Establishment Inspection Report	FEI:	**2246407**
J&J Pharmaceutical R&D, L.L.C.	EI Start:	09/09/2009
Morris Plains, NJ 07950-2523	EI End:	09/09/2009

TABLE OF CONTENTS

SUMMARY

This abbreviated (Level 1 QSIT) inspection of a Class II medical device specification developer (Visine for Contacts, 21 CFR 886.5928, K991620) was initiated per the NWJ-DO FY'09 workplan, FACTS assignment 1015015, OP ID 4003088. The inspection was conducted pursuant to CP 7382.845 "Inspection of Medical Device Manufacturers". Information (and firm response) regarding complaint handling and medical device reporting obtained during a 7/7-31/08 inspection of McNeil-PPC, Inc., 100 Jefferson Road, Parsippany, New Jersey was also used as guidance during this inspection.

The previous inspection of 4/14-23/03 resulted in Pharmaceutical Adverse Event Reporting (AER) observations and was classified VAI. At that time, the site was a corporate headquarters for Pfizer Inc.

This inspection focused on the firm's Benefit Risk Management Division. This division is responsible for adverse pharmaceutical and device event evaluation and reporting. This inspection focused on the firm's procedures and practices associated with Medical Device Reporting (MDRs). The site also houses pharmaceutical and device research and development activities. No design changes have been made to the Visine for Contacts formulation, packaging, or labeling within the past year. No manufacturing or distribution occurs at this site. Two observations were discussed with the firm's management but not documented on an FDA 483.

The firm's management was cooperative and promised to implement corrections and corrective actions associated with the discussed observations. No FDA 483 was issued. No samples were collected. Visine for Contacts is not subject to the medical device tracking regulation. Recalls are not handled from this site.

ADMINISTRATIVE DATA

Inspected firm:	Johnson & Johnson Pharmaceutical Research & Development L.L.C.
Location:	185 Tabor Rd Morris Plains, NJ 07950-2523
Phone:	973-385-2990
FAX:	973-385-3994
Mailing address:	201 Tabor Road Morris Plains, NJ 07950
Dates of inspection:	9/9/2009
Days in the facility:	1
Participants:	Robert G. Ruff, Consumer Safety Officer Charles Chacko, Consumer Safety Officer

I (CSO Ruff) wrote the Establishment Inspection Report (EIR).

On 09/09/09, we (CSOs Ruff and Chacko) displayed our credentials, issued an FDA 482 (NOTICE OF INSPECTION), and explained the purpose of our visit to [redacted] (b) (6) RN, BSN, Associate Director, Global Consumer Safety Operations. Blair Harvey, Manager, Regulatory Affairs, Consumer & Personal Products Worldwide, and Patricia Villani, Senior Counsel, Johnson & Johnson Corporate Legal were also present for the initiation of the inspection. According to Ms. Villani, Ms. [redacted] (b) (6) is authorized to accept the FDA 482 on behalf of Ellen A. Carroll, Ph.D., RNC, Director, Global Consumer Safety Operations (the most responsible Benefit Risk Management Division individual on site). A photocopy of key individuals' business cards appears as Exhibit #1.

HISTORY

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. was incorporated in the state of New Jersey on December 31, 2001 (Exhibit #2). The firm is a wholly owned subsidiary of Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is a publicly held company (NYSE: JNJ). Benefit Risk Management is a division of Johnson & Johnson Pharmaceutical Research & Development, L.L.C. The firm maintains a current active FDA registration (Exhibit #3).

There have been no significant regulatory actions since the previous inspection. The firm does not handle product recalls. The firm's hours of operation are from 0800-1700, Monday through Friday.

FDA correspondence should be sent to Ellen A. Carroll, Ph.D., RNC, Director, Global Consumer Safety Operations. Dr. Carroll's contact information is:

Johnson & Johnson Pharmaceutical Research & Development L.L.C.
Benefit Risk Management Division
185 Tabor Road
Morris Plains, New Jersey 07950
T. (973) 385-2990
F. (973) 385-3994
e-m ecarroll@conus.jnj.com

INTERSTATE COMMERCE

No manufacturing or distribution occurs at this site. Visine for Contacts is manufactured and distributed by JANSSEN PHARMACEUTICA N.V., Turnhoutseweg 30, Beerse, Belgium. Registration and listing information regarding this site appears as Exhibit #4. Exhibit #5 identifies the amount of product distributed from the Beerse site by units sold and total sales in $US for FY '08 (FY = CY). The firm considers this information to be confidential.

JURISDICTION

Medical device reporting and research and development associated with the firm's Visine for Contacts product occur at this site. Visine for Contacts (K991620) is a Class II soft (hydrophilic) contact lens care product (21 CFR 886.5928).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(b) (6) RN, BSN, Associate Director, Global Consumer Safety Operations. Ms. (b) (6) was our primary point of contact, accompanied us, provided information, or arranged for key colleagues to provided information during this inspection. Ms. (b) (6) position description appears as Exhibit #6A.

Other individuals participating in the inspection were: Ellen A. Carroll, Ph.D., RNC, Director, Global Consumer Safety Operations; Blair Harvey, Manager, Regulatory Affairs, Consumer & Personal Products Worldwide; Paul Houri, Senior Director, Global R&D Quality Assurance; Marianne C. Underwood, Senior Director, Quality Assurance, Consumer & Personal Products Worldwide; and Patricia Villani, Senior Counsel, Johnson & Johnson Corporate Legal. Mr. Harvey's and Ms. Villani's position descriptions appear as Exhibit #'s 6B&C, respectively.

Tables of Organization appear as Exhibit #7.

FIRM'S TRAINING PROGRAM

The firm's training program combines computer based (E-University) modules and on-the-job training.

MANUFACTURING/DESIGN OPERATIONS

Visine for Contacts is manufactured and distributed by JANSSEN PHARMACEUTICA N.V., Turnhoutseweg 30, Beerse, Belgium.

This site's operations include research and development associated with Visine for Contacts and medical device reporting. No design changes have been made to the Visine for Contacts formulation, packaging, or labeling within the past year.

Corrective and Preventive Actions (CAPA)

This inspection focused on the firm's Benefit Risk Management Division. This division is responsible for adverse pharmaceutical and device event evaluation and reporting. This inspection focused on the firm's procedures and practices associated with Medical Device Reporting (MDRs). The evaluation of Visine for Contacts complaints with respect to determining if an investigation is necessary is the responsibility of the firm's Consumer & Personal Products Worldwide division (a division of Johnson & Johnson Consumer Companies, Inc.), 199 Grandview Road, Skillman, New Jersey 08558. The point of contact at the Skillman site is Marianne C. Underwood, Senior Director, Quality Assurance.

The following procedures and records were inspected during this inspection:

Case Processing at the Morris Plains Case Management Center, Doc. No. WI-06499, Version 3.0 (Exhibit #8)

Handling Adverse Events Associated with Product Complaints for US Consumer Products, Doc. No. WI-06842, Ver. 1.0 (Exhibit #9)

Quality Assurance Complaint Investigation & Closure for PCH Acquired Products within the Baby, Beauty, and CHC Global Business Units, QSP-000324, Rev. 7 (Exhibit #10)

Processing of Adverse Reports for Consumer Medical Devices (b) (4) Database, WI-06500, Ver. 3.0 (Exhibit #11)

Visine for Contacts Adverse Event Report for Quality Control (3 ea., Exhibit #'s 12A-C)

Data sort criteria for Visine for Contacts Serious Adverse Events and MDRs for past six months (Exhibit #13)

Documentation of software version (Exhibit #14)

Distribution of Monthly Adverse Event Reports (Exhibit #15)

Acronym definitions and call center address (Exhibit #16)

Exhibit #17 documents that the firm occupies (b) (4) and employs (b) (6) colleagues. Exhibit #18 documents that there have been no design changes to Visine for Contacts within the past year.

MANUFACTURING CODES

The firm's Batch Code structure is defined in Exhibit #19.

COMPLAINTS

Activities associated with Visine for Contacts medical device reporting were inspected. Returned goods are not received at this facility. Complaint investigations are not conducted at this facility.

RECALL PROCEDURES

Recalls are not handled from this facility. Recalls are handled by the quality group assigned to the manufacturing site.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No FDA 483 was issued.

REFUSALS

There were no refusals encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Two observations were discussed during the inspection but not documented on an FDA 483. (b) (6) RN, BSN, Associate Director, Global Consumer Safety Operations; Ellen A. Carroll, Ph.D., RNC, Director, Global Consumer Safety Operations; Paul Houri, Senior Director, Global R&D Quality Assurance; and Marianne C. Underwood, Senior Director, Quality Assurance, Consumer & Personal Products Worldwide were present for the discussion of the following items.

1. Upon review of Section 9.2 of the firm's Quality Assurance Complaint Investigation & Closure for PCH Acquired Products within the Baby, Beauty, and CHC Global Business Units Procedure, QSP-000324, Rev. 7 (Exhibit #10) design controls are not included in examples of "some items that may be included in an investigation". I explained that if an assignable cause cannot be identified in production and process controls, a complaint investigation should determine if the lack of appropriate design controls could have contributed to the event. The firm's management agreed.

2. Upon review of "Conclusion codes in (b) (4) contained on page 13 of the firm's Processing of Adverse Reports for Consumer Medical Devices (b) (4) Database Work Instruction, WI-06500, Ver. 3.0 (Exhibit #11), I observed that the codes include "Labeling related" (Code 57), "User error caused the event" (Code 79), and "User error contributed to the event" (Code 80). I explained that all of these conclusion codes represent events that may have occurred due to a lack of appropriate design controls (e.g. inappropriate characterization of user population, inappropriate labeling/product usability studies, etc.). I explained that events with these conclusion codes should still be considered for investigation. The firm's management agreed.

ADDITIONAL INFORMATION

There is no additional information to report.

SAMPLES COLLECTED

No samples were collected.

VOLUNTARY CORRECTIONS

Corrections and corrective actions associated with the previous inspection were not reviewed. These corrections and corrective actions were the responsibility of a different firm (Pfizer Inc.).

EXHIBITS COLLECTED

1. Photocopy, key individual business cards (1 p.)
2. Incorporation information (1 p.)
3. Registration and listing information, Morris Plains facility (1 p.)
4. Registration and listing information, Beerse, Belgium facility (2 pp.)
5. FY '08 Annual sales by units and $US (2 pp.)

6A. Job description, (b) (6) (5 pp.)

6B. Job description, Blair Harvey (1 p.)

6C. Job description, Patricia Villani (1 p.)

7. Tables of organization (2 pp.)
8. Case Processing at the Morris Plains Case Management Center, Doc. No. WI-06499, Version 3.0 (19 pp.)
9. Handling Adverse Events Associated with Product Complaints for US Consumer Products, Doc. No. WI-06842, Ver. 1.0 (20 pp.)
10. Quality Assurance Complaint Investigation & Closure for PCH Acquired Products within the Baby, Beauty, and CHC Global Business Units, QSP-000324, Rev. 7 (17 pp.)
11. Processing of Adverse Reports for Consumer Medical Devices (b) (4) Database, WI-06500, Ver. 3.0 (17 pp.)

12A. Visine for Contacts Adverse Event Report for Quality Control (1 p.)

12B. Visine for Contacts Adverse Event Report for Quality Control (2 pp.)

12C. Visine for Contacts Adverse Event Report for Quality Control (2 pp.)

13. Data sort criteria for Visine for Contacts Serious Adverse Events and MDRs for past six months (2 pp.)
14. Documentation of software version (1 p.)
15. Distribution of Monthly Adverse Event Reports (1 p.)
16. Acronym definitions and call center address (1 p.)
17. Firm physical size (square footage) and number of employees (1 p.)
18. Documentation of no Visine for Contacts design changes in past year (1 p.)
19. Batch code structure breakdown (1 p.)

ATTACHMENTS

1. FDA 483 (dated 09/09/09)

Robert G. Ruff, Consumer Safety Officer

Charles Chacko, Investigator