and your amendment, submitted pursuant to 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for naproxen sodium capsules, 220 mg.

This "Changes Being Effected" supplemental new drug application provides for an update under the "If pregnant or breast-feeding" warning in the Drug Facts labeling in response to the Agency's CBE Supplement Request letter dated April 28, 2021.

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.

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 labeling listed in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	**Dates Submitted**
20-Count outer carton	June 23, 2021
20-Count outer carton with "compare to" statement	June 23, 2021
20-Count outer carton-vertical orientation	June 23, 2021
30-Count outer carton	June 23, 2021
30-Count outer carton with "compare to" statement	June 23, 2021
40-Count outer carton	June 23, 2021
40-Count outer carton with "compare to" statement	June 23, 2021
50-Count outer carton	June 23, 2021
50-Count outer carton with "compare to" statement	June 23, 2021
50-Count outer carton-vertical orientation	June 23, 2021
80-Count outer carton	June 23, 2021

80-Count outer carton with “compare to” statement	June 23, 2021
80-Count outer carton (nonchild resistant packaging)	June 23, 2021
80-Count outer carton (nonchild resistant packaging) with “compare to” statement	June 23, 2021
80-Count outer carton-vertical orientation	June 23, 2021
80-Count outer carton (nonchild resistant packaging)-vertical orientation	June 23, 2021
100-Count outer carton	June 23, 2021
100-Count outer carton with “compare to” statement	June 23, 2021
120-Count outer carton	June 23, 2021
120-Count outer carton with “compare to” statement	June 23, 2021
120-Count outer carton-vertical orientation	June 23, 2021
120-Count outer carton-vertical orientation 2	June 23, 2021
160-Count (2x80-count) twin pack outer carton	June 23, 2021
160-Count (2x80-count) twin pack outer carton with “compare to” statement	June 23, 2021
160-Count outer carton	June 23, 2021
160-Count outer carton with “compare to” statement	June 23, 2021
160-Count immediate container	June 23, 2021
160-Count immediate container with “compare to” statement	June 23, 2021
160-Count immediate container-vertical orientation	June 23, 2021
180-Count immediate container	June 23, 2021
180-Count immediate container with “compare to” statement	June 23, 2021
300-Count immediate container (nonchild resistant packaging) with “compare to” statement	June 23, 2021
20-Count outer carton for menstrual pain line extension	June 23, 2021
20-Count outer carton with “compare to” statement for menstrual pain line extension	June 23, 2021
40-Count outer carton for menstrual pain line extension	June 23, 2021
40-Count outer carton with “compare to” statement for menstrual pain line extension	June 23, 2021
80-Count outer carton for menstrual pain line extension	June 23, 2021
80-Count outer carton with “compare to” statement for menstrual pain line extension	June 23, 2021
50-Count outer carton for back & muscle pain line extension	June 23, 2021
50-Count outer carton with “compare to statement” for back & muscle pain line extension	June 23, 2021
100-Count immediate container for back & muscle pain line extension	June 23, 2021
100-Count immediate container with “compare to statement” for back & muscle pain line extension	June 23, 2021
80-Count carton for “a+health” product line	June 23, 2021
120-Count immediate container (stand-alone bottle) for “a+health” product line	June 23, 2021

180-Count immediate container (stand-alone bottle) for “a+health” product line	June 23, 2021
80-Count carton for “Be Health” product line	June 23, 2021
180-Count immediate container (stand-alone bottle) for “Be Health” product line	October 01, 2021

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-036**.” Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information are 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 Helen Lee, PharmD, Safety Regulatory Project Manager, at 301-796-6848.

[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.

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

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and 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/

VALERIE S PRATT
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