DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969	07/07/2008 - 07/31/2008* FEI NUMBER 2211583

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Roy J. Pera, Director of Operations, Site Leader

FIRM NAME	STREET ADDRESS
McNeil PPC Inc.	100 Jefferson Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Parsippany, NJ 07054	Medical Device and Pharmaceutical 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Medical Device Observations

OBSERVATION 1

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically, complaints maintained in the firm's electronic Product Quality Management System (PQMS) that meet Automatic System Closure ("AUTOCLOSE") criteria may never be investigated to determine whether the complaints are related to nonconformities in production or design processes. For example, the following Visine for Contacts adverse event complaints were "autoclosed" in the PQMS system without investigation:

Tracking No.	Lot/Control No.	Event Description
30000084439	0107101	"consumer (sic) used product and had allergic reaction had to go to ER, had burning and halo sight, even had hearing problem, has been told that a perservative (sic) in our product that can cause a (sic) allergic reaction by opthomologist (sic)"
30000084307	0106353	"cons. (sic) put 3-4 drops in her left eye and immediately had a burning sensation and blurred vision/flushed eye out with water and did not call HCP/sx's"
30000083712	0107262	"Consumer used product and developed a burning sensation in eyes."
30000103643	0107307	"was (sic) using product and the product got on his cheeks and he said his face became swollen and red and it burned. he (sic) still has the burning but it is getting better"
30000104112	Not available	"The burning the drops caused was extremely painful. Visine for contacts would be a good choice with my new contacts. (sic) I was terribly wrong."

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OBSERVATION 2

The corrective and preventive action procedures addressing the investigation of the cause of nonconformities relating to product, processes, and the quality system were not complete.

Specifically, Quality Assurance Report (QAR) Procedure No. 2222, Version 4.0 used to investigate, review, and document deviations from product and process procedures, methods, specifications, etc., does not contain provisions to ensure product design activities are considered for investigation as a potential cause of product nonconformity where applicable.

OBSERVATION 3

Not all data from quality data sources are analyzed to identify existing and potential causes of nonconforming product and other quality problems.

Specifically, adverse event complaint descriptions contained within monthly "ADVERSE EVENT REPORT FOR QUALITY CONTROL" reports used to communicate quality data regarding closed adverse event complaints (as determined by the J&J Benefits Risk Management/Global Product Safety Group) to manufacturing locations contain abbreviated adverse event descriptions. For example, the chart below contains descriptions of Visine for Contacts adverse event complaints "autoclosed" within the firm's electronic Product Quality Management System (PQMS) and descriptions of the same complaints contained within monthly quality reports provided by the Benefits Risk Management/Global Product Safety Group ("BRM/GPS"). The quality data contained within the PQMS event description was not captured for analysis by this manufacturing location's Corrective and Preventive Action system.

Local Ref. No.	PQMS Event Description	BRM/GPS Monthly Report Description
007550720A	"consumer (sic) used product and had allergic reaction had to go to ER, had burning and halo sight, even had hearing problem, has been told that a perservative (sic) in our product that can cause a (sic) allergic reaction by opthomologist (sic)"	"hypersensitivity"
007541148A	"Consumer used product and developed a burning sensation in eyes."	"eye irritation"
007761899A	"was (sic) using product and the product got on his cheeks and he said his face became swollen and red and it burned. he (sic) still has the burning but it is getting better"	"skin burning sensation" "swelling face" "erythema" "accidental exposure"

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OBSERVATION 4

Adequate quality requirements that must be met by suppliers were not established.

Specifically, the Consumer/BRM Compliance Agreement for the Management of Drug Safety and Surveillance contains no specified requirements (including quality requirements) relating to expectations and deliverables associated with investigations of design control activities as a potential source of nonconforming product. For example, Quality Assurance Report (QAR) 07-00287 reports "...(b) (4) (b) (4) ..." was identified during monthly trend analysis in November of 2007. The complaints involved red coloring near the eyes where the product came in contact with skin. QAR 07-00287 documents the investigation of these adverse events and concludes that "...(b) (4) (b) (4) (b) (4) The conclusion of the GPS/BRM group investigation was "(b) (4) (b) (4) " There were no documented requirements (including quality requirements) provided to the GPS/BRM group with respect to expectations and deliverables associated with this investigation (e.g. review of design controls associated with the development of the original formulation).

Pharmaceutical Observations
Quality System

OBSERVATION 5

Written procedures describing the handling of complaints do not include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications and a determination as to the need for an investigation of any unexplained discrepancy.

Specifically,

All product complaints maintained in the firm's electronic Product Quality Management System (PQMS) that meet Automatic System Closure ("AUTOCLOSE") criteria may not be evaluated or investigated by the Quality Unit to determine whether the complaints are related to product quality or require investigation into unexplained discrepancies. For example:

a. Complaint 30000101432, dated 5/28/08, for Visine (unnamed formulation), described burning of the eyes and a smell of chlorine following use. The complaint was not forwarded to the Quality Unit at the manufacturing site for investigation and was automatically closed in PQMS. The complaint was not reviewed or investigated by the Quality Unit.

b. Complaint 30000104929, dated 6/26/08, for Visine Tears described the loss of eyesight following use for three consecutive days. The complaint was not forwarded to the Quality Unit at the manufacturing site for investigation and was automatically closed in PQMS. The complaint was not reviewed or investigated by the Quality Unit.

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c. Complaint 30000105985, dated 7/7/08, for Visine A.C., described the complainant's eyes as red, hot, and swelling shut following use. The complainant questioned whether there was something wrong with the lot and stated that three other family members experienced burning following use of the product. The complaint was not forwarded to the Quality Unit at the manufacturing site and was automatically closed in PQMS. The complaint was not reviewed or investigated by the Quality Unit.

OBSERVATION 6

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, a concurrent process validation study was conducted for (b) (4) as per Process Validation Protocol (b) (4) Revision 3, approved by the Quality Unit on 8/16/06. The second (b) (4) validation batch, # (b) (4) manufactured 1/8/08, did not meet the validation protocol acceptance criteria for (b) (4) assay for the six batch complete samples obtained, (25.0, 25.0, 25.0, 25.0, 25.0, 25.1 mg/g; validation criteria (b) (4) mg/g). No root cause for the low (b) (4) results was determined in investigation 08-00031, dated 4/11/08. The batch was released to the finished product contract manufacturing site on 1/15/08. The (b) (4) were manufactured using the bulk solution which did not meet the validation protocol acceptance criteria and were released on 5/28/08.

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*** DATES OF INSPECTION:**
07/07/2008(Mon), 07/08/2008(Tue), 07/14/2008(Mon), 07/15/2008(Tue), 07/16/2008(Wed), 07/21/2008(Mon), 07/22/2008(Tue), 07/23/2008(Wed), 07/31/2008(Thu)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Erin D. McCaffery, Investigator

Robert G. Ruff, Consumer Safety Officer

SEE REVERSE OF THIS PAGE

DATE ISSUED
07/31/2008