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 Industry Information: www.fda.gov/oc/industry	09/08/2014 - 09/16/2014* FEI NUMBER 1000518646

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David J. Schrage, Vice President Holland Operations

FIRM NAME	STREET ADDRESS
L. Perrigo Company	13295 Reflections Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Holland, MI 49424-8220	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:

LABORATORY SYSTEM

OBSERVATION 1

The reproducibility of test methods have not been established and documented.

Specifically,

No documentation was provided to demonstrate that analysts performing foreign matter testing on raw materials, tablet mixes, and granulations are capable of detecting foreign matter at the level specified in procedures ST-2524 "Foreign Matter in Raw Material, Tablet Mixes, or Granulation" and ST-124 "Foreign Matter in Raw Material and Purchased Products". Both procedures state that significant foreign matter is defined as any particles over (b) (4) of sample. Foreign matter is detected using a magnet and the naked eye.

Analysts are trained using a training lot consisting of 100g of a sample material with foreign matter seeded in the sample. There is no procedure describing how to create the training lot (i.e. materials chosen based on type and color, foreign matter materials and size). Some analysts were trained using (b) (4). The current training lot in use is (b) (4). Employee (b) (6) was trained on this method using this training lot on 10/22/13. This training lot did not include foreign matter small enough (less than (b) (4) mm) to fully validate the test method.

This same employee performed method ST-2524 to evaluate IM Naproxen Sodium Gran lot #4A3471, 4A3472, 4A3473, and 4A3474 on 2/15/14 and recorded a passing result for significant foreign matter particles. These lots of Naproxen Sodium Gran were used in FM Naproxen NA 220 CPLT lot #4C2154V released on 5/12/14.

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OBSERVATION 2

Established test procedures are not documented at the time of performance.

Specifically,

Drug product "FM Esomeprazole MG DR 20 mg Capsules", banded batch number 3G4844, was approved for release from your facility without a documented test procedure specified for the testing of the release requirement "Intactness of band" on 8/15/13.

FACILITIES & EQUIPMENT SYSTEM

OBSERVATION 3

Records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

1. (b) (4)) was used in the production of several drug product lots manufactured between 2-5/2013 without being fully qualified and approved for use by the Quality department. The Equipment Qualification Validation Protocol (SAN: MFG-459) was endorsed on 12/28/2012 and approved by Quality on 5/14/2013 upon successful execution. Drug product lots manufactured with (b) (4) during this period include, but are not limited to: Nicotine 4mg Lozenge Peppermint, lot #3B3764, on 2/21/2013, and APAP PE Sinus 325mg Caplet, lot #3D2782, on 4/13/2013.

2. (b) (4) Press Work Center (b) (4)) was used in the production of several drug product lots manufactured between 11/20/2013 - 5/23/2014 while your firm's SAP equipment status listed it as out-of-service. The status (b) (4) Press Work Center (b) (4)) was not changed in SAP from out-of-service to in-service following successful completion of a maintenance repair on 11/19/2013 and a (b) (4) preventative maintenance (PM) performed on 11/20/2013. As a result (b) (4) month PMs were missed during the period from 11/20/2013 - 05/23/2014. This was attributed to a second *Equipment Control Sheet* form (PMH-FRM-D-85) that was not completed and submitted to the Maintenance System Administration for entry into the SAP system, as required per PMH-SOP-D-85 v. 2.0 *Equipment Control Sheet*. Examples of drug product lots manufactured with (b) (4) during this period include, but are not limited to: Alertness Aid Tablets, lot #3M3489, on 12/26/2013 and Chlorpheniramine Maleate Tablets, lot #3M2746V on 2/27/2014. A similar incident involving incorrect SAP equipment status included (b) (4)).

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*** DATES OF INSPECTION:**
09/08/2014(Mon), 09/09/2014(Tue), 09/10/2014(Wed), 09/11/2014(Thu), 09/12/2014(Fri), 09/16/2014(Tue)

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