



NDA 21920/S-19

SUPPLEMENT APPROVAL

Bionpharma, Inc.
Attention: Sreelatha Panicker
Associate Director, Regulatory Affairs
600 Alexander Road, Suite 2-4B
Princeton, NJ 08540

Dear Ms. Panicker:

Please refer to your Supplemental New Drug Application (sNDA) dated September 16, 2016, received September 16, 2016, 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” supplemental new drug application provides for the addition of the “Heart attack and stroke warning” in accordance with the “Changes Being Effected” (CBE-0) Request Letter from the Agency dated August 18, 2016.

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 agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the naproxen sodium capsules 20-, 30-, 40-, 50-, 80- (child resistant), 100-, 160-count immediate container (bottle) labels and 20-, 30-, 40-, 50-, 80- (non-child resistant and child resistant), 100-, 160-count carton labels submitted on February 24, 2017, and the 80-count non-child resistant immediate container (bottle) label submitted on March 3, 2017, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable. Given distributor labels are included in the supplement, we remind you to ensure that any changes made to the labels and labeling in this NDA are made to any distributor’s labeling. The content of the distributor’s label must be identical to the approved applicant holder’s label, with the exception of trade name, trade dress, and distributor identification information.

The final printed labeling should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 21920/S-019.**” 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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 CAPT Janice Adams-King, Safety 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 and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
03/16/2017