No. 15-_ _ _ _ _ _ _ _ _

UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania

Criminal Division

THE UNITED STATES OF AMERICA

vs.

McNeil-PPC, Inc.

INFORMATION

21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B) (adulterated drugs – 1 count)

A true bill.

_____
Foreman

Filed in open court this _____ day,
Of _____ A.D. 20_____

_____
Clerk

Bail, $_____

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	**CRIMINAL NO. _____**
v.	:	**DATE FILED: _____**
MCNEIL-PPC, INC.	:	**VIOLATION:**
	:	**21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B) (adulterated drugs)**
	:	**Notice of forfeiture**
	:	

INFORMATION

COUNT ONE

THE ACTING UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this information:

BACKGROUND

1. Defendant McNeil-PPC, Inc. ("McNeil") was a corporation operating and existing under the laws of the State of New Jersey that manufactured, processed, packed, labeled, held, and distributed drugs, including over-the-counter ("OTC") drugs, through its unincorporated McNeil Consumer Healthcare Division, headquartered at 7050 Camp Hill Road, Fort Washington, Pennsylvania, within the jurisdiction of the Eastern District of Pennsylvania. McNeil owned and operated through its Consumer Healthcare Division a facility in Fort Washington, Pennsylvania.

2. Defendant McNeil was a wholly owned subsidiary of Johnson & Johnson.

3. Defendant McNeil manufactured, processed, packed, labeled, and held Infants' and Children's OTC liquid drugs at its Fort Washington facility.

4. Defendant McNeil distributed Infants' and Children's OTC liquid drugs into interstate commerce from its Fort Washington facility.

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

5. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA") and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs bore true and accurate information. Pursuant to such responsibility, FDA promulgated and enforced regulations relating to the approval, manufacture, and distribution of drugs.

6. The FDCA defined drugs as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, and prevention of disease in man, and articles (other than food) intended to affect the structure of any function of the body of man. 21 U.S.C. § 32l(g)(l)(B) and (C).

7. The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of any drug that was adulterated. 21 U.S.C. § 331(a).

8. A drug was deemed adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B), if the methods used in, or the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and components were not in conformance with Current Good Manufacturing Practice ("cGMP") requirements for drugs. 21 C.F.R. Parts 210 and 211.

9. Drugs not manufactured, processed, packed, labeled, held and distributed in conformance with cGMP requirements were deemed adulterated as a matter of federal law, without any showing of actual defect.

10. Regulations promulgated pursuant to the FDCA further defined cGMP for drugs. Specifically, under 21 C.F.R. § 211.100(a) & (b): "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess . . . . Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."

11. FDA issued a "Guidance for Industry" in April 2009 that explained that with respect to Q10 Pharmaceutical Quality Systems: "[t]he pharmaceutical company should have a system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, nonconformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring. A structured approach to the investigation process should be used with the objective of determining the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk. . . . CAPA [Corrective Action Preventive Action] methodology should result in product and process improvements and enhanced product and process understanding."

12. Under cGMP, conducting a narrowly focused investigation or making a one-time correction in response to a specific nonconformance event is not the equivalent of implementing a Corrective Action Preventive Action plan. A Corrective Action

Preventive Action plan is designed, among other things, to determine the root cause of the nonconformance event or deviation in order to prevent such events from reoccurring, and help provide assurance that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.

MCNEIL'S FAILURE TO COMPLY WITH CURRENT GOOD MANUFACTURING PRACTICE

13. The OTC drugs manufactured by defendant McNeil at its Fort Washington facility were drugs within the meaning of 21 U.S.C. § 321(g)(1).

14. The OTC liquid drugs manufactured by defendant McNeil at its Fort Washington facility, including Infants' and Children's Tylenol and Infants' and Children's Motrin, were bottled on four lines of machinery dedicated to liquid formulations. McNeil's liquid filling machines at its Fort Washington facility used pistons and cylinders. The pistons were made of a material known as Waukesha 88, which is mostly nickel, but also includes tin, iron, bismuth and chromium. In general, Waukesha 88 was used by manufacturers to prevent galling that can occur from metal-on-metal contact during dynamic applications. The cylinders for the pistons were made from Type 316 austenitic stainless steel which had been chromium plated on the inside surface.

15. The OTC liquid drugs manufactured at defendant McNeil's Fort Washington facility flowed into cylinders within each liquid line's filling machine. The filling operation worked by the piston moving downward, pulling liquid medicine into the cylinder from a reservoir at the top of the filling machine. If a bottle was present, a valve closed the inlet port from the reservoir and opened the dispensing port. As it did this, the piston moved upward and pushed the liquid medicine into the bottle. During

production, the liquid line fillers ran at a speed of 155 to 200 bottles per minute. As a result of this production process, the metal pistons and cylinders had direct contact with the OTC liquid drugs.

16. On or about May 1, 2009, defendant McNeil received a complaint from a consumer regarding the presence of "black specks in the liquid on the bottom of the bottle" of Infants' Tylenol. The consumer returned the bottle to McNeil. The foreign material was later identified as including nickel/chromium-rich inclusions. The nickel/chromium-rich inclusions were not intended ingredients in this OTC liquid drug. In connection with receiving this consumer complaint, McNeil did not initiate or complete a Corrective Action Preventive Action plan.

17. On or about January 19, 2010, defendant McNeil found a particle in a bottle during the filling phase of Infants' Tylenol at its Fort Washington facility. A later laboratory analysis determined that the particle contained nickel, chromium and iron, none of which were intended ingredients in this OTC liquid drug. In connection with finding this particle, McNeil did not initiate or complete a Corrective Action Preventive Action plan.

18. On or about March 16, 2010, defendant McNeil found a particle in a bottle of Infants' Tylenol at its Fort Washington facility. A later laboratory analysis determined that the particle contained nickel, chromium and iron, none of which were intended ingredients in this OTC liquid drug. In connection with finding this particle, McNeil did not initiate or complete a Corrective Action Preventive Action plan.

19. On or about April 8, 2010, defendant McNeil found small black particles in several bottles of Infants' Tylenol being bottled at McNeil's Fort Washington facility.

These particles were subsequently determined to include nickel, chromium, tin, and bismuth, none of which were intended ingredients in this OTC liquid drug. Around this time, McNeil started to connect the existence of these metallic particles to the particles found on or about January 19, 2010, although McNeil continued production of OTC liquid drugs on this liquid line.

20. On or about April 13, 2010, defendant McNeil found discolored OTC liquid drug product on the base of one of its liquid line filler machines while packaging Infants' Tylenol at its Fort Washington facility. The discolored OTC liquid drug product was confirmed to be leaking from the piston assemblies onto the base of the liquid line filler machine. Production on this liquid line was stopped. Later laboratory analyses determined that the sample contained nickel, chromium, iron, tin and bismuth, none of which were intended ingredients in this OTC liquid drug.

2010 FDA INSPECTION OF MCNEIL'S FORT WASHINGTON FACILITY

21. Beginning on or about April 19, 2010, to on or about April 30, 2010, FDA inspected defendant McNeil's Fort Washington facility (the "2010 Inspection"). The most recent prior FDA inspection of McNeil's Fort Washington facility occurred from on or about May 19, 2009, to on or about June 4, 2009 (the "2009 Inspection").

22. During the 2010 Inspection, FDA asked defendant McNeil for a comprehensive list with all non-conformances for particles and the associated OTC drug batches that had occurred since the 2009 Inspection. This document revealed 30 batches of OTC liquid drugs, including Infants' Tylenol, Children's Tylenol, and Children's Motrin.

23. During the 2010 Inspection, FDA asked defendant McNeil for the Corrective Action Preventive Action plan covering the particles and foreign material found in the Infants' and Children's OTC drugs. A McNeil employee confirmed that McNeil did not have such a Corrective Action Preventive Action plan.

24. On or about April 14, 2010, defendant McNeil suspended production of all OTC liquid drugs at its Fort Washington facility.

25. On or about April 30, 2010, at the conclusion of FDA's inspection of defendant McNeil's Fort Washington facility, FDA prepared and issued to McNeil's representatives a detailed List of Inspectional Observations. The FDA inspection determined, and FDA informed McNeil that, while McNeil's Standard Operating Procedures required a Corrective Action Preventive Action plan to be initiated when systemic good manufacturing practice issues or significant trends had been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends, McNeil had failed to initiate a Corrective Action Preventive Action plan for multiple batches from in or around May 2009 to in or around April 2010 where foreign material, particulate matter and/or contamination were observed.

26. On or about April 30, 2010, McNeil Consumer Health Care, a division of defendant McNeil, in consultation with FDA, announced that the company was recalling all lots of certain unexpired Infants' and Children's OTC drugs manufactured at McNeil's Fort Washington facility and distributed in the United States and other countries around the world. McNeil's recall included, but was not limited to, Infants' and Children's Tylenol and Infants' and Children's Motrin. According to a press release issued by McNeil on April 30, 2010, some of the recalled OTC drugs "may contain tiny particles."

27. In certain instances, from in or around May 2009 to in or around April 2010, defendant McNeil's written production and process control procedures were not followed in the execution of production and process control functions (as required by 21 C.F.R § 211.100). Specifically, McNeil's Standard Operating Procedures required a Corrective Action Preventive Action plan to be initiated when systemic good manufacturing practice issues or significant trends had been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends. McNeil's Standard Operating Procedures defined a Corrective Action Preventive Action plan as a process for ensuring that identified corrective and preventive actions were verified for effectiveness.

28. Defendant McNeil failed to initiate a Corrective Action Preventive Action plan for multiple batches from in or about May 2009 to in or about April 2010 where foreign material, particulate matter and/or contamination were observed. Failure to initiate a Corrective Action Preventive Action plan did not comply with McNeil's Standard Operating Procedure, and thus, did not comply with cGMP requirements for drugs. Therefore, certain drugs manufactured, processed, packed, or held not in conformance with cGMP requirements by McNeil were deemed adulterated as a matter of federal law, without any showing of actual defect.

29. From in or around May 2009 to in or around April 2010, including on or about August 24, 2009, in the Eastern District of Pennsylvania and elsewhere, defendant

MCNEIL-PPC, INC.

delivered for introduction into interstate commerce certain batches of OTC drugs, drugs within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g),

which were deemed adulterated as a matter of federal law within the meaning of Title 21 United States Code, Section 351(a)(2)(B), in that such drugs were not manufactured, processed, packed, and held in conformance with the cGMP requirements.

In violation of Title 21, United States Code, Sections 331(a), 351(a)(2)(B), 333(a)(1).

NOTICE OF FORFEITURE

THE ACTING UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violation of Title 21, United States Code, Sections 331(a), 351(a)(2)(B), and 333(a)(l) set forth in this information, defendant

MCNEIL-PPC, INC.

shall forfeit to the United States of America any quantities of certain over-the-counter drugs which were deemed adulterated as a matter of federal law in the United States when delivered for introduction into interstate commerce.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is $5,000,000.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

LOUIS D. LAPPEN
ACTING UNITED STATES ATTORNEY