Establishment Inspection Report

McNeil Consumer & Specialty Pharmaceuticals, Division of McNeil-PPC, Inc.

Fort Washington, PA 19034

FEI: **2510184**

EI Start: 07/22/2003

EI End: 07/22/2003

SUMMARY

This limited inspection of a drug product manufacturer was conducted as a follow up to a consumer complaint, under FACTS ID 292388. The last inspection was conducted in 3/02 and was classified as (b) (2) The current inspection covered the firm's consumer complaint handling, packaging operations of solid dosage forms and handling of rejected drug products. The inspection revealed that the complaint was received by the firm and attempts to investigate were made. The firm's investigation concluded that a previous consumer may have sealed the container with tape and returned it to the retailer, which may have been restocked on the store shelves and ultimately purchased by complainant. The firm's investigation indicated that tape is not used in the cartoning of solid dosage forms. No FDA-483 was issued and no samples were collected. This report was written by Investigator Uy.

ADMINISTRATIVE DATA

Inspected firm:	McNeil Consumer & Specialty Pharmaceuticals, Division of McNeil-PPC, Inc.
Location:	7050 Camp Hill Rd Fort Washington, PA 19034
Phone:	215273-7000
FAX:	
Mailing address:	7050 Camp Hill Rd Fort Washington, PA 19034
Dates of inspection:	7/22/2003
Days in the facility:	1
Participants:	Audrey Therese T. Uy, Investigator

Upon arrival on 7/22/03, credentials were presented to Ms. Paula J. Oliver, Senior Director of Medical and Regulatory Affairs. Ms. Oliver was informed that the inspection was a follow up on a consumer complaint, which reported a suspected tampering of Tylenol children's chewable tablets. Ms. Oliver indicated that Ms. Debra L. Bowen, Vice President of Research and Development, is the most responsible person on site. Credentials were shown and FDA-482 was issued to Ms. Bowen, who identified herself as the most responsible individual at the onset of the inspection. FDA Investigator Vlada Matusovsky was also present at the onset of the inspection. Investigator Matusovsky signed and witnessed the issuance of the FDA-482 to Ms. Bowen, but was not involved with the consumer complaint follow-up.

(b) (2) [redacted]

HISTORY

The firm continues to be a manufacturer of OTC and prescription drug products and the corporate information has remained unchanged since the last inspection. According to Ms. Oliver, Mr. Michael D. Gowen, who was identified as Vice President of Operations in the previous inspection, has been replaced by Mr. T.W. Lipinski (see exhibit #1). The last inspection was conducted on 3/02 and was classified as NAI. The previous inspection was part of a (b)(4) assignment.

JURISDICTION

The firm is a manufacturer of solid and liquid OTC drug products which are distributed and sold in retail nationwide. Brand names that the firm produces include but not limited to Tylenol, Pepcid, Motrin and St. Josephs. Nutritional products such as Splenda, Viactive and Lactaid are distributed by the firm, but are manufactured off-site.

RESPONSIBILITY

The following are individuals who contributed information pertaining to the consumer complaint follow-up inspection:

Paula J. Oliver, Senior Director of Medical and Regulatory Affairs-She provided updated information on the firm's corporate structure and product information.

Ann C. Rademacher, QC/QA Plant Manager-She provided information on sample collection procedures, consumer complaints and product rejects and reconciliation.

David P. Chevoor, Solid Dose Packaging Manager-He provided information on the packaging operations of solid dosage forms.

Christine Wysocki, Senior Compliance Specialist-She provided information on the handling of consumer complaints and investigations.

Ms. Elizabeth Boyles, Solid dos Processing Manager, and Mr. Hakan Erdemir, Solid Dos Manufacturing Manager, provided information on the product rejects and reconciliation.

OPERATIONS AND EQUIPMENT

During the inspection only the blister packaging operations for solid dosage forms were covered. The firm's packaging operations consists of (b)(4) automated blister packaging lines, however only (b)(4)

lines were operating during the inspection. Mr. Chevoor explained that the product is dispensed in a collection bin on top of the line and dispensed into blister cavities, which are heat molded. The filled blisters are sealed, detached into individual blister packs, and then placed into retail cartons. During my inspection 4 individual filled blister packs were being placed and sealed in retail size cartons. During the sealing stage, the flaps of the filled cartons folded and are sealed with glue, which is automatically dispensed from tubes that are built in the packaging line. Depending on the product being packaged, an additional 2-3 sealed cartons would be shrink wrapped together then placed in master shipping cases.

Mr. Chevoor explained that built-in detectors in the packaging line identify partially filled blister packs and poorly filled and sealed cartons, which are automatically be rejected off the line. The first detector is positioned after the filling and sealing of blister packs, which would detect and remove partially filled blisters from the line. The rejected partial filled blisters are collected in a plastic bin located underneath the packaging line. Mr. Chevoor indicated that fully filled blister packs will occasionally be rejected and a 100% inspection would be conducted where fully filled blister packs would be segregated from the partially filled blister packs. The fully filled blister packs would be sent back to the line to be contained in cartons. Partial filled blister packs would be collected and disposed.

A second detector is located after the blisters are placed in the cartons and sealed. The detector will detect unsealed carton, which are rejected off the line. The unsealed carton contained fully filled blister packs would be removed and sent back to the line, where they are placed and resealed in cartons.

A third detector is located at the end of the packaging line, next to the detector described above. Mr. Chevoor explained that this detector would sense missing blisters from sealed cartons based on the sealed carton's density. A destructive test was performed as a demonstration, where an employee opened the carton to remove 1 out of a total of 4 blister packs, then resealed the carton. When the resealed carton containing 3 blister packs was placed back on the line, the resealed carton was rejected as it passed through the density detector.

I asked Mr. Chevoor how issue of tampering was addressed in the packaging operations, specifically after the cartons had been sealed. Mr. Chevoor explained that since the flaps of the cartons are sealed with glue, the cartons would have to be torn apart to gain access to the blister packs. I asked if samples are collected at any point of the packaging operation. Mr. Chevoor indicated that only samples that are in the finished packaged form are collected at the end of the operation and not prior or during the packaging operation. Mr. Erdemir indicated that samples of the product without the packaging materials would be collected during processing. No tapes or plastic Ziploc bags were seen in the packaging area.

COMPLAINTS

This follow up inspection was conducted as a result of a consumer complaint (FACTS (b) (4) who reported finding (b) (4) (b) (4) The complainant also reported that upon purchasing the product the outer packaging appeared to have been previously opened then resealed with tape. The complainant reported the incident to the retailer where the product was purchased. The retailer explained to the complainant that the incident may have been returned by a previous consumer who opened the contents, resealed the container then returned it to the retailer, which was subsequently restocked and eventually sold to the complainant.

This complaint was reported to the manufacturing firm and to Nashville District office on (b) (4) and to the firm on (b) (4) Exhibit #2 is the copy of the complaint investigation report and findings pertaining to the product. Ms. Rademacher and Ms. Wysocki informed me that the actual lot number of the product was (b) (4) as reported in the FACTS consumer complaint report. The report explained that the information there were no similar complaints that were reported during that time pertaining to the lot in question or on similar products.

I looked at (b) (4) which reported cartons resealed with tape. Ms. Wysocki explained that the packaging operations do not use tape to seal the cartons, and that in past experiences, consumers tend to reseal the cartons themselves using tape then returned them to the retailer. Ms. Wysocki added that when a complaint is received, the consumer and retailer would be instructed to return the product to the firm in order to conduct a formal investigation. Ms. Wysocki indicated that product samples would be retained for (b) months to conduct any necessary follow-up investigation. After the (b) month retention period is over, the complaint samples would be destroyed. For the (b) (4) consumer complaint Ms. Wysocki explained that instructions were given to the consumer and the retailer to return the product to the firm, however, there were no responses and no product was received.

I asked Ms. Rademacher about the type of containers used in the sample collections and if (b) (4) bags are used in collections. Mr. Rademacher explained that samples of drug substances and drug products are collected only in plastic or glass containers and never in Ziploc bags. I observed the sampling room and saw several samples contained in plastic bottles or in the finished packaging form. Ms. Boyle and Mr. Erdemir showed me the reconciliation room where rejected products are destroyed by compactor. I observed rejected blistered products contained in a clear large plastic bag awaiting destruction. Ms. Rademacher explained that the entry to the reconciliation room is electronically controlled and authorized personnel have access to the reconciliation room.

EXHIBITS

1. Organization Chart

2. Fax copy of consumer complaint received by McNeil

ATTACHMENTS
FDA-482

Audrey Therese T. Uy, Investigator