

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 | DATE(S) OF INSPECTION 11/07/2006 - 12/15/2006 |
| | FEI NUMBER 1811666 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare

| | |
|---|--|
| FIRM NAME L. Perrigo Company | STREET ADDRESS 515 Eastern Ave. |
| CITY, STATE, ZIP CODE, COUNTRY Allegan, MI 49010 | TYPE ESTABLISHMENT INSPECTED Rx and OTC 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

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Investigations resulting in For Cause metal detection manufacturing orders lacked documented conclusion and follow up. No comparison of the description and type of metal fragments found and isolated by quality control from rejected tablets, to the deviation initiating the For Cause metal detection run was documented.

For example,

a- metal detection manufacturing orders performed 12/2004 on Acetaminophen 500 mg caplet, product (b) (4), lot numbers (b) (4) resulted in QC lab findings of wire like metal fragments though the deviation was initiated because of plenum wear noted in the coating equipment.

b- metal detection manufacturing order for (b) (4) was performed 7/2006 as a result of a deviation investigation (deviation (b) (4)) regarding finding a Hex Nut during compression. The metal detection order resulted in (b) (4) tablets rejected for metal. Fragments isolated by QC from these rejected tablets revealed wire like metal.

In each of the above examples, no further investigation into the wire like metal found by QC from the analysis as part of the initial investigation was performed and documented.

OBSERVATION 2

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. Investigational findings revealing microbiological contamination in a receipt of starch material (b) (4), Perrigo Batch Number (b) (4) supplied to the firm for use in products (b) (4) tablet manufacture, resulted in corrective actions including an increase in sampling of this starch material upon receipt of subsequent batches, and review of

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

**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 | | 11/07/2006 - 12/15/2006 |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | | FEI NUMBER |
| TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare | | 1811666 |
| FIRM NAME | STREET ADDRESS | |
| L. Perrigo Company | 515 Eastern Ave. | |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED | |
| Allegan, MI 49010 | Rx and OTC drug manufacturer | |

supplier practices including shipment and storage.

This investigation (Notification (b) (4)) dated 8/11/05 did not extend to other raw materials to determine if the implemented corrective action should also be applied, or document the rationale supporting the decision not to extend the corrective action.

B. For complaint "Case # (b) (4) received 10/2/2006, the (b) (4) complaint received for product (b) (4) related to degradation issues, the investigation is deficient for the following:

1. the Complaint History Evaluation contains the statement that (b) (4)
2. This same history fails to acknowledge the fact that complaints of vinegar smell (1/27/06) and vinegar smell and funny sour taste" (9/22/06) were also received for this same lot.
3. Examination of the returned consumer sample also noted fibers on the product in the bottle;
4. Lab evaluation and stability data evaluation were deemed to be not in the scope of the investigation without documentation of the rational
5. No stability data to support the 36 month expiration assigned this package size;
6. no root cause was determined and no corrective action required. The lot was stated to be (b) (4) " based on the results of the investigation.

In addition it was determined that none of the complaints received for this lot were forwarded to the contract manufacturer.

C. For complaint # (b) (4) , received 2/20/06, involving product (b) (4) Exp. date 5/31/07 reported (b) (4) ", that some of the tablets were stuck together, and that a funny odor was coming from the bottle, the following deficiencies:

1. The documented Product Complaint History noted (b) (4) complaints of bad smell and (b) (4) complaints of tablets sticking together in the previous 6 months. Retain samples were not inspected, no testing was performed with out rational. No root cause was determined, and no corrective action was required. This report contains the statement (b) (4) " Product stability was not considered as part of this complaint's investigation plan. This product is contract manufactured and there is no indication that the contract manufacturer was notified of the complaint.

OBSERVATION 3

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

1. SOP (b) (4) " does not specify that all packaging configurations be included in the statistical evaluation of a given product. Review of the Reserve Sample Inspection Forms completed for the Product Code (b) (4) (Adult Low Strength Enteric Coated Aspirin Tablets) finds no evaluation of lots representing those manufactured by your contract manufacturer (b) (4) packaged in 500 count bottles. Of the (b) (4) lots selected for the (b) (4) formula, for the review period covering 4/1/2005-3/31/2006; 8/300's, 4/120's and 1/365 count lots were chosen to represent production years 2003-2006. Representing the 2004 and 2005 batches, only 300 count packaged lots were selected. Formula

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

**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 | 11/07/2006 - 12/15/2006 |
| | FEI NUMBER |
| | 1811666 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare

| | |
|--------------------------------|------------------------------|
| FIRM NAME | STREET ADDRESS |
| L. Perrigo Company | 515 Eastern Ave. |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Allegan, MI 49010 | Rx and OTC drug manufacturer |

(b) (4) has been packaged in 500 count bottles since prior to 2002. Examples would include but are not limited to lot numbers: (b) (4).

2. (b) (4) " was not followed with regard to Process Capability Analysis (Cpk) for product (b) (4) (81 mg Enteric Coated Aspirin) manufactured by Perrigo. The Cpk value for the most recent review period (4/1/2005-3/31/2006) was noted to be below (b) (4). According to (b) (4) a Cpk value of (b) (4) for the aspirin assay should have resulted in a project plan for product evaluation by Technical Operations. As of 11/14/06 this had not been initiated.

3. (b) (4) " requires an evaluation of the occurrence of the deviation as part of a (b) (4) tool. In the following deviation investigations, there were inconsistencies in the criteria analyzed in determining the occurrence or resultant deviation code entered into the deviation tracking database upon conclusion of the deviation investigation. This information is used in calculating the Level of Investigation required in the current deviation and any subsequent deviations that may be generated. For example:

a- Deviations (b) (4) pertaining to (b) (4) Acetaminophen 500 mg cool caplet, batch (b) (4) and (b) (4) pertaining to (b) (4) Acetaminophen 500 mg caplet, batch (b) (4) both involved damage to a security screen used in raw material charging operations, and both occurred in plant (b) (4) on Equipment/Line: (b) (4). The occurrence determination for (b) (4) reviewed work orders processed in "Mix" areas of production while (b) (4) reviewed work orders processed in both "Mix" and "Compression" areas of production.

b- Deviation (b) (4) and (b) (4) both pertained to product (b) (4) and both resulted in a root cause conclusion that the deviation was due to the raw material - supplier (the same supplier in both deviations). Both deviations also concluded finding foreign material in the incoming supplier raw material. Deviation (b) (4) was coded as Solid Contamination - Foreign while Deviation (b) (4) was coded as Solid Contamination - Metal. Deviation (b) (4) did not appear on a requested list of all deviations pertaining to Metal Contamination.

OBSERVATION 4

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.

Representative samples selected for the annual visual exam are not opened and examined for signs of deterioration.

Examples include:

| Product # | Name | # of Batches Selected | # of Samples Opened |
|-----------|---------------|-----------------------|---------------------|
| (b) (4) | 81 mg Aspirin | (b) (4) | 1 |
| (b) (4) | 81 mg Aspirin | (b) (4) | 1 |

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 | DATE(S) OF INSPECTION 11/07/2006 - 12/15/2006 |
| | FEI NUMBER 1811666 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare

| | |
|---|--|
| FIRM NAME L. Perrigo Company | STREET ADDRESS 515 Eastern Ave. |
| CITY, STATE, ZIP CODE, COUNTRY Allegan, MI 49010 | TYPE ESTABLISHMENT INSPECTED Rx and OTC drug manufacturer |

| | | | |
|---------|---------------------|---------|--|
| (b) (4) | Ibuprofen 200 mg | (b) (4) | |
| (b) (4) | Mint Liq. Antacid | (b) (4) | |
| (b) (4) | Loperamide HCl | (b) (4) | |
| (b) (4) | APAP Ext. Rel Cplt. | (b) (4) | |
| (b) (4) | Naproxen 250 mg, Rx | (b) (4) | |
| (b) (4) | Naproxen 375 mg Rx | (b) (4) | |

* opened during an investigation which lead to a recall for incomplete logo
** 5 lots packaged in blisters were visually observed but not opened

OBSERVATION 5

Results of stability testing are not used in determining expiration dates.

For enteric coated 81 mg aspirin, product code (b) (4), the decision to label 500 count bottles with a 36 month expiration date was not supported by stability data for this package size. The only available stability data supporting 36 months, for lots produced since 2000, was for 120 count bottles. The only lot packaged in 500 count bottles placed on stability in 2004, lot (b) (4) failed drug release at the 24 month test point. There is no stability data available to support the 36 month expiration date assigned to (b) (4) lots with labeled expiration dates from 1/07 - 1/09.

OBSERVATION 6

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

1. Written procedures do not exist for the maintenance of product transfer hoses used in the liquids manufacturing processes located in Plant (b) (4). Product transfer hoses are not identified so as to track when they are placed into service. Reportedly a length of service has not been established for these multi product hoses which are cleaned with the same detergent as the holding tanks. For example:

| Product # | Name | Lot # |
|-----------|-----------------------------------|---------|
| (b) (4) | APAP PSE Free Infant Cherry Drops | (b) (4) |
| (b) (4) | Ibuprofen Suspension | |
| (b) (4) | Daytime PE Original 6 hour | (b) (4) |
| (b) (4) | Children's IB Suspension Berry | (b) (4) |
| | Moist Nasal Spray | (b) (4) |

2. Standard Operating Procedure (b) (4), states that procedure (b) (4) is used: for manufacturing equipment that will not be used to hold suspension formulas. This procedure was used to clean the (b) (4) pre Mix tank (b) (4) after and before product (b) (4) (b) (4) Batch (b) (4). SOP (b) (4) states that procedure (b) (4) should be used for Antacid, Ibuprofen/APAP Suspension Formulas.

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

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 | 11/07/2006 - 12/15/2006 |
| | FEI NUMBER |
| | 1811666 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare

| | |
|--------------------------------|------------------------------|
| FIRM NAME | STREET ADDRESS |
| L. Perrigo Company | 515 Eastern Ave. |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Allegan, MI 49010 | Rx and OTC drug manufacturer |

OBSERVATION 7

Investigations of a failure of a batch or any of its components to meet any of its specifications 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.

Consumer complaint (b) (4) 4 dated 4/4/06 reported finding 3 foreign tablets, identified as Perrigo's (b) (4) (APAP 500 mg caplets) mixed inside a bottle of Perrigo's Naproxen Sodium 220 mg Caplets lot (b) (4). Investigation conducted under deviation (b) (4), initiated 4/5/06, did not determine a definitive root cause for this deviation. However, it also did not include an evaluation of remaining inventory of the complaint lot despite noting a 4 hour packaging overlap on "adjacent" packaging lines for the complaint lot (b) (4) and a lot (b) (4) of the APAP 500mg caplets product noted by a consumer to be mixed with it.

OBSERVATION 8

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

Written procedures did not coincide with established in process control documents in the following:

a - Coating solution hold study, SAN (b) (4) supporting coating solution hold times specified a flush of "at least 200mL of solution" through the bottom valve prior to sampling for microbiological analysis. SOP (b) (4) also requires a flush prior to starting the coating process, but does not specify an amount. Additionally, batch card coating instructions reviewed for product (b) (4) were observed specifying only a 100g sample (for appearance testing) required to be collected prior to coating.

b - The Process Qualification Report for this same hold study (SAN (b) (4)) did not encompass a worst case scenario as permitted per incoming raw material specifications regarding microbial limits, particularly for (b) (4) limits.

Specifically, as stated in the study, (b) (4)

(b) (4)

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 | DATE(S) OF INSPECTION 11/07/2006 - 12/15/2006 |
| | FEI NUMBER 1811666 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare

| | |
|---|--|
| FIRM NAME L. Perrigo Company | STREET ADDRESS 515 Eastern Ave. |
| CITY, STATE, ZIP CODE, COUNTRY Allegan, MI 49010 | TYPE ESTABLISHMENT INSPECTED Rx and OTC drug manufacturer |

Additionally (b) (4)

c- Review of deviation (b) (4) dated 12/01/05 for batch (b) (4), (b) (4), Children's Ibuprofen Suspension, found that the operator failed to notify appropriate personnel when the (b) (4) 2 mixer added an additional (b) (4) of corn syrup for sub (b) (4). In the operating batch card instructions, the employee is to notify appropriate personnel when the addition of any material added is over (b) (4).

d- SOP (b) (4) Equipment cleaning and use logs states that equipment repairs are to be recorded on the equipment cleaning and use logs. This is not always documented as observed during the review of batch records and equipment logs for line (b) (4). Example Batch (b) (4) dated 11/28/06.

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

The method of charging RM (b) (4) into a tote during manufacture of Acetaminophen 500 mg caplet, product (b) (4), as observed on 11/07/06, revealed metal on metal contact at the hopper - tote interface through which the charged raw material passes.

OBSERVATION 10

Deviations from written production and process control procedures are not justified.

Fryma Cleaning procedure as documented in the protocol SAN (b) (4), for validation of the (b) (4) cleaning agent, included hand written changes to the directions for batch (b) (4) dated 11/8-9/06 and Batch (b) (4) dated 11/20/06 without justification for these changes or documented evidence that these changes were included in the on going validation of the clean.

| | |
|---------------------------------|---------------------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED 12/15/2006 |
|---------------------------------|---------------------------|

**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 | | 11/07/2006 - 12/15/2006 |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | | FEI NUMBER |
| TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare | | 1811666 |
| FIRM NAME | STREET ADDRESS | |
| L. Perrigo Company | 515 Eastern Ave. | |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED | |
| Allegan, MI 49010 | Rx and OTC drug manufacturer | |

OBSERVATION 11

Employees are not given training in the particular operations they perform as part of their function.

Deviation (b) (4) concluded the cause was an error by the operator in dispensing, by failing to tare container 88 prior to dispensing sodium benzoate for sub lot (b) (4). This dispensing failure lead to OOS result for Sodium benzoate in Product (b) (4) (Ibuprofen Suspension). While manpower was found to be the root cause, there is no documentation that the persons responsible were trained in the correct procedures.

In addition, deviation (b) (4) (b) (4) Infant suspension drops Batch (b) (4), noted manpower again as the reason for the deviation. The LIMS technician failed to make the required changes to the limit levels for Acetaminophen Assay. While the first line persons responsible were addressed, there is no documentation that the persons responsible for the secondary review, whom also did not detect the reason for the deviation, were alerted of their oversight.

Also, deviation (b) (4) dated 12/01/05 for batch (b) (4), product (b) (4), Children's Ibuprofen Suspension, which resulted in the over addition of corn syrup by (b) (4) did not address the fact that the operator failed to follow the batch record instructions which states that an addition over (b) (4) of any raw material should be brought to the supervisors attention. The deviation did not document any training of the persons involved.

OBSERVATION 12

The written stability testing program is not followed.

Specifically, Ibuprofen Suspension Product code (b) (4) Stability Testing Program states that the first (b) (4) commercial production lots of Product packaged in each size will be placed on stability. There is no documentation that (b) (4) lots of PC (b) (4) 8oz were ever placed on stability even though this product has been shipped as evident by lot (b) (4). Also, there is no evidence that the first (b) (4) 4oz or 8oz (which was the result of a formula change) nor the first (b) (4) lots of (b) (4) 4 oz or 8oz (which was also a result of a formula change) were placed on stability as dictated by the stability protocol. All sizes (4oz and 8oz) and formula changes (b) (4) have been released for shipment. The current product code is (b) (4) 4 oz and 8oz.

OBSERVATION 13

Established sampling plans are not followed.

SOP (b) (4) " states that if a batch is stopped prior to completion, then contact must be made to the QC lab, Microbiology lab and Quality to ensure the quantity of samples pulled is appropriate and

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 | DATE(S) OF INSPECTION 11/07/2006 - 12/15/2006 |
| | FEI NUMBER 1811666 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare

| | |
|---|--|
| FIRM NAME L. Perrigo Company | STREET ADDRESS 515 Eastern Ave. |
| CITY, STATE, ZIP CODE, COUNTRY Allegan, MI 49010 | TYPE ESTABLISHMENT INSPECTED Rx and OTC drug manufacturer |

the reason for being down should be documented on the batch record and Record of Test Samples. There is no documented evidence to assure this step in the procedure is followed when the packaging line goes down. For example Batch (b) (4) PC (b) (4) line (b) (4) dated 11/05/06 and Batch (b) (4) dated 11/28/06.

OBSERVATION 14

The entries in the equipment cleaning and use logs are not in chronological order.

Equipment cleaning and use logs are not in chronological order when the production process is down for any period of time and a line cleaning is perform. For example:

a- line (b) (4) Batch number (b) (4) Daytime PE 6Hr Original Liquid (b) (4) shows production start of 11/28/06 at 2225 and end production at 11/30/06 at 0045. The next entry was a Cleaning SOP (b) (4) Part 4 performed on 11/29/06 at 1058 and ended at 11/29/06 at 1114. The restart of the production lot was not entered on a separate line after the cleaning entry.

b- line (b) (4) Batch (b) (4) IB 100mg Children Suspension (b) (4) started production at 11/29/06 at 0200 and ended 11/30/06 at 1450. The next entry was a cleaning procedure SOP (b) (4) performed on 11/30/06 at 0810 and ended 11/30/06 at 0936. The restart of the production lot was not entered on a separate line after the cleaning entry.

OBSERVATION 15

Written records of major equipment maintenance are not included in individual equipment logs.

Maintenance on lines is not always written on the equipment cleaning and use logs as noted during the review of batch records and entry logs for line (b) (4). Example Batch (b) (4) dated 11/28/06.

OBSERVATION 16

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

Specifically, premix tanks are used to hold cleaning solution (b) (4) for in line cleaning of line (b) (4) as part of SOP (b) (4). No verification testing has been documented to show that (b) (4) is adequate to remove any residue from (b) (4) before being used to pre mix product for the (b) (4) mixers. Both the (b) (4) a mixers and the premix tanks have not been validated to be cleaned with (b) (4). For example the premix tank (b) (4) was used as part of the cleaning of line (b) (4) on 11/27/06 and then (b) (4) clean was done of the premix tank on 11/27/06 before being used to premix product for Lo (b) (4) on 11/28/06.

| | |
|---------------------------------|---------------------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED 12/15/2006 |
|---------------------------------|---------------------------|

**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 | | 11/07/2006 - 12/15/2006 |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | | FEI NUMBER |
| TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer Healthcare | | 1811666 |
| FIRM NAME | STREET ADDRESS | |
| L. Perrigo Company | 515 Eastern Ave. | |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED | |
| Allegan, MI 49010 | Rx and OTC drug manufacturer | |

OBSERVATION 17

Batch production and control records do not include complete information relating to the production and control of each batch.

Batch records do not always include the reason the line was down as dictated by the SOP (b) (4) example Batch (b) (4) date 11/05/06 the line was down between 0706 and 2002 without documented reasoning for this down time.

OBSERVATION 18

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

Specifically, sampling of pumps, product code (b) (4), used in nasal products is not representative of the lot. Verification testing for the pumps includes one sample regardless of lot size. Deviation (b) (4) for bent spray nozzle for lot (b) (4) dated 10/5/05 for product (b) (4) batch is an example of this. Incoming inspection of product (b) (4), 8/27/05, (b) (4) pumps received was visually examined.

OBSERVATION 19

Complaint records are deficient in that they do not include the known reply to complainant.

Specifically, complaint files do not always include a copy of the reply sent to the complainant and hard copies of the complaint handling program (b) (4) does not show documentation that the "type of letter" field is always complete when and if a reply is sent. For example closed complaint (b) (4) dated 11/29/06, (b) (4) dated 11/29/06.

| | |
|---------------------------------|-------------|
| SEE REVERSE OF THIS PAGE | DATE ISSUED |
| | 12/15/2006 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

300 River Place, Suite 5900
Detroit, MI 48207
(313) 393-8100 Fax: (313) 393-8139

DATE(S) OF INSPECTION

11/07/2006 - 12/15/2006

FEI NUMBER

1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John T. Hendrickson, Executive Vice President & General Mgr. Consumer
Healthcare

FIRM NAME

L. Perrigo Company

STREET ADDRESS

515 Eastern Ave.

CITY, STATE, ZIP CODE, COUNTRY

Allegan, MI 49010

TYPE ESTABLISHMENT INSPECTED

Rx and OTC drug manufacturer

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Patsy J Domingo, Investigator

Martha Sullivan Myrick, Investigator

Rebecca E. Dombrowski, Investigator

**SEE REVERSE
OF THIS PAGE**

DATE ISSUED

12/15/2006