

SUPREME COURT STATE OF NEW YORK  
COUNTY OF NEW YORK

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PEOPLE OF THE STATE OF NEW YORK BY  
ERIC T. SCHNEIDERMAN, ATTORNEY GENERAL  
OF THE STATE OF NEW YORK,

PLAINTIFF,

v.

JOHNSON & JOHNSON CONSUMER INC. AND  
JOHNSON & JOHNSON.

DEFENDANT.  
-----X

TO: THE ABOVE NAMED DEFENDANT:

SUMMONS

Index No. \_\_\_\_\_  
IAS Part \_\_\_\_\_  
Justice \_\_\_\_\_

Plaintiff designates New York

County as the Place of Trial

YOU ARE HEREBY SUMMONED to answer in this action and serve a copy of your answer, or if the complaint is not served with the summons to serve a notice of appearance, on the plaintiff's attorney within twenty (20) days after the service of the summons, exclusive of the day of service. If the summons is not personally served upon you, or if the summons is served upon you outside of the State of New York, then your answer or notice of appearance must be served within thirty (30) days. In case of your failure to appear or answer, judgment will be taken against you by default, for the relief demanded in the complaint.

Dated: New York, New York  
May 24, 2017

Respectfully submitted,

ERIC T. SCHNEIDERMAN  
Attorney General of the  
State of New York  
Attorney for Plaintiff

By:



Benjamin J. Lee  
Assistant Attorney General  
Bureau of Consumer Frauds and Protection  
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TO: THE SUPREME COURT OF THE STATE OF NEW YORK

Plaintiff, the People of the State of New York, by their attorney, Eric T. Schneiderman, Attorney General of the State of New York, alleges the following upon information and belief:

**JURISDICTION & PARTIES**

1. Plaintiff is the People of the State of New York, by Eric T. Schneiderman, Attorney General of the State of New York.
2. The Attorney General brings this complaint pursuant to Executive Law § 63(12) and General Business Law ("GBL") §§ 349 and 350. Executive Law § 63(12) authorizes the Attorney General to seek injunctive relief, restitution, damages and costs when any person or business entity has engaged in or otherwise demonstrated repeated fraudulent or illegal acts in the transaction of business. GBL § 349 empowers the Attorney General to seek injunctive relief and restitution when any person or entity has engaged in deceptive acts or practices in the conduct of any business. GBL § 350 empowers the Attorney General to seek injunctive relief and restitution when any person or entity has engaged in false advertising. GBL § 350-d empowers the Attorney General to seek civil penalties in the amount of \$5,000 for each violation of GBL §§ 349 and 350.

3. Defendant Johnson & Johnson is a New Jersey corporation and its principal place of business and executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933.

4. Defendant Johnson & Johnson Consumer Inc., a wholly-owned subsidiary of Defendant Johnson & Johnson ("J&J"), is a New Jersey corporation with its principal place of business at 199 Grandview Road, Skillman, NJ 08558. McNeil-PPC, Inc., which subsequently merged into Johnson & Johnson Consumer Inc., manufactured, promoted, advertised, offered for sale, sold, and distributed over the counter ("OTC") drugs, through its unincorporated McNeil Consumer Healthcare Division, headquartered at 7050 Camp Hill Road, Fort Washington, Pennsylvania. McNeil owned and/or operated, through its Consumer Healthcare Division, facilities in Fort Washington, Pennsylvania; Las Piedras, Puerto Rico; and Lancaster, Pennsylvania. McNeil Consumer Healthcare Division formerly a division of McNeil-PPC, Inc., is now a division of Johnson & Johnson Consumer Inc. ("McNeil").

5. McNeil transacts business in New York and nationwide by manufacturing, promoting, advertising, offering for sale, selling, and/or distributing adult, children, and infant OTC drugs, including but not limited to the following product brands: Tylenol, Motrin, Benadryl, St. Joseph Aspirin, Sudafed, Pepcid, Mylanta, Roloids, Zyrtec, and Zyrtec Eye Drops with different formulations of these drugs for adults, infants, and children.

6. Defendants have waived their right to receive pre-litigation notice pursuant to GBL §§ 349 (c) and 350-c.

7. By failing to comply with current Good Manufacturing Practices ("cGMP") between 2009 and 2011, and failing to initiate Corrective Action Preventive Action plans while representing that quality and safety were a top priority and that McNeil complied with current

cGMP, Defendants have engaged in repeated and persistent fraud and illegality in violation of New York Executive Law § 63 (12), deceptive acts or practices in the conduct of its business in violation of New York General Business Law (“GBL”) § 349, and false and misleading advertising in violation of GBL § 350.

8. Accordingly, based on the above violations of New York law, the Attorney General brings this action seeking permanent injunctive relief, civil penalties, disgorgement, restitution for injured consumers and for all other proper relief.

### **FACTUAL ALLEGATIONS**

9. McNeil represented that quality and safety were a top priority and that McNeil complied with current cGMP.

10. Between 2009 and 2011, McNeil announced voluntary recalls of certain lots of OTC medicines, including but not limited to the following:

- a. On September 11, 2009, McNeil announced a voluntary recall of 57 product lots of Infants’ and Children’s Tylenol liquid products manufactured at its Fort Washington, Pennsylvania facility.
- b. On November 6, 2009, December 18, 2009, and January 15, 2010, McNeil announced voluntary recalls of 595 product lots of Tylenol, St. Joseph, Benadryl, Roloids, and Motrin products manufactured at its Fort Washington, Pennsylvania and Las Piedras, Puerto Rico facilities.
- c. On April 30, 2010, McNeil announced a voluntary recall of approximately 1,200 product lots of Infants’ and Children’s Tylenol, Motrin, Benadryl, and Zyrtec liquid products manufactured at its Fort Washington, Pennsylvania facility.

11. During this time period, McNeil delivered for introduction into commerce certain batches of OTC medicines that were not manufactured, processed, packed, or held in conformance with certain federal cGMP.

12. McNeil stipulated in a Guilty Plea and Sentencing Memorandum with the United States that some of its OTC drugs were not manufactured, processed, packed, labeled, held, or distributed in conformance with cGMP requirements, and therefore were deemed adulterated as a matter of federal law, without any showing of actual defect, and that the Federal Food, Drug, and Cosmetic Act prohibited the introduction or delivery for introduction into interstate commerce of any drug that was deemed adulterated.

13. McNeil also stipulated that it did not initiate any Corrective Action Preventive Action plans ("CAPA Plans") for multiple batches of OTC drugs between May 2009 and April 2010 when foreign material, particulate matter and/or contamination were observed, even though its own operating procedures required CAPA Plans. Failure to initiate CAPA Plans did not comply with McNeil's operating procedures, and therefore, did not comply with cGMP requirements for these drugs.

14. McNeil stipulated that it delivered for introduction into interstate commerce certain batches of OTC drugs that were deemed adulterated as a matter of federal law and cGMP requirements.

**FIRST CAUSE OF ACTION**  
**VIOLATION OF GENERAL BUSINESS LAW § 350**

15. Plaintiff repeats, re-alleges, and incorporates paragraphs one through fourteen contained herein.

16. GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade

or commerce or in the furnishing of any service in [New York].”

17. GBL § 350-a further provides that “false advertising” is advertising that is “misleading in a material respect.”

18. By engaging in the advertising alleged above, Defendants have engaged in false advertising in violation of GBL § 350.

**SECOND CAUSE OF ACTION**  
**VIOLATION OF GENERAL BUSINESS LAW § 349**

19. Plaintiff repeats, re-alleges, and incorporates paragraphs one through fourteen contained herein.

20. GBL § 349 declares unlawful “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York].”

21. By engaging in the acts and practices alleged above, Defendants have engaged in deceptive and misleading practices in violation of GBL § 349.

**THIRD CAUSE OF ACTION**  
**VIOLATION OF EXECUTIVE LAW § 63(12) (FRAUD)**

22. Plaintiff repeats, re-alleges, and incorporates paragraphs one through fourteen contained herein.

23. Executive Law § 63(12) authorizes the Attorney General to seek injunctive relief whenever any person engages in repeated fraudulent or illegal conduct or otherwise demonstrates persistent fraud or illegality in the carrying on, conducting, or transaction of business.

24. By the acts and practices alleged above, Defendants have engaged in repeated and persistent fraudulent and illegal conduct in violation of Executive Law § 63(12).

WHEREFORE, Plaintiff requests that this Court issue an Order and Judgment pursuant to Executive Law § 63(12) and GBL §§ 349, 350 and 350-d:

(a) permanently enjoining Defendants from engaging in the fraudulent, deceptive and illegal conduct alleged in the Complaint;

(b) directing Defendants to pay restitution and damages to injured consumers, known and unknown;

(c) directing Defendants to disgorge all profits illegally obtained in order to effectuate a just result, and make payment of such amounts to the State of New York;

(d) directing Defendants to pay a civil penalty to the State of New York pursuant to GBL § 350-d in the sum of five thousand dollars (\$5,000) for each violation of GBL § 349 and GBL § 350;

(e) directing Defendants to pay to Plaintiff the costs of this proceeding, including the sum of two thousand dollars (\$2,000) to cover additional costs pursuant to CPLR § 8303(a)(6); and

(f) granting Plaintiff such other and further relief as the Court deems just and proper.

Dated: New York, NY  
May 24, 2017

Respectfully submitted,

ERIC T. SCHNEIDERMAN  
Attorney General of the State of New York  
Attorney for Plaintiff

By:



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