DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 09 2007 30 7 AUG 10 A9:36

Kendle Regulatory Affairs
Attention: Anthony C. Celeste
7361 Calhoun Place – Suite 500
Rockville, MD 20855

Docket No: 2006P-0253/CP1

Dear Mr. Celeste:

This is in response to your inquiry dated June 6, 2007, directed to Dr. Steven K. Galson, regarding your abbreviated new drug application (ANDA) Suitability Petition and requesting the status of the Agency's response. Your petition requests a change in dosage form from tablets to orally dissolving strips for loperamide hydrochloride, a non-prescription drug product. Please be assured that your ANDA Suitability Petition is under review by the Center for Drug Evaluation and Research.

The assessments of these types of petitions are very complex and require input from several organizations within the Center to address issues such as the "Pediatric Research Equity Act of 2003" (PREA). PREA requires that all applications for new dosage forms, and other changes, include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. If the change proposed in an ANDA suitability petition does not qualify for a waiver of the pediatric studies, that petition will be denied because, under PREA, clinical studies are required to demonstrate the safety or effectiveness of the change (Section 505(j)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act).

In addition, a petition is reviewed to determine if any clinical studies are necessary to demonstrate the safety or effectiveness of the changes proposed in the petition, regardless of PREA. The safety and effectiveness issues, along with the pediatric waiver request, must be evaluated by different components of the Center as part of the petition process. The outcome of these evaluations, among other considerations, determines whether the petition may be approved. Also, pursuant to the discussion of the petition at the meeting, the committee members may request additional information prior to making final recommendation on the petition. If it is determined that clinical studies are required to support the change, the petition is recommended for denial and requires further Agency review before the response is issued. The Center must be assured that all products are safe and effective for the American consumer.

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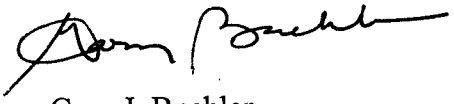
Again, please be assured that the Agency is working on this petition. Kendle will be notified in writing when the assessment of the petition is complete. Another option for Kendle to pursue, if you do not wish to wait for the review of your ANDA Suitability Petition to be completed, is to submit an application pursuant to Section 505(b)(2) of the Act. The Office of New Drugs would review this application.

We hope that this information is helpful to you. A copy of this letter regarding 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,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: Steven K. Galson, M.D., M.P.H.