Kendle Regulatory Affairs/AAC Consulting
Attn: Anthony C. Celeste
7361 Calhoun Place
Rockville, Maryland 20855

Docket No. FDA-2006-P-0397[1]

Dear Anthony C. Celeste:

This is in response to your petition received on June 16, 2006, by the U.S. Food and Drug Administration (FDA or the Agency) seeking a determination that your proposed drug product Loperamide Hydrochloride Orally Dissolving Strips, 2 mg is suitable for submission in an Abbreviated New Drug Application (ANDA) based on the reference listed drug (RLD) Imodium A-D (Loperamide Hydrochloride) Tablets, 2 mg (over-the-counter (OTC)), approved under New Drug Application (NDA) 019860 and held by Johnson and Johnson Consumer Inc. McNeil Consumer Healthcare Division.

Your request involves a change in dosage form from that of the listed drug product (i.e., from tablets to orally dissolving strips). 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.

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, that investigations must be conducted to show the safety and effectiveness of the drug product. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(i).

The Agency has determined that your proposed change in dosage form raises questions of safety. Specifically, an investigation must be conducted to show that the drug with the proposed change in dosage form to orally dissolving strips can be delivered accurately by consumers to certain pediatric populations. The labeling for the listed drug recommends administering a ½ "caplet" dose to certain pediatric populations. Your proposed labeling similarly recommends administering a ½ dissolving strip to certain pediatric populations. A clinical investigation showing that a ½ dissolving strip can be delivered accurately to certain pediatric populations would be necessary to demonstrate the safety of your proposed product.

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective,

[1] This petition was originally assigned docket number 2006-P-0253. The number changed to FDA-2006-P-0397 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

unless this requirement is waived. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. See section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)].").

Because you are seeking a change in dosage form, this proposed product triggers PREA. This petition is being denied because a clinical investigation must be conducted to show the safety of the proposed change to the drug. Therefore, because your petition does not meet the applicable requirements under section 505(j)(2)(C) of the Act and 21 CFR 314.93, it is not necessary to address the question of whether pediatric studies are necessary under PREA. Please contact the Office of New Drugs, Office of Drug Evaluation IV, Division of Nonprescription Drug Products at 301-796-2080, if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the acceptability 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,

Howard D. Chazin -S

Digitally signed by Howard D. Chazin -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300195068, cn=Howard D. Chazin -S
Date: 2019.04.29 11:35:52 -04'00'

Howard Chazin, M.D.
Acting Deputy Director
Office of Generic Drugs
Center for Drug Evaluation and Research