NDA 21920/S-033

SUPPLEMENT APPROVAL

Bionpharma Inc.
Attention: Usha Sankaran
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 24, 2020, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for naproxen sodium capsule, 220 mg.

This Prior Approval supplemental new drug application provides for labeling with an alternate design in the Principal Display Panel (PDP).

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, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling for Approval	Date Submitted
20-count outer carton	June 24, 2020
50-count outer carton	October 28, 2020
80-count outer carton	June 24, 2020
80-count outer carton (nonchild-resistant packaging)	June 24, 2020
120-count outer carton (design 1)	June 24, 2020
120-count outer carton (design 2)	June 24, 2020
20-count immediate container	October 28, 2020
50-count immediate container	June 24, 2020
80-count immediate container	June 24, 2020
80-count immediate container (nonchild-resistant packaging)	June 24, 2020
120-count immediate container	June 24, 2020
160-count stand-alone immediate container	June 24, 2020

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-033**." 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.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of*

[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

Proprietary Names and *PDUFA Reauthorization Performance Goals and Procedures – Fiscal Years 2018 Through 2022*.)

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

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Deputy Director
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/

NUSHIN F TODD
12/12/2020 12:18:39 PM