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ONE HUNDRED ELEVENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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May 6, 2010

The Honorable Margaret A. Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Hamburg:

We are writing in regard to the recent recall of popular over-the-counter pediatric products. 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 concerns surrounding the quality, purity, and potency of the products. Brands affected by this recall include Tylenol, Motrin, Zyrtec, and Benadryl products.

The FDA inspection of McNeil's Fort Washington, Pennsylvania, plant uncovered several alarming deficiencies in the manufacturing of these products. 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.<sup>1</sup>

However, FDA's most alarming finding was that raw materials used to make these infant and children's products were contaminated with potentially harmful bacteria. Thankfully, according to FDA, the bacteria have not been found in any finished product and no illnesses or deaths have been reported.

This recall was the third major recall made by McNeil in the last eight months due to quality problems. The first recall occurred in September 2009 when 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

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<sup>1</sup> Food and Drug Administration Form 483 for McNeil Consumer Healthcare, Fort Washington, PA. Issued on April 30, 2010.

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.

Taken together, these recalls point to a major problem in the production of McNeil products, and raise questions as to the adequacy of FDA's response to repeated problems with McNeil's manufacturing practices. It has been reported that FDA has been working with McNeil since May 2009 to address its quality problems. According to one report, FDA met with McNeil in February to express its concerns about McNeil's production practices and had assured FDA that it was addressing its problems.<sup>2</sup> A clarification of the timing of the events that spurred the recall is important in understanding both McNeil's and FDA's response to the problem.

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 pediatric products. To assist the Committee in its investigation, we request that you provide the following information and records:

1. What prompted FDA's April 2010 inspection of McNeil's Fort Washington plant? For example, was this a "for cause" inspection or was this a routine current good manufacturing practice (GMP) inspection as required by statute?
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 identify the bacteria that were found in the raw materials at McNeil's Fort Washington plant in April 2010. Were any raw materials at this plant adulterated or contaminated in any way besides the reported bacteria contamination?
4. Please identify the supplier or suppliers of the raw materials in which bacteria or any other contamination or adulteration was found at McNeil's Fort Washington plant in April 2010.
5. If any of the contaminated or adulterated raw materials used by this facility came from foreign sources, please identify those foreign facilities and indicate when FDA last inspected them.
6. Please provide a chronology of events from January 1, 2008, through April 30, 2010, that led to the McNeil recalls in September 2009, November 2009, December 2009, January 2010, and April 2010.

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<sup>2</sup> "Children's Tylenol Recall: FDA Report Rips Quality Control at Plant." ABC News. May 5, 2010.

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

We also request that you brief Committee staff on the status of your investigation as soon as possible.

Please deliver 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 Kevin Barstow of the Majority staff at (202) 225-5051 or Molly Boyl of the Minority staff at (202) 225-5074.

Sincerely,



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Edolphus Towns  
Chairman



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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.