Attachment# 5
Wyeth Pharm Div of Wyeth Holdings
EI: 8/27/08-10/08/08 JW
Pearl River, NY 10965

DEPARTMENT OF HEALTH AND HUMAN SERV
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave Jamaica, NY 11433 718-340-7000	8/27/08-10/8/08*
	FEI NUMBER 2410662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael P. McDermott, Vice President Site Operations

FIRM NAME	STREET ADDRESS
Wyeth Pharmaceutical, Div WyethHolding Corp	401 N. Middletown Rd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pearl River, NY 10965	Mfr of Dietary Supplements

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

1. Laboratory exam and test methodologies do not appear to be appropriate for their intended use. Specifically, the test method using (b) (4) instruments ((b) (4)) produced negative trends that report equipment drifts, OOS CV standards and/or invalid results that required a re-test on several mineral lots, but this test method continues to be used, and has not been replaced with a more reliable method.

2. Failure to use an appropriate scientifically valid method to test the seal over plastic bottles to ensure uniformity of the sealing process across all plastic bottles. The current method requires testing the integrity of the seal by applying pressure (using finger pressure) over the middle of the seal and visually inspecting the rim over the mouth of the bottle. No specifications were established for the amount of pressure and dwell time to apply or use of measurable tool to evaluate the integrity of the seal.

3. Specifications for dietary ingredient(ginseng) are listed under Monograph (b) (4) (code (b) (4)) and this monograph requires verification on the supplier's COA that pesticide (tricyclazole) was tested, but COAs for code (b) (4) do not include test results for this pesticide, and was not revised to include the actual name and address of the lab currently responsible for furnishing this information.

4. In the packaging area, failure to demonstrate all requirements were met. Specifically, as part of Master Packaging Record, specifications for cap adjustments(distance from cap to bottom of sealing head) were established to show proper alignment to the sealer; however adjustments were not documented to support proper set-up. Also, when product changeovers occur bulk materials (to include tablets stored in metal detector challenge bottles) must be removed from the packaging line and destroyed; however there is no evidence that tablets inside metal detector bottles were emptied and removed from the packaging line.

5. As part of your Master Corrective action plan established to test minerals under LIR commitment (b) (4) only 4 of 5 corrective actions were implemented.

6. Your hand washing facility does not dispense water at a suitable temperature. Specifically, the automatic hand washing sinks for one side of men's restroom on the (b) (4) floor furnished only cold water.

*DATES OF INSPECTION: 8/27-29/08, 9/3-5, 9-12, 15-18, 23-26, 29/08 &10/8/08

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Jacqueline Warner, CSO	10/8/08

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