Kendle

0366 7 JUN 13 A9:37

June 6, 2007

Dr. Steven K. Galson (HFD-1)
Director
Center for Drug Evaluation and Research
Food and Drug Administration
5515 Security Lane
Rockville, MD 20852

Re: Docket Number 2006P-0253

Dear Dr. Galson:

The purpose of this letter is to request a response to the suitability petition that we filed on behalf of a client on June 16, 2006.

The petition requested the agency to make a determination that an abbreviated new drug application may be submitted for Loperamide Hydrochloride Orally Dissolving Strip, 2 mg. The drug is currently marketed as an over-the-counter oral tablet, Imodium A-D, pursuant to a new drug application. The change in dosage form proposed by the petition would help consumers safely manage their health by providing an easier and more convenient method of using the product, improved consumer compliance, and better portability.

The statute and the regulations require FDA to furnish a response by approving or disapproving the petition within 90 days after it has been filed. 21 U.S.C. 355(j)(2)(C); 21 CFR 10.30(e)(4), 314.93(e). Here, it has been nearly one year since the petition was filed, but we have not received any communication concerning the merits of the petition, the status of this matter, or an explanation of the circumstances that have delayed a response that is legally mandated.

We recognize that the agency has many public health responsibilities, but we believe that we are entitled to a response to the petition. Your consideration of our request would be greatly appreciated.

Sincerely yours,

Anthony C. Celeste

Anthony C. Celeste
Senior Vice President

cc
Virginia Behr (HFD-1)
Sheldon T. Bradshaw (GCF-1)
Division of Dockets Management (HFA-305)

2006P-0253

LET 1

Kendle Regulatory Affairs
7361 Calhoun Place
Suite 500
Rockville, MD 20855
Tel: +1 301 838 3120
Fax: +1 301 838 3182

www.kendle.com