ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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WASHINGTON, DC 20515–6143

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September 28, 2010

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
Room 5541 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Levinson:

As you may know, the Committee on Oversight and Government Reform is investigating consumer safety failures at Johnson & Johnson, including the recall of Motrin caplets by Johnson & Johnson's subsidiary McNeil Consumer Healthcare (McNeil).[1] In the course of this investigation, it has come to my attention that the U.S. Food and Drug Administration (FDA) has (1) issued statements to the media that are inconsistent with key facts related to the investigation; (2) an FDA official apparently attempted to mislead Congress by omitting key facts about FDA's knowledge of Johnson & Johnson's market withdrawal efforts in 2009; and (3) the FDA has refused to make available to Committee investigators an employee with clear first-hand knowledge of an FDA failure. I ask that you initiate an investigation to determine if FDA employees, through these actions and others, have purposely and improperly sought to impede and mislead a Congressional oversight investigation.

Facts are Clear: FDA Knew about Motrin Market Withdrawal No Later than April 21, 2009

On April 21, 2009, McNeil's Quality Site Leader for the Las Piedras, Puerto Rico plant, Mayra Pujals, filed a Field Action Report (FAR) with FDA San Juan Office District Director Maridalia Torres notifying the FDA that Motrin had been and would continue to be removed from store shelves.[2] The report states clearly:

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[1] Committee on Oversight and Government Reform hearing *Johnson & Johnson's Recall Of Children's Tylenol And Other Children's Medicines*, May 27, 2010.

[2] U.S. Food and Drug Administration NDA-Field Action Report, April 21, 2009, See enclosed MCNEIL HC 8286 - 8288.

> As stated in the previous Field Alert Report follow-up issued on March 23, 2009, in order to confirm the availability of Motrin batches SHC003 and SHC004 at the retail level, a statistical sampling of approximately ten (10) percent of stores across the US that received these batches were visited (250 stores out of 2000)....**The product from the subject lots found in the stores was removed during the visits. Visits to remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.**[3]

One day earlier, on April 20, 2009, a Senior Director of Quality Assurance at McNeil, Paul DiPaolo, sent an email to a number of McNeil officials, including Peter Luther, the President of McNeil, celebrating confirmation from FDA San Juan District Director that a national recall would not be required. Specifically, Mr. DiPaolo said:

> Just received some good news from San Juan FDA District Director. She is in agreement with continuing to pull product from the rest of the stores and NOT consider this a National Recall.[4]

In addition, an email exchange dated April 20, 2009, between Ms. Pujals and Mr. DiPaolo recounts a conversation with Ms. Torres in which Ms. Torres apparently agreed to allow McNeil to continue the market withdrawal of Motrin.[5] The first written acknowledgement by the FDA was an email dated June 16, 2009, by Neisa Alonso, Investigator with FDA.[6]

Enclosed for your review are copies of all FARs filed with the FDA and subsequently produced to the Committee regarding the Motrin caplets withdrawal. As you will note, the earliest FAR is November 26, 2008.[7] This FAR is concrete evidence that FDA knew that McNeil was conducting an investigation into the Motrin caplet dissolution issue.[8] In fact, the March 23, 2009, FAR noted a third party contractor had been hired by McNeil to perform an audit.[9]

Emails from Eddie Carrillo of McNeil dated January 19, 2009, to Maridalia Torres of FDA show attempts by McNeil to communicate with FDA on this matter.[10] Additionally, Mr. Carrillo, in an email dated March 12, 2009, recounts to his colleagues a

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[3] U.S. Food and Drug Administration NDA-Field Report Alert, April 21, 2009, See enclosed MCNEIL HC 8286 – 8288(emphasis added).
[4] See enclosed MCNEIL HC 8280.
[5] See enclosed MCNEIL HC 8919.
[6] See enclosed MCNEIL HC 8890-8892.
[7] U.S. Food and Drug Administration NDA-Field Report Alert, November 26, 2008, See enclosed MCNEIL HC 7922 – 7928.
[8] *Id.*
[9] U.S. Food and Drug Administration NDA-Field Report Alert, March 23, 2009, See enclosed MCNEIL HC 8004 – 8006.
[10] See enclosed MCNEIL HC 8740.

conversation with Ms. Torres during which she agreed to review the data provided by McNeil prior to recommending or not recommending a recall.[11]

There are numerous internal McNeil communications discussing conversations between McNeil employees and FDA officials.[12] For example, a McNeil document referred to as a "record of regulatory quality authority contact" was filled out by Ms. Pujals. In this record she states:

> Ms. Mayra Pujals contacted Ms. Maridalia Torres to confirm the strategy to be followed to complete the product withdrawal due to the Motrin dissolution failure on two batches. Ms. Pujals mentioned that our intention was to continue visiting the retail stores to collect all the product and that decision was based on the low volume which was out of the distribution centers at he moment it was decided to retrieve the product. It was also mentioned that this strategy was previously discussed between her and Mr. Eddie Carrillo and sent in an FAR follow-up dated 3/23/09. She [Ms. Torres] agreed with the strategy.[13]

On March 23, 2009, McNeil submitted the FAR which explained:

> In order to confirm that neither affected lots is available [sic] at the store level, a third party has been contracted to perform an in store assessment. A statistical sampling of twenty-five (25) percent of all stores across the US that received these batches will be visited. If this assessment confirms that there is no product from batches SCH003 and SCH004 at the store level, a recall will be considered not necessary due to unavailability in the market; otherwise a recall of these Motrin batches will be recommended to be performed. The assessment is expected to be completed by April 15, 2009.[14]

While the documented facts appear to make clear that FDA – by April 21, 2010 at the latest – was made aware of the effort to remove Motrin from store shelves by contractors conducting a market withdrawal, FDA officials have publicly stated a very different sequence of events. The sequence of events publicly put forward by FDA officials is at odds with the facts of the situation. It demonstrates FDA's failure to fulfill its responsibility to make decisions based on the interests of consumer safety when the agency first received information about the problems with Motrin. Lastly, it illustrates

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[11] See enclosed MCNEIL HC 8742.
[12] While these are McNeil's internal communications, according to Johnson & Johnson's attorneys, FDA has received copies of all document production made to the Committee.
[13] See enclosed MCNEIL HC 8780.
[14] U.S. Food and Drug Administration NDA-Field Report Alert, Mar. 23, 2009, MCNEIL HC 8003 - 8006 (enclosed).

FDA's failure to object to McNeil's stated plans to proceed with a market withdrawal instead of ordering a full recall.

1. Misleading Public Statements:

In a *Reuters* article dated September 21, 2010, FDA spokeswoman Elaine Bobo denied that, until July 2009, her agency was aware of an effort to remove Motrin from store shelves as part of a market withdrawal that has been popularly dubbed McNeil's "phantom recall" of Motrin.[15] Specifically, Ms. Bobo said:

> Any effort to suggest to the contrary [that FDA had knowledge of the "phantom recall"] is based on quoting documents selectively and out of context and ignores other evidence as to what occurred.
>
> McNeil's own written account of its communications with FDA does not support the conclusion that McNeil disclosed the activities associated with its 'phantom recall' to FDA.[16]

Likewise, a September 22, 2010, *CNN* article quotes an unnamed FDA source, who continues to contend on behalf of the agency, that the FDA first learned about the Motrin purchase effort in July 2009. According to an FDA statement cited by *CNN*:

> When the FDA learned that McNeil had hired contractors to secretly purchase product off the shelves, the agency advised McNeil to do a full recall which the company agreed to initiate in July 2009. FDA then voiced its objections about McNeil's 'phantom recall' activities to the senior leadership of Johnson & Johnson in a February 2010 meeting.[17]

This is contrary to the information received by FDA in the April 21, 2009 FAR filed by McNeil. Similar comments were also reported in the *Wall Street Journal* and by the *Associated Press*.[18]

These press statements appear inconsistent with known facts and are deeply misleading about the FDA's knowledge of and the role it played in the 2009 market withdrawal of Motrin.

2. Misleading Congressional Testimony:

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[15] Ransdell Pierson, *Panel Asks if FDA Knew About Secret J&J Recall*, REUTERS, Sept. 21, 2010.
[16] *Id.*
[17] Parija Kavilanz, *FDA: Motrin Maker Played Us Over Recall*, CNNMONEY.COM, Sept. 22, 2010.
[18] Jonathan D. Rockoff, *New Details on Defective Motrin*, WALL ST. J., Sept. 21, 2010; Matthew Perrone, *Lawmaker Asks J&J for Proof of Recall Agreement*, ASSOCIATED PRESS, Sept. 21, 2010.

At the Committee's hearing on May 27, 2010, FDA's witness, Dr. Joshua Sharfstein, omitted communications by McNeil employees to FDA about the Motrin market withdrawal efforts in recounting a sequence of events. His testimony paints a deeply misleading sequence of events that many interpreted to mean that FDA first learned of the Motrin market withdrawal efforts from a state agency in July 2009. Specifically, he said:

> The company notified FDA that they were going to be evaluating whether there was product on the shelves to recall. **Then we were alerted, I believe, by one of the State Boards of Pharmacy** that instead of just looking to see whether or not there was medication to recall, the company had a contractor that was going out and trying to buy up....[19]

Again, this statement is far from an accurate recount of events and appears to follow a pattern of FDA officials seeking to mislead Congressional investigators and the public. Until documents painting a different picture of the Motrin recall were brought to the Committee's attention, Dr. Sharfstein's sequence of events appears to have largely been taken by media outlets and Congressional investigators at face value.

3. FDA's Refusal to Make Key Employee/Witness Available to Committee Investigators:

On Thursday, September 23, 2010, Committee Minority Staff requested that FDA make San Juan District Office Director Maridalia Torres available to speak with Committee staff about events surrounding the Motrin recall and the FDA's knowledge of such efforts. As mentioned earlier, Ms. Torres' name appears again and again in emails from McNeil officials referencing contact with FDA about the Motrin recall. Ms. Torres was also the named recipient of McNeil's April 21, 2010, FAR overtly stating a plan to continue efforts to remove Motrin from store shelves, through a market withdrawal. On Friday, September 24, 2010, FDA officials informed Committee staff that Ms. Torres would not be made available to speak with investigators.

The refusal to make Ms. Torres available to speak to Congressional investigators, has the appearance of a concerted effort to suppress the statement of a witness who, based on documents, appears likely to contradict a false storyline being pushed by FDA officials that the FDA did not know about the Motrin market withdrawal until July 2009.

Conclusion

FDA officials appear to have purposely and improperly sought to impede and mislead a Congressional oversight investigation through press statements, Congressional

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[19] *Hearing on Johnson and Johnson's Recall of Children's Tylenol & Other Children's Medicines*, Hearing Transcript, 111th Cong. at 26 (May 27, 2010)(enclosed for your review).

testimony, and the denial of access to a relevant witness. FDA has also so far failed to produce documents requested by Chairman Edolphus Towns that are of critical importance for a hearing scheduled for September 30, 2010. Taken together, there appears to be an egregious and intentional effort by a regulatory entity entrusted with the public health, to mislead the American public and avoid accountability. Accordingly, I request that you investigate the matters outlined in this letter and determine the extent to which FDA officials engaged in an inappropriate effort to mislead and impede this investigation.

If you have any questions, please do not hesitate to have your staff contact Sery Kim at 202-225-5074. Thank you in advance for your cooperation in this matter.

Sincerely,

Darrell Issa
Ranking Member

cc: The Honorable Edolphus Towns, Chairman

Enclosures

From: Alonso, Nelsa M [redacted]@fda.hhs.gov]
Sent: Tuesday, June 16, 2009 3:48 PM
To: Parziale, Carolyn [MCCUS]
Subject: RE: Contact regarding McNeil Consumer Healthcare

Carolyn:

My apologies, I was out for almost 3 weeks and there were some issues with my phones and e-mail. Nevertheless, about your question, please forward me the information via e-mail on pdf files, no need to send originals.

Any other question, please feel free to contact me on my cell at [redacted]. Also, just in case, I will be out of the office next week (6/22-26) attending a training in FDA Hqrts, but you are welcome to contact me if needed.

Nelsa M. Alonso
Investigator
Recall & Emergency Coordinator

U.S. Food and Drug Administration
466 Fernandez Juncos Avenue
San Juan, PR 00901-3223
[redacted] Direct
[redacted] Fax
[redacted]@FDA.HHS.GOV e-mail

From: Parziale, Carolyn [MCCUS] [mailto:[redacted]ts.jnj.com]
Sent: Tuesday, June 16, 2009 12:45 PM
To: Alonso, Nelsa M
Cc: DiPaolo, Paul [MCCUS]; Pujals, Mayra [MCCPR]
Subject: Contact regarding McNeil Consumer Healthcare

Dear Ms. Alonso,

Can you advise us on below? We would like to move forward on sending reports to your office & with the destruction of some of the materials we have already accumulated at our Distribution Center.

Your support will be very much appreciated!

Carolyn

Director Quality Assurance

McNeil Consumer Healthcare, Inc.

Global Quality Assurance

Ft. Washington, PA 19034

Tele: [redacted]

Fax: [redacted]

Note: 3rd written attempt & 2nd phone attempt.

From: Parziale, Carolyn [MCCUS]
Sent: Tuesday, June 09, 2009 3:45 PM
To: [redacted]@fda.hhs.gov'
Cc: DiPaolo, Paul [MCCUS]; Pujals, Mayra [MCCPR]
Subject: RE: Contact Regarding McNeil Consumer Healthcare

Hello again Ms. Alonso,

We have not heard back from you regarding your preferred method of receiving monthly reports, so we wanted to do a follow-up. In addition, can you give us guidance on whether the Agency would like to witness the actually destruction of the product, when we are ready to proceed some time later this year?

Thanks very much,

Carolyn Parziale

From: Parziale, Carolyn [MCCUS]
Sent: Thursday, June 04, 2009 11:21 AM
To: [redacted]@fda.hhs.gov'
Cc: DiPaolo, Paul [MCCUS]; Pujals, Mayra [MCCPR]
Subject: Contact Regarding McNeil Consumer Healthcare

Dear Ms. Alonso,

I would like to introduce myself. I am Carolyn Parziale and I have called to leave you a few voice mail messages because I'm the central Recall Coordinator for McNeil Consumer Healthcare U.S. & Puerto Rico. I will be your point person for communications regarding the Motrin Vials process. Generally speaking, I am the person who sends monthly reports for recall or retrieval activities and I wanted to verify your preferred method of receiving reports. Do you prefer direct mailing or e-mail with pdf attachments or both?

Please let us know if you have any specific requests and thank you for all your support to date!

Carolyn

Director Quality Assurance

Global Quality Assurance

McNeil Consumer Healthcare, Inc.

Ft. Washington, PA 19034

Tele: [redacted]

Fax [redacted]

McNeil Healthcare, LLC

RECORD OF REGULATORY QUALITY AUTHORITY CONTACT

Date: April 20, 2009 (recorded on 07/16/09)	**Name:** Mayra Pujals, QA Manager **Location:** McNeil Healthcare, LLC **Phone:** [redacted]
Product: N/A	**Drug Filing Number:** N/A

Regulatory Quality Authority Contact:
Name: Ms. Maridalia Torres, [redacted]
Title: District Director
District: FDA - San Juan District Office

Purpose of Contact:
Motrin Caplets (product retrieval)

Summary:
Ms. Mayra Pujals contacted Ms. Maridalia Torres to confirm the strategy to be followed to complete the product retrieval due to the Motrin dissolution failure on two batches. Ms. Pujals mentioned that our intention was to continue visiting the retail stores to collect all the product and that decision was based on the low volume which was out of the distribution centers at the moment it was decided to retrieve the product. It was also mentioned that this strategy was previously discussed between her and Mr. Eddie Carrillo and sent in an FAR follow-up dated 03/23/09. She agreed with the strategy.

Actions:
1. An FAR Final document was sent on 04/21/09, stating the aforementioned agreed strategy.

c: P. DiPaolo
R. Foster
B. Miller
N. Ramirez
LP Regulatory File (FDA/DEA/MHRA, etc.)

From: Vandermolen, Lily [MCCUS] [redacted]@its.jnj.com]

Sent: Monday, April 20, 2009 11:01 AM

To: DiPaolo, Paul [MCCUS]; Davey, Frank [MCCUS]; Degen, Jenna [MCCUS]; Figus, Daniel [MCCUS]; Martina, Aubrey [MCCUS]; Chonka, Janet [MCCUS]; Parziale, Carolyn [MCCUS]; Cocolin, Lisa [MCCUS]; Boston, Marc [MCCUS]; Cohen, Joan [MCCUS]

Subject: Re: Motrin Recall Committee Meeting

Great news! Thank you for your diligence. We'll need to coordinate accordingly with Sales to determine appropriate vendor and SOP. I'm out of the office this week but Jenna can be your Marketing key contact.

Marc... Let me know your thoughts on whether it is still worthwhile to prepare a statement should there be any questions.

Thanks,
lv.

----- Original Message -----
From: DiPaolo, Paul [MCCUS]
To: Benedict, Gary [MCCUS]; Nieradka, Maria [MCCUS]; Kuffner, Ed [MCCUS]; DeLaurentis, Shelley [MCCUS]; Jacobs, Bonnie [MCCUS]; Parziale, Carolyn [MCCUS]; Guzman, Cecilia [MCCPR]; Chonka, Janet [MCCUS]; Vandermolen, Lily [MCCUS]; Mann, Andre [MCCUS]; Degen, Jenna [MCCUS]; Constable, Lawrence [MCCUS]; Miller, Bob [MCCUS]; Luther, Peter [MCCUS]; Kirkup, Ruby [MCCUS]; Hooda, Rohinish [MCCUS]; Lim, Janet [MCCUS]; Ramirez, Nuria [MCCPR] GM; Ralls-Morrison, Desiree [MCCUS]; Pujals, Mayra [MCCPR]; Pawelski, Lynn [MCCUS]; Widmer, Kathy [MCCUS]

Sent: Mon Apr 20 10:03:03 2009
Subject: Motrin Recall Committee Meeting

All
Just received some good news from San Juan FDA District Director. She is in agreement with continuing to pull product from the rest of the stores and NOT consider this a National Recall. We can limit withdrawal to the convenience store group of customers using the firm that we used to execute the audits of the 250 stores. A Field Alert Report will be submitted to FDA within the next day to document this agreement. Please do not hesitate to contact me with questions.

Paul

Paul-Michel Di Paolo
Senior Director, Quality Assurance, OTC, US/PR
McNeil Consumer Healthcare
[redacted] office
[redacted] cell

Guzman, Cecilia [MCCPR]

From: Pujals, Mayra [MCCPR]
Sent: Thursday, July 16, 2009 1:11 PM
To: Guzman, Cecilia [MCCPR]
Subject: FW: Motrin product retreival

Ceci: Por favor hazme un FDA contact de esta conversacion.

****

Mayra Pujals
Acting Quality Site Leader
McNeil Healthcare LLC
a *Johnson & Johnson Company*
Telephone: [redacted]
Fax: [redacted]
e-mail: [redacted]@mccus.jnj.com

From: DiPaolo, Paul [MCCUS]
Sent: Monday, April 20, 2009 10:06 AM
To: Pujals, Mayra [MCCPR]
Subject: Re: Motrin product retreival

Carolyn Parziale will have all the information.
Paul

Paul-Michel Di Paolo
Senior Director, Quality Assurance, OTC, US/PR
McNeil Consumer Healthcare
[redacted] office
[redacted] cell

From: Pujals, Mayra [MCCPR]
To: DiPaolo, Paul [MCCUS]
Sent: Mon Apr 20 09:23:23 2009
Subject: Motrin product retreival
As I discussed with you by phone, FDA (Maridalia Torres) agreed to continue visiting the stores and retrieve the product if any is available, but we have to have documented evidence of this retrieval. Please let me know who can help us to receive a report that eventually will be send to the FDA as an evidence.

****

Mayra Pujals
Quality Site Leader
McNeil Healthcare LLC
a *Johnson & Johnson Company*
Telephone: [redacted]
Fax: [redacted]
e-mail: [redacted]@mccus.jnj.com

Form Approved: OMB No. 0910-0001. Expiration Date: May 31, 2008
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
Ms. Maridalia Torres, District Director
FDA - San Juan District Office
466 Fernández Juncos Ave.
San Juan, PR 00901-3223

TYPE OF REPORT
☒ Initial ☐ Follow-Up ☐ Final

In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO.
19-012 Motrin Caplets

2. NDC No.
50580-110-68

3. GENERIC NAME OF DRUG PRODUCT
Ibuprofen

4. TRADE NAME *(if any)* OF DRUG PRODUCT
Motrin Caplets

5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED
McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR 00771-2009

6. FEI
2650141

7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Motrin Tablets - Ibuprofen 200mg - 8 count vials

8. LOT NUMBER(S)
SHC003

9. EXPIRATION DATE(S) OF DRUG PRODUCTS
03/2011

10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
November 21, 2008

11. HOW WAS PROBLEM DISCOVERED
During the routine stability testing (3-month interval)

12. STATE PROBLEM(S)
Dissolution failure during the 3-month interval stability testing
Actual results:
- S1 = Average: 72% (min. 64%)
- S2 = Average: 71% (min. 64%)
- S3 = Average: 71% (min. 58%)

13. PROBABLE CAUSE(S) OF PROBLEM(S)
Investigation is in progress.

14. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Remaining inventory in the distribution centers has been placed on hold.

15. REMARKS
* This batch (SHC003), along with two others, was placed on stability in order to fulfill the marketed product stability requirements for new packaging codes (8 and 10 count vials). The other two batches are showing satisfactory dissolution results at S1 stage.

* On October 23, 2008 a communication was issued in order to discontinue the sale of this product display due to low volume sales.

* The retain samples of the finished product were tested and the results were within specifications (average 98, range 82-106, n=12)

* Bulk product is manufactured at McNeil Healthcare, LLC in Las Piedras and product is packaged at Reed Lane, Inc. in New Jersey.

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT	
NAME AND MAILING ADDRESS *(Include ZIP Code)* McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009	
NAME AND TITLE OF AUTHORIZED REPRESENTATIVE Eddie Carrillo	TELEPHONE *(Include Area Code)* [redacted]
SIGNATURE OF AUTHORIZED REPRESENTATIVE [redacted]	DATE SUBMITTED 11/26/2008

Form Appr[illegible] OMB No. 0910-0001. Expiration Date: May 31, 2009
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
Ms. Maridalia Torres, District Director
FDA - San Juan District Office
466 Fernández Juncos Ave.
San Juan, PR 00901-3223

TYPE OF REPORT
☐ Initial ☒ Follow-Up ☐ Final

In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 6/8 NO.
19-012 Motrin Caplets

2. NDC No.
50580-110-68

3. GENERIC NAME OF DRUG PRODUCT
Ibuprofen

4. TRADE NAME *(if any)* OF DRUG PRODUCT
Motrin Caplets

5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED
McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR 00771-2009

6. FEI
2650141

7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Motrin Caplets - Ibuprofen 200mg - 8 count vials

8. LOT NUMBER(S)
SHC003

9. EXPIRATION DATE(S) OF DRUG PRODUCTS
03/2011

10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
November 21, 2008

11. HOW WAS PROBLEM DISCOVERED
During the routine stability testing (3-month interval)

12. STATE PROBLEM(S)
Dissolution failure during the 3-month interval stability testing
Actual results:
- S1 = Average: 72% (min. 64%)
- S2 = Average: 71% (min. 64%)
- S3 = Average: 71% (min. 58%)

Specification
S1 = Each unit NLT Q + 5, Q = 80%
S2 = Average of S1 + S2 is equal to or greater than Q, No unit less than Q-15%
S3 = Average of S1+S2+S3 is equal to or greater than Q. Not more than 2 units less than Q-15%. No unit less than Q-25%

13. PROBABLE CAUSE(S) OF PROBLEM(S)
Investigation is in progress.

14. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Remaining inventory in the distribution centers has been placed on hold.

15. REMARKS

* This batch (SHC003), along with two others, was placed on stability in order to fulfill the marketed product stability requirements for new packaging codes (8 and 10 count vials). The other two batches are showing satisfactory dissolution results at S1 stage.

* On October 23, 2008 a communication was issued in order to discontinue the sale of this product display due to low volume sales.

* The retain samples of the finished product were tested and the results were within specifications (average 98, range 82-106, n=12)

* Bulk product is manufactured at McNeil Healthcare, LLC in Las Piedras and product is packaged at Reed Lane, Inc. in New Jersey.

Follow-up Status

* Bulk retained sample of batch SCH003 was tested and confirmed initial out of specification result.
Average = 76%, Range 65 - 99% (n=24)

* Fresh stability samples of lot SHC003 were tested in our Fort Washington affiliate and results passed dissolution specifications at S2.
Average = 80%, Range 71-94% (n=12)

* Fresh stability samples of lot SHC003 were tested in Las Piedras facility and the S1 results confirmed initial out of specification
Average = 74%, Range 69-79% (n=6)

* Temperature and humidity assessment to the stability chamber and retention room were performed and no atypical value was observed.

* Manufacturing batch record was reviewed and no atypical situation was observed.

* Retain bulk samples of four associated granulation batches were tested. Only compression lot SDA0000807 failed dissolution S3 criteria. The other three batches were within specification. This additional bulk batch, which failed dissolution, was already on hold and it was packaged in vials. Investigation is ongoing to understand the cause of these out of specification results.

* Assay, IB related compound Isobutylacetophenone, and Impurities results of stability batch SCH003 for the 3-month interval are well within specification.

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT

NAME AND MAILING ADDRESS *(Include ZIP Code)*

McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR. 00771-2009

NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	TELEPHONE *(Include Area Code)*
Eddie Carrillo	[redacted]
SIGNATURE OF AUTHORIZED REPRESENTATIVE [redacted] for E. Carrillo	DATE SUBMITTED 12/18/2008

Form Appr[redacted]: OMB No. 0910-0001, Expiration Date: May 31, 2008
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
Ms. Maridalia Torres, District Director
FDA - San Juan District Office
466 Fernández Juncos Ave.
San Juan, PR 00901-3223

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☐ Initial ☒ Follow-Up ☐ Final

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19-012 Motrin Caplets

2. NDC No.
50580-110-68

3. GENERIC NAME OF DRUG PRODUCT
Ibuprofen

4. TRADE NAME *(if any)* OF DRUG PRODUCT
Motrin Caplets

5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED
McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR 00771-2009

6. FEI
2650141

7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Motrin Caplets - Ibuprofen 200mg - 8 count vials

8. LOT NUMBER(S)
SHC003

9. EXPIRATION DATE(S) OF DRUG PRODUCTS
03/2011

10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
November 21, 2008

11. HOW WAS PROBLEM DISCOVERED
During the routine stability testing (3-month interval)

12. STATE PROBLEM(S)
Dissolution failure during the 3-month interval stability testing
Actual results:
- S1 = Average: 72% (min. 64%)
- S2 = Average: 71% (min. 64%)
- S3 = Average: 71% (min. 58%)

Specification:
S1 = Each unit NLT Q + 5, Q = 80%
S2 = Average of S1 + S2 is equal to or greater than Q. No unit less than Q-15%
S3 = Average of S1+S2+S3 is equal to or greater than Q. Not more than 2 units less than Q-15%. No unit less than Q-25%

13. PROBABLE CAUSE(S) OF PROBLEM(S)
Investigation is in progress.

14. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Remaining inventory in the distribution centers has been placed on hold.

16. REMARKS

* This batch (SHC003), along with [redacted] others, was placed on stability in order to fulfill the marketed product stability requirements for new packaging codes (8 and 10 count vials). The other two batches are showing satisfactory dissolution results at S1 stage.

* On October 23, 2008 a communication was issued in order to discontinue the sale of this product display due to low volume sales.

* The retain samples of the finished product batch SH003 were tested and the results were within specifications (average 98, range 82-106, n=12)

* Bulk retained sample of batch SCH003 was tested and result confirmed initial out of specification result.
Average = 76%, Range 65 - 99 (n=24)

* Fresh stability samples of lot SHC003 were tested in our Fort Washington affiliate and results passed dissolution specifications at S2.
Average = 80%, Range 71-94% (n=12)

* Fresh stability samples of lot SHC003 were tested in Las Piedras facility and the S1 results confirmed initial out of specification
Average = 74%, Range 69-79% (n=6)

* Temperature and humidity assessment to the stability chamber and retention room were performed and no atypical value was observed.

* Retain bulk samples of four associated granulation batches were tested. Only compression lot SDA0000807 failed dissolution S3 criteria. Result obtained for this batch was:
Average = 60%, Range 49-71% (n=24)
This additional bulk batch, which failed dissolution, was packaged also in vial and was already on hold in the distribution center. Investigation is ongoing to understand the cause of these out of specification results. The other three batches were within specification.

* Assay, IB related compound Isobutylacetophenone, and Impurities results of stability batch SCH003 for the 3-month interval are well within specification.

* During a detailed assessment of the manufacturing records from granulation step for the compression batch of packaging lot SCH003, a downtime of 1 hour and 25 minutes during drying was observed. This downtime is allowed by procedure, however it was found to be an atypical situation. Various other lots from 2006 through 2008 having similar and longer downtime during the granulation drying process were assessed. One lot on stability was made using granulation having a similar downtime as SCH003. The stability results through eighteen (18) months of storage are well within specification. In addition, retain samples from three batches made with granulation having longer drying downtime than that of SCH003 were assessed, one from each assessed year was identified. Retain bulk of these three batches were tested for dissolution and S1 results were well within specifications.
Lot MDA0002299: Average = 100%, Range 97 - 102% (n=6)
Lot PHA0002970: Average = 101%, Range 99 - 102% (n=6)
Lot SHA0000372: Average = 100%, Range 99 - 101% (n=6)

* A medical assessment was requested and it concludes that the use of Motrin IB caplets from these lots is not likely to cause an increased risk of serious adverse health consequences.

* Up to this point, although more investigative work is being performed, it is considered that this event is isolated to the original vial batch number SCH003 and batch SCH004, in which a result not meeting S3 dissolution specification was observed during retained bulk testing. Batch SCH004 was also packaged in vials. All remaining inventory of these two batches and other batches in this product code are currently on hold in our distribution centers. As stated before, this product code was discontinued.

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT	
NAME AND MAILING ADDRESS *(Include ZIP Code)* McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009	
NAME AND TITLE OF AUTHORIZED REPRESENTATIVE Eddie Carrillo	TELEPHONE *(Include Area Code)* [redacted]
SIGNATURE OF AUTHORIZED REPRESENTATIVE [redacted]	DATE SUBMITTED 1/22/2009

Form Approved: OMB No. 0910-0001, Expiration Date: May 31, 2009
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
Ms. Maridalia Torres, District Director
FDA - San Juan District Office
466 Fernández Juncos Ave.
San Juan, PR 00901-3223

TYPE OF REPORT
☐ Initial ☒ Follow-Up ☐ Final

In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO.
19-012 Motrin Caplets

2. NDC No.
50580-110-68

3. GENERIC NAME OF DRUG PRODUCT
Ibuprofen

4. TRADE NAME *(if any)* OF DRUG PRODUCT
Motrin Caplets

5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED
McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR 00771-2009

6. FEI
2650141

7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Motrin Tablets - Ibuprofen 200mg - 8 count vials

8. LOT NUMBER(S)
SHC003

9. EXPIRATION DATE(S) OF DRUG PRODUCTS
03/2011

10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
November 21, 2008

11. HOW WAS PROBLEM DISCOVERED
During the routine statibility testing (3-month interval)

12. STATE PROBLEM(S)
Dissolution failure during the 3-month interval stability testing
Actual results:
- S1 = Average: 72% (min. 64%)
- S2 = Average: 71% (min. 64%)
- S3 = Average: 71% (min. 58%)

Specification
S1 = Each unit NLT Q + 5, Q = 80%
S2 = Average of S1 + S2 is equal to or greater than Q. No unit less than Q-15%
S3 = Average of S1+S2+S3 is equal to or greater than Q. Not more than 2 units less than Q-15%. No unit less than Q-25%

13. PROBABLE CAUSE(S) OF PROBLEM(S)
Investigation is in progress.

14. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Remaining inventory in the distribution centers has been placed on hold.

15. REMARKS

* This batch (SHC003), along with two others, was placed on stability in order to fullfill the marketed product stability requirements for new packaging codes (8 and 10 count vials). The other two batches are showing satisfactory dissolution results at S1 stage.
* On October 23, 2008 a communication was issued in order to discontinue the sale of this product display due to low volume sales.
* The retain samples of the finished product batch SH003 were tested and the results were within specifications (average 98, range 82-106, n=12)
* Bulk retained sample of batch SCH003 was tested and result confirmed initial out of specification result.
  Average = 76%, Range 65 - 99 (n=24)
* Fresh stability samples of lot SHC003 were tested in our Fort Washington affiliate and results passed dissolution specifications at S2.
  Average = 80%, Range 71-94% (n=12)
* Fresh stability samples of lot SHC003 were tested in Las Piedras facility and the S1 results confirmed initial out of specification
  Average = 74%, Range 69-79% (n=6)
* Temperature and humidity assessment to the stability chamber and retention room were performed and no atypical value was observed.
* Retain bulk samples of four associated granulation batches were tested. Only compression lot (SDA0000807) failed dissolution S3 criteria. Result obtained for this batch was:
  Average = 60%, Range 49-71% (n=24)
  This additional bulk batch, which failed dissolution, was pakaged also in vial and was already on hold in the distribution center. Investigation is ongoing to understand the cause of these out of specification results. The other three batches were within specification.
* Assay, IB related compound Isobutylacetophenone, and Impurities results of stability batch SCH003 for the three month interval are well within specification.
* During a detailed assessment of the manufacturing records from granulation step for the compression batch of packaging lot SCH003 a downtime of 1 hour and 25 minutes during drying was observed. This downtime is allowed by procedure, however it was found to be an atypical situation. Various other lots from 2006 through 2008 having similar and longer downtime during the granulation drying process were assessed. One lot on Stability was made using granulation having a similar downtime as SCH003. The stability results thru eighteen (18) months of storage are well within specification. In addition, retain samples from three batches made with granulation having longer drying downtime than that of SCH003 was assessed, one from each assessed years was identified. Retain bulk of these three batches were tested for dissolution and S1 results were well within specifications.
Lot MDA0002299 : Average = 100%, Range 97-102% (n=6)
Lot PHA0002970 : Average = 101%, Range 99 -102% (n=6)
Lot SHA0000372 : Average = 100%, Range 99 - 101% (n=6)
* A medical assessment was requested and it concludes that the use of Motrin IB caplets from these lots is not likely to cause an increased risk of serious adverse health consequences.
* Up to this point, although more investigative work is being performed, it is considered that this event is isolated to the original vial batch number SCH003 and batch SCH004 which a result not meeting S3 dissolution specification was observed during retained bulk testing. Batch SCH004 was also packaged in vials. All remaining inventory of these two batches and other batches in this product code are currently on hold in our distribution centers. As stated before, this product code was discontinued.

A Health Hazard assessment was performed and it concludes that the Motrin IB caplets from these lots are not likely to cause an increased risk of serious adverse health consequences.

Two experimental batches have been manufactured re-creating the downtime specified above and have been packaged in bottles and vials. These will be placed in accelerated stability condition in order to assess the process downtime hypothesis.

As stated above, this Motrin product line was discontinued on October 23, 2008, due to low sales. Remaining inventory in the Distribution Centers and Packaging Contractor of Motrin batches SCH003 and SCH004 were placed on hold in November 2008. It is expected that none of these affected lots are available at the store level. A review of our complaint history indicates that neither affected lot has had a complaint registered against it from November 1st, 2008 through March 19, 2009. This finding further supports the hypothesis that neither of these lots are available at the store level.

In order to confirm that neither affected lots is available at the store level, a third party has been contracted to perform an in store assessment. A statistical sampling of twenty-five (25) percent of all stores across the US that received these batches will be visited. If this assessment confirms that there is no product from batches SCH003 and SCH004 at the store level, a recall will be considered not necessary due to unavailability in the market; otherwise a recall of these Motrin batches will be recommended to be performed. The assessment is expected to be completed by April 15, 2009.

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT	
NAME AND MAILING ADDRESS *(Include ZIP Code)* McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009	
NAME AND TITLE OF AUTHORIZED REPRESENTATIVE Eddie Carrillo	TELEPHONE *(Include Area Code)* [redacted]
SIGNATURE OF AUTHORIZED REPRESENTATIVE [redacted] for Eddie Carrillo	DATE SUBMITTED 3/23/2009

Form Approved: OMB No. 0910-0001, Expiration Date: May 31, 2008
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
bMs. Maridalia Torres, District Director
FDA - San Juan District Office
466 Fernández Juncos Ave.
San Juan, PR 00901-3223

TYPE OF REPORT
☐ Initial ☐ Follow-Up ☒ Final

In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO.
19-012 Motrin Caplets

2. NDC No.
50580-110-68

3. GENERIC NAME OF DRUG PRODUCT
Ibuprofen

4. TRADE NAME *(if any)* OF DRUG PRODUCT
Motrin Caplets

5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED
McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR 00771-2009

6. FEI
2650141

7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Motrin Tablets - Ibuprofen 200mg - 8 count vials

8. LOT NUMBER(S)
SHC003 and SHC004

9. EXPIRATION DATE(S) OF DRUG PRODUCTS
03/2011

10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
November 21, 2008

11. HOW WAS PROBLEM DISCOVERED
During the routine stability testing (3-month interval)

12. STATE PROBLEM(S)
Dissolution failure during the 3-month interval stability testing (Lot SHC003)
Actual results:
- S1 = Average: 72% (min. 64%)
- S2 = Average: 71% (min. 64%)
- S3 = Average: 71% (min. 58%)

Specification
S1 = Each unit NLT Q + 5, Q = 80%
S2 = Average of S1 + S2 is equal to or greater than Q. No unit less than Q-15%
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13. PROBABLE CAUSE(S) OF PROBLEM(S)
Investigation is in progress.

14. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Remaining inventory in the distribution centers has been placed on hold.

15. REMARKS

As stated in the previous Field Alert Report follow-up issued on March 23, 2009, in order to confirm the availability of Motrin batches SHC003 and SHC004 at the retail level, a statistical sampling of approximately ten (10) percent of all stores across the US that received these batches were visited (250 stores out of 2000). The assessment performed demonstrated that, on a statistical basis, a low amount of product (approximately 1% of the batches) is potentially still at the retail level. The product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.

A Health Hazard assessment has indicated that the use of Motrin IB caplets of the above batches is not likely to cause an increased risk of serious adverse health consequences. In addition, a review of our complaint history indicates that neither affected lots have had complaints registered against them from November 1, 2008 through April 13, 2009.

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT

NAME AND MAILING ADDRESS *(Include ZIP Code)*

McNeil Healthcare, LLC
PO Box 2009
Las Piedras, PR 00771-2009

NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	TELEPHONE *(Include Area Code)*
Mayra Pujals Quality Site Leader	[redacted]
SIGNATURE OF AUTHORIZED REPRESENTATIVE [redacted]	DATE SUBMITTED 4/21/2009

From: Carrillo, Eddie [MCCPR]
Sent: Monday, January 19, 2009 12:37 PM
To: [redacted]@fda.hhs.gov'
Subject: Consejo

Saludos Maridalia,

Espero que heyas pasado unas excelentes navidades. Tambien te deseo muchas felicidades y mucho exito en este año. Te escribo ya que me gustaria poder hablar contigo para ver tu opinion sobre lo que me interesaria hacer sobre el caso del FAR que te he enviado de Motrin. Me gustaria pasar por tu oficina para ver que consejo/opinion me das o si se te hace mas facil te podria llamar por telefono. Podrias dejarme saber cuando tendrias un tiempo disponible en tu agenda para yo poder llamarte o pasar por tu oficina.

Muchas gracias anticipadas por tu ayuda.

Eddie Carrillo
McNeil Healthcare, LLC

From: Carrillo, Eddie [MCCPR]
Sent: Thursday, March 12, 2009 10:23 AM
To: DiPaolo, Paul [MCCUS]; Miller, Bob [MCCUS]
Subject: FDA / Motrin - confidential

Paul / Bob

This morning I finally had the opportunity to discuss the Motrin issue with Maridalia. She said that she is willing to evaluate the data that reflect that there is no product in the market. In addition she would like to see a Health hazard report. We already have a draft of the Medical report from Andre. He hasn't finished it because he wanted to wait and see if we have an assignable cause. He will be contacted today in order to let him know that what we have is a most probable cause, and that we need this report completed today or tomorrow if possible. I mentioned to Maridalia that I will be sending a f/up FAR stating this approach along with the Medical Report. She was very emphatic that the discussion that we had was between her and myself because nobody can state that she is in agreement to/or not to recall the batch. I mentioned her that this will be treated very confidential between her and myself. My only concern will be the new Compliance Officer that she have in SJ. She comes from Florida, I met already with her and she seems like a person that does not negotiate, but anyway I will recommend to issue the f/up FAR stating the reasons why we believe there is no product in the market, state that we will conduct the "effectiveness check" at store level, and will include the Medical report. Let me know your thoughts!

Please treat my conversation with Maridalia very confidential!!

Thanks

Eddie

believes McNeil did as described in these FDA documents that we received.

Dr. SHARFSTEIN. Can you say that again? I am sorry.

Chairman TOWNS. On the screen there, Doctor.

Dr. SHARFSTEIN. Oh, I see.

Chairman TOWNS. On the screen.

Dr. SHARFSTEIN. What do we believe actually happened here?

Chairman TOWNS. Yes.

Dr. SHARFSTEIN. This is something that is troubling to the Agency. I am not sure we know the complete full story, but basically there was a problem with how Motrin tablets dissolve and whether or not patients would get the right dose. The company notified FDA that they were going to be evaluating whether there was product on the shelves to recall.

Then we were alerted, I believe, by one of the State Boards of Pharmacy that instead of just looking to see whether or not there was medication to recall, the company had a contractor that was going out and trying to buy up all the medicine when they went into the store, and the information said you should simply act like a regular customer while making these purchases, there must be no mention of this being a recall of the product. If asked, simply state your employer is checking the distribution chain

of this product and he needs to have some of it purchased for the project.

I don't think we really fully understood exactly what was going on. It was troubling to us and, when FDA found out about this, we insisted that an actual recall occur. And we did think that it reflected poorly on the company, and it was one of the things that FDA brought to their attention during this extraordinary meeting that happened in February.

Chairman TOWNS. Thank you. After the recall, FDA recommended consumers buy drugstore alternatives for their children. The vast majority of those drugstore products are made by Perrigo, a company in Michigan that had ongoing quality control problems. When was the last time FDA inspected the plant in Michigan that makes infants' and children's problems? Do you know when it was inspected last?

Dr. SHARFSTEIN. I do. I may ask Deb Autor to answer that because she oversees the compliance efforts at the Center for Drugs. I believe there were several inspections in the last couple years.

Ms. AUTOR. I don't have the exact dates here, but there have been several inspections in the last few years. I believe there have been two in 2010, but I would have to double-check those facts.

Chairman TOWNS. But you agree with the fact there have been some issues with quality control?