DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Attn. Sean Kassim U.S. Food and Drug Administration 10903 New Hampshire Avenue Building 22, RM 1471, Silver Spring, MD 20993 Phone: (301) 796 5032 Industry Information: www.fda.gov/oc/industry	29 May -31 May 2018
	FEI NUMBER 3002807904

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Biserka Cetina-Cizmek, Preformulation Senior Director

FIRM NAME	STREET ADDRESS
Pliva Croatia Ltd. c/o Teva Pharmaceuticals, USA	425 Privet Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Horsham, PA 19044	Analytical facility

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

These observations pertain to the particle size distribution (PSD) data that was reported in Study (b) (4) :

1. Stability of test product (b) (4) was not demonstrated, specifically:
   a) Stability was not demonstrated for (b) (4) during the dialysis experiment using an analytical assay at ambient temperature for the duration of the study.
   b) Stability of the dialyzed (b) (4) solution stored before dynamic light scattering (DLS) analysis using an analytical assay was not demonstrated under storage conditions at ambient temperature to cover the duration that samples were stored before analysis.

2. Documentation is not available to demonstrate the storage condition of (b) (4) during dialysis and storage post dialysis.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephanie Mangigian, MS/OSH, RN, CSO Himanshu Gupta, Ph.D., Staff Fellow	05/31/2018