Baxter

June 08, 2016

Division of Dockets management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fisher Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam:

The undersigned submits this petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.20 and 10.30, to request the Commissioner of the Food and Drug Administration to amend the Approved Drug Products with Therapeutic Equivalence Evaluation (commonly known as the "Orange Book") to designate Levofloxacin in Dextrose 5% in Plastic Container, A090343, as a second reference listed drug "RLD" product. The product currently designated as the RLD is Levaquin in Dextrose 5% in Plastic Container, NO20635, held by Janssen Pharmaceuticals.

A. Action Requested

The undersigned request the Commissioner of the Food and Drug Administration (FDA) to amend the "Orange Book" to designate a second RLD for Levofloxacin Injection in 5% Dextrose for purposes of submitting an ANDA application for a generic version of this drug product.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications (ANDA's). That list, referred to as the "Orange Book", contains all the FDA approved drug products. The current edition of the Orange book designates Levaquin in Dextrose 5% in Plastic Container, NO20635, held by Janssen as the RLD for the Levofloxacin product.

Due to market withdrawal (Attachment 1), the RLD product is not currently available for evaluation/comparison for development of a generic. There are several generic products listed in the Orange Book with the same strengths, dosage form, and route of administration as the RLD Product, Levaquin (Attachment 2). A review of the approval dates indicates that the generic Levofloxacin in Dextrose 5% in Plastic Container product, A090343, held by ACS Dobfar, has been approved by the FDA since July 2011. A review of product labeling and marketing information on DailyMed also indicates that both Sandoz Inc. and Sagent Pharmaceuticals (current Levofloxacin market leader) reference A090343 as the Application Number or Monograph Citation reference. As a result, the Petitioner respectfully requests that Dobfar's Levofloxacin in Dextrose 5% in Plastic Container, ANDA 090343, be designated as a second RLD.

Baxter Healthcare Corporation
One Baxter Parkway / Deerfield, Illinois 60015
T 224.948.2000

C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

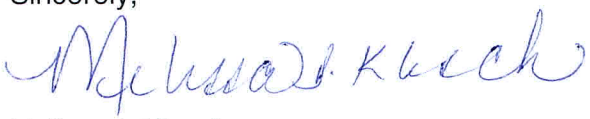
D. Economic Impact Statement

Pursuant to 21 C.F.R. § 10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The under signed certifies, that to the best of its knowledge, this petition includes all information on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the petition.

Sincerely,



Melissa I. Klesch
Manager / Global Regulatory Affairs
Baxter Healthcare Corporation
32650 N. Wilson Road WG1-3 Round Lake, IL 60073 / USA
Telephone: 224.270.3698
melissa_klesch@baxter.com