DEPARTMENT OF HEALTH AND HUMAN SEI ES
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	11/17/2009 - 01/14/2010 FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph Papa, President and CEO

FIRM NAME	STREET ADDRESS
L. Perrigo Co.	515 Eastern Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allegan, MI 49010-9070	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 WE OBSERVED:

OBSERVATION 1

Reserve drug product samples are not representative of each lot or batch of drug product.

A. There is no assurance that reserve samples, for finished packaged tablet drug products, include a representative sample of each of the bulk tablet batches manufactured/marketed. These lots were packaged prior to 6/25/09, and contain multiple bulk tablet batches packaged under the same lot number. Examples include but are not limited to:

Product Name	Product #	Lot Number	Exp. Date	No. of bulk lots/ bulk lots numbers
APAP 500 mg ETS Tablet 100's	227AA	8KE1113	07/10	4/ 8H0891, 8H1063, 8H1064, 8H1065
APAP 500 mg ETS Tablet 100's	227AA	8GE0008		4 / 8E1937, 8E1938, 8E1939, 8E1940
APAP 500 mg ETS Tablet 50's	227AA	8KE1203	07/10	3/ 8H0891, 8H1957, 8H1958
APAP 500 mg ETS Tablet 100's	227AA	9BE1544	11/10	4/ 8M4312, 8M5238, 8M5239, 9A3468
APAP 500 mg ETS Tablet 100's	227AA	9BE1619	11/10	4/ 9A3469, 9A3470, 9A3814, 9A3815
APAP 500 mg ETS Tablet 100's	227AA	9BE1864	11/10	3/ 9A3816, 9A3817, 9A3832
APAP 500 mg ETS Tablet 100's	227AA	9BE1984		3/ 9A3817, 9A3832, 9A3816
Ibuprofen 200 mg brown tablets	604AO	8DE0003	01/10	4/ 8C0145, 8C0146, 8C0147, 8C0148
Ibuprofen 200 mg brown tablets	604AO	8HE0214		4
Ibuprofen 200 mg brown tablets	604AO	8JE1516	08/10	3/8J2421, 8J2417, 8J2413
Ibuprofen 200 mg brown tablets	604AO	8CE0364		4
Ibuprofen 200 mg brown tablets	604AO	9BE1359	12/10	4/ 9A3776, 9A3777, 9A4274, 9A4276
Ibuprofen 200 mg brown tablets	604AO	9BE1360		3
Ibuprofen 200 mg brown tablets	604AO	9BE1433		3

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EMPLOYEE(S) SIGNATURE

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Martha Sullivan Myrick, Investigator Martha My
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Ibuprofen 200 mg brown tablets	604AO	9BE1438	11/10	4/ 8M4283, 8M4350, 8M4883, 8M4884
Ibuprofen 200 mg brown tablets	604AO	9BE1801		3
Ibuprofen 200 mg brown tablets	604AO	9BE1933		3
Ibuprofen 200 mg brown tablets	604AO	9BE1934	12/10	4/ 9A4298, 9A4299, 9A4300, 9A4897
Ibuprofen 200 mg brown tablets	604AO	9BE1935	12/10	4/ 9A4911, 9A4912, 9A4913, 9A4914
Ibuprofen 200 mg brown caplets	647AJ	9BE1350	12/10	4/ 8M5091, 9A3549, 9A3550, 9A3551
Naproxen Sodium 220 mg Caplets	368AB	9BE1435	09/11	4/ 8L3030, 8L3765, 8M3310, 8M3311
Naproxen Sodium 220 mg Caplets	368AB	9BE1384		3
Naproxen Sodium 220 mg Caplets	368AB	9BE1388	10/11	4/ 8M3312, 8M3403, 8M3949, 8M3951
Naproxen Sodium 220 mg Caplets	368AB	9AE2297	09/11	4/ 8M3254, 8M3306, 8M3309, 8M3310
Naproxen Sodium 220 mg Tablets	490AB	9AE1225	05/11	4/ 8F1762, 8F1763, 8G0113, 8G0114

B. Complaint follow-up may be hampered by the lack of a representative reserve sample:

Reserve samples collected prior to 6/25/09 were taken at the beginning, middle and end of the packaging run and did not include bulk specific samples. Since two, three or four bulk lots were utilized in the filling of many of the various lots, and product was packaged under any number of customer labels, assurance that a sample representing the lot the complainant's product came from is not always possible. For example:

1. Investigative follow-up for complaint 115400 received for APAP 500 mg ETS tablets batch 8KE1113 packaged under customer (b) (4) label, included opening one reserve sample from those maintained for the lot. Lot 8KE1113 included 4 bulk tablet batches and was packaged under (b) (4) customer labels. None of the reserve samples were for customer (b) (4)
2. Investigative follow-up for complaint 150135 received for Ibuprofen batch 8DE0003, included opening one reserve sample from those maintained for the lot . Lot 8DE0003 included 4 bulk tablet batches all packaged under the same customer label.
3. Investigative follow-up for complaint 124467 received for Naproxen Sodium batch 9AE1225, included opening one reserve sample from those maintained for the lot. Lot 9AE1225 included 4 bulk tablet batches with four of the 6 reserve samples collected from one customer label and 2 from another.
4. Investigative follow-up for complaint 147212 received for Naproxen Sodium batch 8GE0861packaged under customer (b) (4)

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label, included opening one reserve sample from those maintained for the lot. Lot 8GE0861 included 2 bulk tablet batches and "(b) (4)".

5. Investigative follow-up for complaint 129756 received for APAP 500 mg tab lot 9BE1864, included opening one reserve sample from those maintained for the lot. Lot 9BE1864 included 3 bulk tablet batches with four of the 6 reserve samples collected from one customer label and 2 from another.

OBSERVATION 2

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

A. Investigation of Deviation (b) (4) involving a cracked waste water pipe, located in the ceiling above the (b) (4) coating pan/suite, that had leak into the (b) (4) Coating Pan containing APAP 500 mg caplet batch 9A4360 did not extend to previous batches produced in this same equipment beyond the one batch completed 5 hours earlier that same day (Friday 1/30/09). The investigation cited increased use of the 2nd floor restroom as the "(b) (4) (b) (4), yet batches produced prior to Tuesday evening were not rejected or considered at risk. The last major cleaning, which would have included swabbing, of the coating equipment had occurred 10/15/08.

B. Investigation of deviation (b) (4) involving Ibuprofen brown Caplet lot 8ME1731 and the finding of an Ibuprofen brown Tablet in the filler slat while packaging on12/10/08, was not complete. The investigation documents there was an Ibuprofen brown Tablet lot 8ME1624 packaged on the same line from 12/8-9/08 with an Ibuprofen orange tablet lot 8ME1728 packaged in between these two lots. The investigation does not address the possibility of foreign tablet contamination of Ibuprofen orange lot 8ME1728, review of the packaging records for this previous batch, nor review of the cleaning record between the Ibuprofen brown tablet lot 8ME1624 and the Ibuprofen orange tablet lot 8ME1728.

OBSERVATION 3

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

A. SOP# (b) (4) (b) (4) written to assure all labeling meets legal and regulatory requirements was not followed with regard to editing and verifiying label content for Cherry flavored Milk of Magnesia for one of your customer's. This failure resulted in product incorrectly labeled as sugar free to be marketed for seven months. Examples include: Lot numbers 9DK0168, 9DK0376, 9EK0118, 9EK0173, 9EK0367, 9EK0525, 9FK0044, 9FK0256, 9FK0425, 9FK0521, 9GK0049, 9GK0308, 9GK0436, 9GK0668, 9HK0106, 9HK0285, 9HK0372, and 9JK0126.

B. SOP # (b) (4) (b) (4) was not followed with regard to verifying the Ingredient Disclosure and Excipeint threshold Limit for completeness and accuracy when the 6/2/2008 and 8/8/2008 changes were made to the Final Ingredient Disclosure documents for Milk of Magnesia Regular (formula (b) (4) and Milk of Magnesia Mint (formula (b) (4) flavors. Calculation errors resulting in incorrect magnesium and calcium content declared on the product label for multiple customers and the recall of over 200 lots in total for the two products.

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C. SOP # (b) (4) (b) (4) "; written to assure a partial batch identified as needing to be reworked, or rejected, was not followed for Ibuprofen 200 MG tablet lot 9BE1961. A portion of this batch ((b) (4) bottles) rejected due to metal contamination was released, shipped, and subsequently recalled.

D. SOP (b) (4) " [redacted] " was not followed with regard to process capability analysis (Cpk) for Product Code 086 FM Laxative Tablets during the Annual Product Review dated 2/1/2008 to 1/31/2009. The SOP requires the [redacted]

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

A. SOP (b) (4) "(b) (4) [redacted] " allows for a single AQL acceptance sampling when additional overweight/underweight "suspect" tablets are observed after the passing sample evaluation. "No further action is required". The following are examples where a second finding of oversized tablets, within the same packaging operation, did not trigger a quality evaluation of the entire lot:

1. One oversized tablet was found in the filler slat during packaging of material (b) (4) (Ibuprofen 200mg brown Tab) lot 8JE1516 from bulk batch 8J2421 on 9/26/08. An AQL sample found no oversized tablets. Packaging continued and a second oversized tablet was found for the same bulk batch. No sampling was performed following the 2nd oversized tablet find. An additional 16 oversized tablets were found while running out the filler for bulk batches 8J2421, 8J2417, and 8J2413 (all packaged as lot 8JE1516). A second AQL sampling found no suspect tablets and the batch was released.

2. One oversize tablet was found in the filler during the packaging of bulk batch 9C3919, Material (b) (4) (Ibuprofen 200mg brown Tab) as lot 9DE2068, on 04-30-09. AQL sampling and inspection found no suspect tablets. Packaging resumed. According to COMMENT Page in batch record an additional 16 oversized tablets were found in batch 9C3919. Packaging again resumed and another 16 oversized tablets were found in the filler during the end of batch 9C3919.

3. Two oversized tablets were found (5/8/09) during packaging of bulk batch 9B3683, product 074AC (Ibuprofen Orange 200mg Tablets) as lot 9FE1546. AQL sampling found no oversized tablets. Packaging of bulk batch 9B3683 continued and one additional oversized tablet was found on 5/10/09. A second AQL sampling found no suspect tablets. A third event with three additional oversized tablets were noted in bulk batch 9B3683 and the third AQL sampling found 2 oversized tablets - "sampling plan fails" per SOP (b) (4) On 6/1/09 Deviation (b) (4) was opened as a result of this 3rd AQL sample failure.

B. There have been upwards of (b) (4) oversized tablet instances in the last year with 50 of these considered by Quality Assurance to be low risk (b) (4) per SOP (b) (4). In multiple cases no investigation beyond an AQL sample pulled at the point the oversized tablet(s) were found occurred during the packaging run. In most instances, sampling did not involved the

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portion of the batch already packaged. During this same time period two different Project Teams, (b) (4) and (b) (4) existed due to the noted oversized tablet problem. Examples include:

Date	Product	Lot	Incident #	Findings
9/5/08	IB 200 mg	8JE0709	(b) (4)	AQL passed
9/13/08	IB 200 mg	8JE1037		AQL passed
9/17/08	IB 200 mg	8JE1104		AQL passed
12/12/08	IB 200 mg	8ME1661		AQL passed
3/17/09	IB 200 mg	9CE2424		AQL passed
3/17/09	IB 200 mg	9CE2424		AQL passed
3/23/09	IB 200 mg	9CE2722		AQL passed
3/25/09	Aspirin 325	9CE2249		AQL passed
4/4/09	IB 200 mg	9C4369		AQL passed
5/27/09	IB 200 mg	9EE1532		AQL passed
6/20/09	IB 200 mg	9FE2144		AQL passed

OBSERVATION 5

Inspection of the packaging and labeling facilities immediately before use is not done to assure that all drug products have been removed from previous operations.

The following are examples of line clearance problems

A. The following are examples (deviations) that document inadequate packaging line clearance resulting in foreign tablets found in product stream portion of the equipment while packaging a different product:

Deviation #	Date	Product Involved	Foreign product
(b) (4)	12/10/08	Ibuprofen Brn. Caplet lot 8ME1731	Ibuprofen tablet
	2/13/09	Ibuprofen Caplets lot 9BE1926	Ibuprofen tablet
	4/10/09	Ibuprofen Brn. Caplets lot 9DE1562	Ibuprofen orange caplets

B. The following deviations/complaint investigations pertain to investigation of complaints of foreign tablets found. In each case the foreign tablet found was the same product packaged just prior to the complaint lot:

Deviation #	Date	Product Involved	Foreign product

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[redacted]	5/11/09	Naproxen Sodium tablet lot 9AE1225	Naproxen Caplet
	7/14/09	Naproxen Sodium tablet lot 9AE1225	Naproxen Caplet
	8/26/09	Naproxen Sodium Caplets lot 8GE0861	Naproxen tablet
	10/29/09	APAP 500mg fast rel. gelcap lot 9HE2087	APAP caplets

C. Multiple incidents, deemed to be low risk with no formal investigation, of:
"failed" or "improper" line clearances, foreign tablet(s) found, foreign bottle found or foreign cap found during packaging operation. Example includes: Incident # [redacted] dated 10/27/09, - line clearance issue as previous product found at the base of the [redacted] filler.

OBSERVATION 6

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Annual product reviews conducted May, 2009 to the present, for tableted products packaged in opaque plastic bottles, did not include evaluation of the reserve samples for deterioration. For example:

Naproxen Sodium 220 mg Caplet annual product review period 8/1/08-7/31/09 for the [redacted] reserve samples documented to have been reviewed, zero were opened.
In total, the annual review conducted May, 2009 to present, for [redacted] different formulas/products, were performed without evaluating the samples for deterioration.

OBSERVATION 7

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

A. For the following manufacturing equipment, cleaning procedures have not been shown (validated) to be effective for the campaign lengths currently planned and executed for the various products listed below:

[redacted] cu ft [redacted] blenders	multiple products including: 194 (Famotidine 20 mg Tab), 552, 402, 094, 223, 234, 272 (APAP PE Sinus 325 mg Caplet), 355, 364XA, 431, 437, 476, 479, 03437, 04437, 04837, 33560, 34251, 34414, 34660
[redacted] Pot	multiple products including: 31690, 33843, 33866, 34200, 34250, 34283, 34660 (IM Diphen Citrate Gran)
[redacted] coating pans	multiple products including: 4V6AC, 477AE (Fiber Laxative), 054AA, 368AB (Naproxen Sodium Caplets), 490AB, 919AA,

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484AK (APAP 500 mg Caplets)

For example (b) (4) pan 1 (b) (4) was used to process (b) (4) batches of product 484AK (APAP 500 mg Caplets), from 10/17/08 - 1/30/09, since the last "Major" cleaning had occurred.

B. For the (b) continuous coaters, no validation data exists regardless of the campaign length:

Product Numbers associated
604AO, 604AJ (Ibuprofen tablets)
647AJ (Ibuprofen Caplets)
074AC (Ibuprofen 200 mg Orange Tablet USP)
517AC (Ibuprofen 200 mg Orange Tablet USP)
368AC (Naproxen Sodium Caplets)
490AC (Naproxen Sodium Tablets)
484AO, 484AS (APAP 500 mg Caplet)

C.Cleaning validation does not always include all possible contaminants. Specifically:
1- Cleaning between orange and brown Ibuprofen products families does not take into account FD&C Red No. 40 and Yellow No. 6 used in the Orange product but not in the brown product.
2- In addition, validation for the (b) (4) for PAI submission (b) (4)

(b) (4)

D.
1- the (b) (4) mixer (b) (4) in suite (b) (was identified as having a "crack". There was no evidence on the equipment/ maintenance log of this crack and the bowl contained Product 7559 batch 9L4188 on 11/18/09. On Friday 11/20/09 management informed the investigators the crack was identified on Sunday 11/15/09 by the third shift. The identification was placed on the (b) (4) but no personnel was verbally notified. An assessment was completed and a work order was submitted to repair the crack on 11/18/09 after the FDA inquired as to the status and meaning of the "crack" written on the outside of the mixer bowl.

2- Deviation (b) (4) dated 2/6/09 for Batch 9A4963 product 409AB Naproxen Sodium 220 TAB discovered rinse water at clean was pink tinged. The investigation concluded the utensils used were not cleaned. This was concluded during an interview of cleaners 10 days post cleaning.

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OBSERVATION 8

There was a failure to handle and store components at all times in a manner to prevent contamination.

The following are examples (rejects) where operators did not follow the procedures adequately to prevent contamination of material:

1- RID ID (b) (4) material (b) (4) (RM IBUPROPHEN USP) dated 20090909 where (b) (4) kg of lot 9147289 material 17628 was mixed with a different raw material 26607 lot 9148469.

2- RID ID (b) (4) Material (b) (4) (RM FLAVOR GIV) dated 20090710 where (b) (4) kg of lot 9137556 was dumped into a dirty bucket.

3- RID ID (b) (4) Materia (b) (4) (RM FLAVOR) dated 20081029 where the container was not cleaned out before dispensing of (b) (4) kg of lot 8085226.

4- RID ID (b) (4) Material (b) (4) (RM METHYLSILCYLATE) dated 20081125 where (b) (4) kg was placed into a contaminated container.

5- RID ID (b) (4) Materia (b) (4) RM ACETAMINOPHEN USP) dated 20090217 where (b) (4) kg of lot 8099007 was dispensed into a used flavor bucket. According to the RID, Perrigo does not reuse flavor drums in the dispensing area due to the strong odor that is left in the drums.

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