DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	05/11/2010 - 05/21/2010* FEI NUMBER 1010370

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kenneth J. Yamashita, General Manager

FIRM NAME	STREET ADDRESS
Schering Corporation	13900 Nw 57th Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Miami Lakes, FL 33014-3103	Drug 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 I OBSERVED:

OBSERVATION 1

Representative samples are not taken of each shipment of each lot of components for testing or examination.

Specifically, Schering Corporation receives (b) (4) used in the production of Miralax OTC. The firm relies on the (b) (4) manufacturer to sample the raw material as "tailgate samples". These tailgate samples are used for the raw material testing and acceptance. The firm has not analytically validated the tailgate sampling process nor demonstrated that the tailgate samples are representative of the respective lots they are associated with.

OBSERVATION 2

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, your firm is not validating at any demonstrated interval the content of the certificate of analysis for (b) (4) (b) (4) that is accepted in lieu of testing for free (b) (4) (composite), (b) (4) (composite) and residual solvents (b) (4) (composite) as stated on your QC Specification and Test Procedure for (b) (4) (Granular). Further, your firm does not have established procedures for continued validation (at appropriate intervals) of manufacturer's certificates of analysis where results are accepted in lieu of testing.

*** DATES OF INSPECTION:**
05/11/2010(Tue), 05/12/2010(Wed), 05/13/2010(Thu), 05/14/2010(Fri), 05/17/2010(Mon), 05/20/2010(Thu), 05/21/2010(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sarah E. McMullen, Investigator	05/21/2010