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	08/02/2005 - 08/10/2005
	FEI NUMBER 1833336

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eric W. Kolodziej, Vice President, Quality

FIRM NAME	STREET ADDRESS
L. Perrigo, Co	1761 Airport Park Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Holland, MI 49423-9370	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

Drug products failing to meet established quality control criteria are not rejected.

Fiber Therapy (543AC) batch 3M1393 was determined to fail the Foreign Matter routine testing performed on 12/23/03 and 1/19/04 as green particles later determined to be epoxy coating from green colored equipment carts used to transfer manufacturing parts between production and cleaning rooms were found in samples sent to the Quality Control Laboratory. The original particle documented as "Significant amount found" was lost. Resample of the lot found a second particle smaller in size but confirming the original failing result. Deviation (b) (4) justification for release of this lot and associated packaged lots included the statement "(b) (4) (b) (4) "

OBSERVATION 2

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

SOP (b) (4) "Dispensing Cleaning Procedure" was not followed in that the "DISPENSING WASH CHECKLIST" was not performed between dispensing or transferring dissimilar materials as follows:

5/13/05 between premix (b) (4) lot 5D1214 and raw material (b) (4) (citric acid) lot #5014641
5/26/05 between raw material (b) (4) (Sucrose) lot 5023427 and premix (b) (4) lot 5E0365
7/07/05 between premix (b) (4) lot 5F0886 and raw material (b) (4) (citric acid) lot 5016289
7/08/05 between raw material (b) (4) lot 5020286 and premix (b) (4) lot 5F0887
7/20/05 between premix (b) (4) lot 5G0357 and raw material (b) (4) lot 5020287

OBSERVATION 3

Procedures describing the warehousing of drug products are not followed.

SOP (b) (4) "Monitoring and Recording Temperature Readings at APC" calls for (b) (4)

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(b) (4) (b) (4) (b) (4) '. Review of the alarms generated 12/03 - present revealed several instances where temperature sensors were in alarm ((b) (4)) or registering as (b) (4) (the default for malfunction) for extended time periods as follows:

Location	Alarm Began	Alarm Ended	Temperature registering as	# Days
Rack (b) (4) South	12/10/03	12/12/03	(b) (4) F	2+
Pole (b) (4) High	02/03/04	02/18/04	F	15
Pole (b) (4) Low	05/10/04	05/18/04	F	8
"	07/20/04	08/09/04	F	20
"	08/09/04	09/02/04	F	17
Pole (b) (4) High	10/03/04	10/08/04	F	5
"	10/10/04	10/23/04	F	13
"	10/24/04	10/28/04	F	4
"	11/04/04	12/16/04	F	42
"	12/16/04	03/19/05	F	93
Pole (b) (4) High	04/06/05	06/03/05	F	58

There is no data available documenting evaluation/investigation of the above sensor malfunctions, no documentation of maintenance performed, and no evidence of the existence of an excursion binder. Mean Kinetic Temperature, when calculated, includes these (b) (4) temperature readings.

OBSERVATION 4

Written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs.

Bulk Transfer System (b) (4) used for citric acid and sucrose dispensing does not have an equipment cleaning, maintenance and use log. Examples of material dispensed using this equipment include Citric Acid Anhydrous lot 5014641 dispensed on 5/13/05 and Sucrose lot 5023427 dispensed on 5/23/05.

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

A. Deviation (b) (4) was initiated for an error in raw material transfer that was noted on 10/6/04. SOP (b) (4) "Unplanned Deviation Process" was not followed in that it (b) (4) (b) (4) The deviation was not initiated until 11/24/04 and the corrective action, creation of an SOP ((b) (4) (b) (4) implementing specific transferring procedures was not accomplished until 12/2/04.

B. Deviation (b) (4) dated 4/11/05 was initiated following a cleaning validation failure associated with SOP (b) (4)

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"Cleaning procedure for the (b) (4) (b) (4). The SOP has been in effect since 11/26/03. The failure deamed to be as a result of the operator's failure to perform the hand cleaning portion of the SOP (on or about 3/18/05) and the Supervisor's failure to inspect the equipment following cleaning. The corrective action includes recommendation that a cleaning checklist be added to this cleaning SOP. As of 8/4/05 a cleaning checklist has not been initiated.

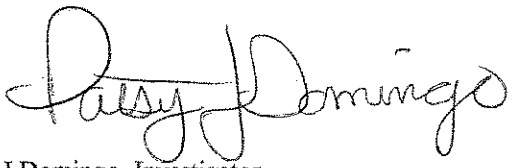
C. Deviation (b) (4) dated 1/17/05 initiated after finding plastic in sublot (b) (4) of lot 4M0896 has a documented short term action plan to interview the operator and no long term action plan.

OBSERVATION 6

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed.

SOP (b) (4) "Environmental Monitoring at the Airport Center Facility" in that the May 2004 monthly "Environmental Monitoring - Air" result exceeded the action limit for mold count, result recorded as "TNTCC", and no evaluation was performed and an OOS investigation was not initiated.

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:



Patsy J Domingo, Investigator

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