CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022524Orig1s000

OTHER ACTION LETTERS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-524 **COMPLETE RESPONSE**

Par Pharmaceutical Companies, Inc.
Attention: Cheryl Elder, PharmD
Senior Director, Regulatory Affairs
300 Tice Boulevard
Woodcliffe Lake, NJ 07677

Dear Dr. Elder:

Please refer to your new drug application (NDA) dated and received on April 7, 2009, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zuplenz (Ondansetron) Oral Soluble Film 4 and 8 mg.

We acknowledge receipt of your amendments dated May 1, 2009, August 10, 2009, September 22, 2009, October 19, 2009, November 4, 2009 and January 11, 2010.

We have completed the review of your application, as amended, and have determined that we cannot approve the application at this time. We have described below our reasons for this action and, where possible, our recommendations to address these issues.

1. Due to Agency-wide restrictions on foreign travel, we postponed the inspection of the clinical and analytical sites for the bioequivalence study, An Open-Label Randomized, Single Oral Dose, Two Way Crossover Bioequivalence Study To Compare Ondansetron Orally Dissolving Film Strip (ODFS) 8mg with Zofran Orally Disintegrating Tablets [ODT® (Containing Ondansetron 8 mg)] in 48 Healthy, Adult, Human Study Participants Under Fasting Conditions. We will schedule and perform an inspection of these sites as soon as we can. Please notify us in writing when the inspections of these sites have been completed. A satisfactory inspection report for these sites must be received before this application can be approved.

2. Product labeling remains unresolved. We will continue discussions based on the enclosed version.

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's *Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants*, May 2009 at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Frances Fahnbulleh, Regulatory Project Manager, at (301) 796-0942.

Sincerely,

{See appended electronic signature page}

Donna Griebel, MD
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:
Package Insert

27 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22524	ORIG-1	PAR PHARMACEUTICAL	ZUPLENZ (ONDASETRON) ORALLY-DISSOLVING F

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DONNA J GRIEBEL
02/05/2010