DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 13, 2013

Whe-Yong Lo, Ph.D.
Vice President R & D and Regulatory Affairs
Tedor Pharma Inc.
400 Highland Corporate Drive
Cumberland, RI 02864

Dear Dr. Lo:

Your petition to the Food and Drug Administration requesting to determine whether Metadate® ER 10 mg (Methylphenidate Hydrochloride) Tablets (ANDA 040-306) by UCB Inc, has been voluntarily withdrawn for safety or effectiveness reasons, was received by this office on 03/13/2013. It was assigned docket number FDA-2013-P-0303/CP1, and it was filed on 03/13/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)