Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street NW, Suite 1200
Washington, DC 20005-5929
Attn: Kurt Karst

Sent via email to: KKarst@hpm.com

Docket No. FDA-2020-P-1730

Dear Kurt Karst:

This is in response to your petition received on August 3, 2020, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug products: Loperamide Hydrochloride Capsules, 1 mg and 4 mg. The listed drug product to which you refer in your petition is Imodium (Loperamide Hydrochloride) Capsules, 2 mg, approved under NDA 017694 and held by Johnson & Johnson Consumer Inc. McNeil Consumer Healthcare Div.

Your request involves a change in strength from that of the listed drug product (i.e., from Loperamide Hydrochloride Capsules, 2 mg to Loperamide Hydrochloride Capsules, 1 mg and 4 mg). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

However, for the reasons explained below, the Agency denies your request.

One of the requirements for approval of a petition under section 505(j)(2)(C) of the Act is that there is not "[a] drug product… approved in an NDA for the change described in the petition." 21 CFR 314.93(e)(1)(vi). Therefore, FDA denies your petition for Loperamide Hydrochloride Capsules, 1 mg, because a drug product is approved in an NDA for the change described in the petition (Loperamide Hydrochloride Capsules, 1 mg, approved under NDA 021855, held by BionPharma Inc.).

With respect to Loperamide Hydrochloride Capsules, 4 mg, we have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(iv).

The Agency has determined that your proposed change in strength raises questions of safety. The proposed change in strength would necessitate safety-related changes to the existing loperamide labeling, such as changes that warrant alerting and informing healthcare providers, caregivers, and patients regarding safety considerations surrounding a loperamide 4 mg, higher strength dose (as compared to the available 1 mg and 2 mg doses), within the Warnings for Cardiac Adverse Reactions (including Torsades de Pointes and Sudden Death), Overdosage, Drug Abuse and Dependence, and/or other sections of the label.

FDA, therefore, denies your petition to submit an ANDA for the 4 mg strength. The proposed strength requires significant labeling changes because the requested change to the drug product, Loperamide Hydrochloride Capsule, 4 mg, would necessitate significant labeling changes to address the newly introduced safety problem posed by the proposed strength, which differs from the listed drug product. Please contact the Center for Drug Evaluation and Research, Office of Immunology and Inflammation, Division of Gastroenterology at (301) 796 - 2120 if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William H. Chong -S

Digitally signed by William H. Chong -S
Date: 2024.07.08 07:46:58 -04'00'

William Chong, M.D.
Director
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