NDA 21920/S-026

SUPPLEMENT APPROVAL

Bionpharma, Inc.
Attention: Usha Sankaran
Associate VP, 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 10, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for naproxen sodium capsules, 220 mg.

This Changes Being Effected (CBE) supplemental new drug application provides for the addition of "[bullet] taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin" under the ***Warnings*** subheading, "**Ask a doctor or pharmacist before use if you are**", in accordance with the Agency's May 9, 2019, CBE Supplement Request Letter.

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

Submitted Labeling for Approval	Date Submitted
20-count outer carton	September 09, 2019
20-count outer carton with “compare to statement”	September 09, 2019
30-count outer carton	September 09, 2019
30-count outer carton with “compare to statement”	September 09, 2019
40-count outer carton	September 09, 2019
40-count outer carton with “compare to statement”	September 09, 2019
50-count outer carton	September 09, 2019
50-count outer carton with “compare to statement”	September 09, 2019
80-count outer carton	September 09, 2019
80-count outer carton with “compare to statement”	September 09, 2019
80-count outer carton (nonchild-resistant packaging)	September 09, 2019
80-count outer carton (nonchild-resistant packaging) with “compare to statement”	September 09, 2019
100-count outer carton	September 09, 2019
100-count outer carton with “compare to statement”	September 09, 2019
120-count outer carton	September 09, 2019
120-count outer carton with “compare to statement”	September 09, 2019
160-count outer carton	September 09, 2019
160-count outer carton with “compare to statement”	September 09, 2019
160-count (2 x 80-count) outer carton (promotional twin-pack)	September 09, 2019
160-count (2 x 80-count) outer carton (promotional twin-pack) with “compare to statement”	September 09, 2019

SUBMITTED LABELING FOR APPROVAL	Date Submitted
20-count immediate container	October 31, 2019
20-count immediate container with “compare to statement”	October 31, 2019
30-count immediate container	October 31, 2019
30-count immediate container with “compare to statement”	October 31, 2019
40-count immediate container	October 31, 2019
40-count immediate container with “compare to statement”	October 31, 2019
50-count immediate container	October 31, 2019
50-count immediate container with “compare to statement”	October 31, 2019
80-count immediate container	October 31, 2019
80-count immediate container with “compare to statement”	October 31, 2019
80-count immediate container (nonchild-resistant packaging)	September 09, 2019
80-count immediate container (nonchild-resistant packaging) with “compare to statement”	September 09, 2019
100-count immediate container	October 31, 2019
100-count immediate container with “compare to statement”	October 31, 2019

120-count immediate container	October 31, 2019
120-count immediate container with “compare to statement”	October 31, 2019
160-count immediate container	October 31, 2019
160-count immediate container with “compare to statement”	October 31, 2019
160-count stand-alone immediate container	November 15, 2019
160-count stand-alone immediate container with “compare to statement”	November 15, 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-026**.” 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 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).

[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

If you have any questions, call CAPT Janice Adams-King, Safety Regulatory Project Manager, at 301-796-3713.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- 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
12/09/2019 01:06:42 PM