DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	06/11/2012 - 06/15/2012 FEI NUMBER 1876582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Marilyn J. Graybill, Senior Director of Operations

FIRM NAME	STREET ADDRESS
Pfizer, Inc.	1200 Parkdale Rd
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Rochester, MI 48307-1744	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Two successful media fill simulations run in 2011 did not challenge filling at the fastest line speed ((b)(4)% drive, approximately (b)(4) bpm) for a minimum of (b)(4) tubs as required on Form 4615 under section "Planned Media Simulation Challenges for Penicillin Filling". Media Fill lot 63715 was recorded on this form as challenging the line speed at (b)(4)% drive speed, however, the filling interventions recorded for this batch on Form 4566 (part 2) only document the fastest line speed at (b)(4)% drive speed. Bicillin LA 600,000 in 1mL, lot 63078 filled in 8/2011 was run at (b)(4)% drive speed.

OBSERVATION 2

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

A defined minimum review time interval was not presented for the current 100% semi-automated inspection process as performed according to written procedure, SOP-MAN-PEN-03815-RO, Bicillin Product Inspection, and as supported by process qualification data. This written procedure is followed in performance of the 100% inspection of all products manufactured at the firm including Bicillin LA 1,200,000 in 2 mL, lot 65572 as observed on 6/11/2012.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily J Orban, Investigator Rebecca E. Dombrowski, Investigator	06/15/2012