NDA 22429/S-026

SUPPLEMENT APPROVAL

Bionpharma Inc.
Attention: Usha Sankaran
Vice President, Regulatory Affairs
400 Alexander Park
Suite 2-4 B
Princeton, NJ 08540

Dear Usha Sankaran:

Please refer to your supplemental new drug application (sNDA) dated August 9, 2025, and received August 11, 2025, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for cetirizine hydrochloride capsules, 10 mg.

This "Changes Being Effected" supplemental new drug application provides for a revision to the Drug Facts label to include a warning about new onset pruritus that occurs after discontinuation of cetirizine, in response to the Agency's CBE Supplement Request letter dated July 11, 2025.

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 identical to the labeling listed in the table below:

Draft Submitted Labeling	Date submitted
25-count carton	11/28/2025
30-count carton	11/28/2025
40-count carton	11/28/2025
65-count carton	11/28/2025
80-count carton	11/28/2025

90-count carton	11/28/2025
25-count a+Health carton	11/28/2025
40-count a+Health carton	11/28/2025
65-count a+Health carton	11/28/2025

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 22429/S-026**." Approval of this submission by FDA is not required before the labeling is used.

We note a 5 mg product associated with this NDA, which you indicate has not been marketed. If you are interested in marketing the 5 mg product in the future, a supplement must be submitted to include a warning on the Drug Facts label about new onset pruritus that occurs after discontinuation of cetirizine. We encourage you to contact us about plans for such a supplement prior to submission.

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.

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 2023 Through 2027*.)

---

[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

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, please contact Helen Lee, Safety Regulatory Project Manager, at 301-796-6848 or Helen.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Dorothy Chang, 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/

DOROTHY N CHANG
01/30/2026 11:45:13 AM