ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5051
FACSIMILE (202) 225–4784
MINORITY (202) 225–5074

www.oversight.house.gov

May 6, 2010

Mr. William C. Weldon
Chairman and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Dear Mr. Weldon:

We are writing in regard to your recent recall of over-the-counter pediatric products produced by Johnson & Johnson. On April 30, 2010, McNeil Consumer Healthcare, a subsidiary of Johnson & Johnson, recalled over 40 variations of infant and children's liquid products after a Food and Drug Administration (FDA) inspection uncovered problems surrounding the quality, purity, and potency of your products. Many popular brands such as Tylenol, Motrin, Zyrtec, and Benadryl were affected by this recall. These medicines are widely used by parents all across the country to treat their children, which makes this recall deeply troubling.

FDA's latest inspection of McNeil's Fort Washington, PA, plant uncovered several alarming deficiencies in the production of these pediatric medicines. For instance, FDA found that McNeil did not properly test its products, did not properly train its employees, failed to maintain equipment, and lacked other important quality controls. FDA also found that McNeil failed to sufficiently investigate problems in its manufacturing and in its drugs.[1]

Particularly alarming is FDA's finding that raw materials used to manufacture infant and children's products were contaminated with potentially harmful bacteria. While FDA has stated that bacteria have not been found in any finished product and no illnesses or deaths have been reported, this finding alone suggests serious deficiencies in your plant's quality control and quality assurance processes.

We are also concerned that this recall does not appear to be an isolated incident. This was the third major quality-related recall made by Johnson & Johnson/McNeil in the last eight

[1] Food and Drug Administration Form 483 for McNeil Consumer Healthcare, Fort Washington, PA. Issued on April 30, 2010.

months. The first occurred in September 2009 when Johnson & Johnson/McNeil recalled infant and children's Tylenol products because an inactive ingredient did not meet quality standards. Then, in November 2009, five lots of over-the-counter Tylenol arthritis pain medication were recalled after an unusual moldy, musty, or mildew-like odor in these products caused reports of nausea, stomach pain, vomiting, and diarrhea. This recall was expanded in December 2009 to include all product lots of this medication. This recall was further expanded in January 2010 to include a variety of other over-the-counter products. While it has been reported that FDA has been working with Johnson & Johnson/McNeil since May 2009 to address its quality problems, and that Johnson & Johnson/McNeil had assured FDA that it was addressing these underlying problems, clearly, these purported efforts have fallen short.

The Committee on Oversight and Government Reform is the principal oversight committee in the U.S. House of Representatives, with jurisdiction over "any matter." Under Rules X and XI of the Rules of the House of Representatives, the Committee is investigating the recent recall of over-the-counter Johnson & Johnson/McNeil pediatric products. To assist the Committee in its investigation, we request that you provide the following information and records:

1. When did Johnson & Johnson and McNeil first become aware of the issues that resulted in the April 30, 2010, recall? Please provide a narrative of all inspections, audits, and evaluations by either FDA or others that identified issues relating to this recall. Please also indicate which systems, analyses, or testing methods failed to detect or prevent the anomalies which resulted in the need for this series of recalls.

2. Please provide copies of all records, in an unredacted form, relating to inspections of all McNeil Consumer Healthcare manufacturing facilities, including Form 483s and Establishment Inspection Reports, since January 1, 2008.

3. Please provide a list of all source material providers, both foreign and domestic, for both active and inactive ingredients used in the products subject to this series of recalls. If any such ingredients or materials originated from foreign sources, please identify the foreign facilities from which such ingredients or materials originated and when such facilities received a cGMP audit from the FDA. Also, if any ingredients were foreign-sourced, please provide any quality control or cGMP audits you or a third party working on your behalf performed for the facility.

4. Please provide copies of all records in the care, custody, or control of Johnson & Johnson and McNeil Consumer Healthcare that relate in any way to the decision to recall the children's medication announced on April 30, 2010.

5. What steps have Johnson & Johnson and McNeil taken to ensure that the recalled products are actually taken off the shelves in stores around the United States?

6. What steps have Johnson & Johnson and McNeil taken to ensure that consumers are actually notified that they should not use the recalled products?

7. Please provide copies of all complaints or adverse events associated with any McNeil product since January 1, 2008.

8. Please identify the bacteria found in the raw materials at McNeil's Fort Washington plant in April 2010, as reported on FDA's form 483. Were any raw materials at this plant adulterated or contaminated in any way besides the stated bacteria contamination?

9. Please provide all records related to any internal investigations conducted by Johnson & Johnson, McNeil, or a third party before or after the relevant recalls.

Please deliver two copies of the requested information and records to the Committee on Oversight and Government Reform, room 2157 Rayburn House Office Building, no later than 4:00 p.m. on Monday, May 17, 2010. To facilitate delivery and review, we prefer that the records be delivered in digital form. Please note that the terms "records" and "relating to" are defined in the attachment to this letter.

Should you or your staff have any questions with regard to this request, please contact Chris Staszak or Kevin Barstow of the Majority staff at (202) 225-5051 or Molly Boyl or Ashley Callen of the Minority staff at (202) 225-5074.

Sincerely,

Edolphus Towns
Chairman

Darrell Issa
Ranking Member

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.