



NDA 21855/S-014

## 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 on March 10, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for loperamide hydrochloride (HCl) capsule, 2 mg.

This "Prior Approval" supplemental new drug application provides for new labeling for loperamide HCl capsule, 2 mg under the "a+health" line of products.

### **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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and be identical to the following:

<b>Submitted Labeling</b>	<b>Date Submitted</b>
24-count (blister) carton, 2 mg a+health	June 9, 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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 21855/S-014.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you to continue to limit package sizes to 48 mg loperamide HCl total, per FDA Safety Communication: FDA limits packaging for anti-diarrhea medicine loperamide (Imodium) to encourage safe use.

## **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.<sup>2</sup> 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 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).

---

<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

If you have any questions, call Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

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:

- Carton 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  
06/22/2020 12:00:00 AM