DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

LEE PENNINGER, SENIOR COUNSEL
ADMINISTRATIVE & CIVIL REMEDIES BRANCH
OFFICE OF COUNSEL TO THE INSPECTOR GENERAL
330 INDEPENDENCE AVENUE, SW
COHEN BUILDING - ROOM 5527
WASHINGTON, DC 20201
TELEPHONE: (202) 690-5910
FACSIMILE: (202) 205-0604
EMAIL: LEE.PENNINGER@OIG.HHS.GOV

April 3, 2013

Patricia L. Glover
Vice President, US Chief
Compliance Officer
Teva Pharmaceuticals
901 East 104Street
Suite 900
Kansas City, MO 64131

Re: OIG Site Visit Summary – February 28, 2013

Dear Ms. Glover:

The Office of Inspector General (OIG) of the Department of Health and Human Services conducted an on-site visit to Teva Pharmaceuticals in Frazer, Pennsylvania on February 28, 2013 to evaluate Teva's implementation of the obligations of two Corporate Integrity Agreements (CIAs), Ivax Pharmaceuticals, Inc. and Ivax Corporation (Ivax) and Cephalon, Inc. (Cephalon). Both businesses subsequent to the execution each CIA, was acquired by Teva Pharmaceuticals, Inc. (Teva). The Frazer Pennsylvania office is the location where most of the compliance personnel are located and is considered the home office for the US compliance program organization and operations.

OIG representatives, Maame Gyamfi, Senior Counsel and Lee Penninger, Senior Counsel, acknowledge Teva's cooperation and assistance during the visit and appreciate the time and effort put forth by the Teva staff. This letter is intended to provide Teva with a summary of the on-site visit activities.

The OIG is responsible for monitoring entities that are subject to Corporate Integrity Agreements (CIAs) and as part of our monitoring responsibilities, the OIG conducts on-site visits. The purpose of the on-site visit is to observe the implementation and day-to-day operations of Teva compliance program. The OIG considers the on-site visit an opportunity to: 1) meet with the senior management staff and discuss the compliance program; 2) conduct an in-person verification that the CIA requirements have been

verification that the CIA requirements have been implemented; and 3) gain a better understanding of Teva's day-to-day business operations.

Compliance Site Visit Summary

Compliance Program Overview and Policies and Procedures

We arrived on site and were greeted by US operations Chief Compliance Officer, and were introduced to Richard Wright, Internal Audit, Meredith Taylor, Associate Director CNS, and Victoria Titus, Associate Director CIA/Generics. The agenda for the day was confirmed and included: Compliance Program Overview, the Investigative Process, Auditing and Monitoring, Training and Teva LMS Demonstration, Ineligibility Screening for employees, vendors and health care professionals, Interviews with the Compliance team, discussion of the Ivax IRO findings, and Cephalon IRO findings. Ms. Glover explained that compliance is developing a risk assessment model to governor the post-CIA activities and that the current compliance focus is on all products manufactured by Teva including generic, brand, or over-the-counter drugs.

The Compliance Program Overview, along with the supporting policies and procedures including Teva integrity principles were presented. The Global Compliance Program was explained as well as the development of the global policies and the worldwide regional structure. Ms. Glover provided us with an overview of the US Compliance Organization and information about the Teva Code of Business Conduct and Teva Integrity Principles as well as details regarding the Compliance focus areas. She explained that the current focus areas are promotional materials and informational presentations, interactions with medical science liaisons, meals and education items, speaker programs, interactions with patients, grants and donations, promotional support reimbursement, billing codes, pricing, and sample management.

A compliance Associate Director is assigned to each business management team that includes CNS (central nervous system) Market Access/Shared Solutions (call center, managed care, and privacy) Oncology and Women's Health, Generics, Medical Affairs, Respiratory and Teva Specialty Brands, Privacy Officer, and Compliance Operations (transparency and Share System).

Investigative Process

We discussed the Investigation Review Committee (IRC) which was chartered to provide oversight direction and resources for all investigative matters (excluding quality). The membership includes corporate security, compliance, legal human resources and internal audit. It investigates matter related to suspected or confirmed violations of the Teva Code Of Conduct and other company policies, suspected or confirmed violations of laws or regulation, loss of or risk to the company's assets, unsafe working conditions, suspected or confirmed irregularities of any nature which could cause harm or damage to the company in North America. Reports are submitted through the IRC Report Intake Portal on a simple one page form. The reports are mapped to the appropriate party for

management and all reports are available on line. An example on an actual investigation was demonstrated.

Auditing and Monitoring

The auditing and monitoring activities include the Ivax quarterly Arrangements review, the field force monitoring program, medical information requests, message recall studies, expense reports, call activity and do not compensate calls, sample audits, aggregate spend audit and CARE.

The Ivax Arrangements Review involves a review of wholesaler and Group Purchasing Organization contracts for the required certification language, transactions including credits price changes and rebates and Health care practitioner arrangements. Compliance oversees the quarterly review and the results are reported to the Compliance Committee.

The Field force monitoring involves 30 ride alongs annually. The Compliance lead is given product training and the rides-alongs extend beyond the Cephlon products to all Teva products. Teva asked the OIG about the number of ride alongs it should conduct once the CIA has ended. We discussed the activity.

The monitoring of medical information is reviewed quarterly for high volumes, duplicate requests, and is compared by month/year by product. Message recall monitoring is conducted during the first and third quarter for the legacy Cephalon products. Teva asked how useful other manufacturers have found this process. We discussed this matter.

Training

The CIA requires that training be tracked and documented. We were provided with a demonstration of the electronic Teva learning management system. Human resources is to notify compliance of all new hires and transfers. Compliance is responsible for assigning the required compliance training. There is an auto notification process for users and if training is not completed, reports are sent to compliance and there is an escalation process in place. In-person training is conduct at national sales meetings, regional managers and medical affairs meetings, executive leadership meetings, speaker training, and home office business unit meetings. We were provided with a live demonstration and were able to access and review individual training records as evidence that training was completed as required.

Screening

New hire screening is tracked by Human Resources and completed by a third party vendor. All discrepancies are cleared before proceeding with an employment offer. Ineligible persons are not hired. Annual screening is completed by the Internal Audit department and it is tracked in Compliance e-room system. No ineligible persons were identified in 2012. The health care professional disciplinary check process includes ineligibility screening. It includes OIG, FDA, DEA, and State medical board sanctions. This process is completed on a monthly basis and if issues are identified the HCP is removed from the speaker bureau, the call plan, and sample eligibility program. We were

shown evidence of the screening which is date stamped and stored in the persons electronic file.

Independent Review Organization Findings

The findings of the Ivax year three Independent Review Organization (IRO) report were discussed. There were a total of four findings regarding the Ivax Arrangement Review. Three were related to the sample selection and the corrective actions were completed at the time of this visit. One finding related to a standard operating procedure was in process and due to be complete once the revised SOP was approved.

The findings of the Cephalon year four IRO report were discussed. There were four findings regarding the Promotional and Product Services System review. Three of the four corrective action plans were complete by this site visit. The fourth finding is in process and Compliance continues to work with sales operations and sales management to implement a flag system for debarred HCP related to call plans. There were five finding regarding the Transaction Review and the five corrective actions are complete.

Summary

Teva Pharmaceuticals has implemented a comprehensive compliance program for its US operations. It acquired two organizations that each had CIAs with different review procedures. Teva has chosen to implement the elements of each CIA across its organization and is currently expanding the compliance program to its global operations. Cephalon and Ivax appear to be in compliance with their respective CIA obligations.

Again, thank you for your assistance and cooperation during the site visit. We enjoyed meeting you and the other members of Teva's staff. We appreciated the opportunity to learn about Teva and its compliance program. If you have any questions about this letter, please do not hesitate to contact me at 202-690-5910 or Lee.Penninger@oig.hhs.gov.

Sincerely,

Lee Penninger

Lee Penninger
Senior Counsel