DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787)-474-9500 Fax:(787) 729-6809 Industry Information: www.fda.gov/oc/industry	09/20/2010 - 11/02/2010* FEI NUMBER 2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Delfin Lorenzo, General Manager

FIRM NAME	STREET ADDRESS
McNeil Healthcare, LLC	Rd # 183 Km 19.8 Bo. Montones
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Piedras, PR 00771	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

Motrin IB 200 mg caplets, 8 count vials, obtained dissolution failures at stability testing for batch SHC003 (b) (4) (b) (4) on 11/20/08 and at retain testing for bulk lot SDA237 packaged as lot SHC004 on 12/16/08.

Your firm failed to follow procedure (b) (4) Ver. (b) effective from 02/28/2008 to 06/23/2010, that defined product stability failures as one of the potential problems that could result in a recall. On 04/16/2009, during a "Recall Committee Meeting", your firm agreed to remove the defective product from the market by continuing the "reverse distribution at the wholesale/retail level". The reverse distribution process is used by your firm for the return of products that are not associated to quality defects/issues.

Batches SHC003, SHC004 and other four lots (SHC002, SHC042, SHC043 and SLC009) were retrieved from the market from 04/02/2009 to 07/15/2009 by a third party contractor that purchased the available amounts at retail outlets. However, your firm has no written and approved procedures for the actions taken in the retrieval of Motrin IB 200 mg caplets.

The failure of your Quality Unit to follow written and approved procedures is a recurrent observation.

OBSERVATION 2

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. Investigation (b) (4) was initiated on 03/15/2010 to document the recall decision for Motrin IB caplet - lot SDA149 after conclusion of investigations (b) (4) and (b) (4) (dissolution failures Motrin IB SHC003 and SHC004). The

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investigation concluded that no definitive root cause was determined for the atypical behavior of the dissolution failures. However, your firm's investigation did not include documented evidence that the characteristics of the container/closure system (e.g. permeability) were thoroughly assessed as part of the investigation.

B. On 05/03/10, your firm initiated Quality Notification (QN) # (b) (4) to investigate two (2) batches of Benadryl Allergy Ultra Tab (BAU) 100ct product lots AJA008 and SHA012 that reported confirmed "musty/moldy" complaints. The investigation determined that some lots meeting the original broad criteria for the TBA recall were not included on the 01/14/10 TBA Recall List due to the high number of affected lots and the manual process utilized. In addition, the investigation found that two lots (ASA066 and ASA202) were released in error by site QA as a result of a Quality Specialist human error. However, the following situations were not addressed in QN# (b) (4)

- McNeil Las Piedras Quality Management (Quality Site Leader and Quality Associate Director) temporarily replaced the processes for release and disposition of finished products stipulated on SOPs (b) (4) and (b) (4) with an informal process not specified in the procedures. However, the investigation did not address the responsibilities of your Quality Management in the release of lots ASA202, ASA066 and ADA194.

- Lot ADA194 was also on hold and then released by McNeil Las Piedras QA as part of the same event. However, this lot was not addressed in the investigation.

- Benadryl Lot (b) (4) was packaged with bottles supplied by (b) (4) Although, the investigation states that one of the potential root cause is that (b) (4) provided bottles to Las Piedras site on pallets which were contaminated with TBP, this was not further investigated at the supplier's site.

- TBA Recall List used in that process was not properly verified for accuracy and completeness and was not controlled to assure proper accountability and traceability. This resulted in the recall of twenty-six (26) additional lots of Motrin IB, Benadryl Allergy Tablets and Tylenol products between June 2010 and July 2010.

Your firm became aware of these deficiencies during the current inspection. As a result of our findings, a 3rd party will conduct a retrospective review of the investigations conducted or approved by the Quality Management involved in this event.

C. Laboratory Investigation (b) (4) was initiated on 08/11/2010 because during the product disposition process a QA specialist found that the product description and code reported in the Certificate of Analysis of lot BHA0001647 (Extra Strength Tylenol Tablet EZ) did not correspond to this lot number. As a preventive action, the (b) (4) will be programmed with an acceptance limit in the product description field to alert the analyst when the product description does not correspond to the product to analyze.

Review of similar instances found investigation (b) (4) initiated on 02/24/2010, to document that during the sample preparation of lot BBA000510, the (b) (4) acquired the balance tare (0.00000 g) instead of the sample weight corresponding to the assay sample preparation. According to the information provided by your firm during the current inspection, it is not clear what caused the data acquisition error. As a preventive action, the (b) (4) will

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also be coded with an acceptance limit in the sample weight field to avoid recurrences.

Investigation (b) (4) was reviewed by a 3rd party on 10/02/2010 in accordance to your Comprehensive Action Plan dated July 15, 2010. Our review of the investigation after the 3rd party review/approval, found that there is no documented evidence that your firm has performed a thorough assessment of the (b) (4) to identify what other changes/modifications are needed to prevent recurrence of documentation and/or data acquisition errors. In addition, investigation (b) (4) does not document as part of the corrective and preventive actions the need of such assessment/review. There is no assurance that the corrective/preventive actions identified by your firm as part of investigation (b) (4) are adequate.

D. QN# (b) (4) and QN # (b) (4) were initiated to investigate that on 02/16/10 and 02/17/10, during the compression process of Tylenol Extra Strength Rapid Release Gel lots (b) (4) and (b) (4) the (b) (4) was operated outside the velocity critical parameters (Maximum velocity: (b) (4) tablets per minute (TPM) / Actual velocity: (b) (4) TPM). The investigation states that on 03/01/10 lot (b) (4) was segregated and identified with an Alert Notification. However, this activity was not performed even though impacted lots (b) (4) and (b) (4) were recommended for destruction at the end of the investigation process.

The issuance of alert notifications is the primary control for the handling of rejected work-in-process (WIP) material. Although the batches were destroyed, our review found that your firm's investigations did not include the identification and implementation of actions to prevent this recurrence.

OBSERVATION 3

Drug products failing to meet established quality control criteria are not rejected.

Specifically,

There is no assurance that the established material controls are adequate to prevent the approval of finished product, in-process materials, and raw materials in "quarantine" ("hold/block") or "rejected" status. For example,

A. On 05/03/10, your firm initiated Quality Notification (QN) # (b) (4) to investigate two (2) batches of Benadryl Allergy Ultra Tab (BAU) 100ct product lots AJA008 and SHA012 that reported confirmed "musty/moldy" complaints. During the investigation your Quality Unit found that lots ASA066 and ASA202, which were included in the TBA Recall List, were placed on hold on 01/08/10. However, your Quality Unit inadvertently released the lots in (b) (4) on 03/15/10. Lot ASA202 was distributed to the market and then recalled in June 2010. Lot ADA194 was also identified as being on hold, released by your Quality Unit on 03/02/10 and then recalled in June 2010. Amendment to QN# (b) (4) identified as the root cause that the site Quality Management implemented temporary alternate processes during the TBA review without adequate controls to ensure the accuracy and effectiveness of the product disposition process.

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Our review found the following examples related to lack of adequate controls of rejected materials:

B. On 01/22/10, your Quality Unit placed the active ingredient Diphenhydramine HCL (DPH) lot (b) (4) on "block" status in (b) (4) (materials control system). However, on 02/11/10, a granulation area operator used the (b) (4) (b) (4) The "blocked" status material was weighed and used in eight (8) Tylenol PM Common granulation lots. QN# 1003220052, dated 02/16/10, was opened after the situation was detected by the group leader on 02/13/10. The investigation concluded that the blocked status material should have not been available for use in the manufacturing area as per SOP (b) (4) Receiving Chemical Components, Packaging Components and Bulk Product"; that the material was not identified with an Alert Notification as per SOP (b) (4) Deviations Investigation and Documentation Procedure"; and the procedures should detail when to use the manual transaction in (b) (4) Therefore, the root cause of the investigation was related to human error and inadequate procedures. However, corrective actions did not include additional controls in the (b) (4) to avoid manual transactions for material on "block" status. In addition, awareness training was not provided to the warehouse operators that dispatched the material from the warehouse to the granulation area in "blocked" status.

C. On 10/16/09, the QA specialist approved Tylenol Extra Strength Release Gels (ERG) lot (b) (4) (materials control system) for release to the Distribution Center and did not detect that the lot was associated to a Temporary Hold. Quality Notification (QN) # (b) (4) dated 10/22/09, found that the Temporary Hold for lot AMA046 was not identified in (b) (4) and the Alert Notification form was not attached to the batch record.

D. On 10/09/09, your firm detected that Tylenol PM Caplet lot ALA251 was released in (b) (4) on 10/06/09 with an open Temporary Hold (b) (4) associated to a validation. Quality Notification (QN (b) (4) dated 10/09/09, found that the QA specialist received a verbal authorization to deliver lot ALA251 to the warehouse for shipping to the distribution center as part of the "(b) (4) process. The "(b) (4) allows movement of materials but not release in (b) (4) However, the QA Specialist approved the lot inadvertently by human error.

OBSERVATION 4

The written stability program for drug products does not include sample size based on statistical criteria for each attribute examined to assure valid estimates of stability.

Specifically,

Our review of Rolaids manufacturing process found a trend of out-of-specification (OOS) and out-of-trend (OOT) results for low assay of Calcium Carbonate in the production of 2009 and 2010 (27 confirmed OOT, 9 confirmed OOS low assay). Your firm identified variability issues in the (b) (4) and (b) (4) Although corrective actions were implemented in June 2010, QN# (b) (4) was initiated on July 15, 2010 due to OOS results in the Calcium Carbonate test of batch (b) (4) Rolaids ES Freshmint Bulk. This investigation was still open at the start of the current inspection and a root cause had not been identified.

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Our review of your stability program found that the Calcium Carbonate assay is not monitored in stability although a downward trend in the assay values of Calcium Carbonate was observed in (b) (4) batches from time point 0 to time point (b) (4) The range of difference observed was from (b) (4)

In addition, variability is observed in the product manufactured until April 2010. For example,

Packaged Batch #	Number of compression batches used in the packaged batch	Range of Calcium Carbonate Assay Average Values at release for the individual compression batches Release spec: (b) (4) Stability spec: (b) (4)
Rolaids ES Freshmint 40s #0009PA	(b) (4)	(b) (4)
Rolaids ES Freshmint 100s #AMA178		(b) (4)
Rolaids Peppermint 150s # BDA267		(b) (4)
Rolaids Extra Strength Freshmint #AMA178		(b) (4)

However, your stability program does not consider that variability. According to your procedures, the stability sample is taken from only one (1) compression lot having the oldest granulation date.

There is no assurance that your program is adequate to support the stability of Rolaids products throughout shelf-life.

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

Our review found a trend of events initiated in 2010 showing that production and process control procedures related to the addition of components and containers are not followed. For example,

A. Manufacturing Investigation # (b) (4) was initiated on 07/26/2010 because during the compression process of Extra Strength Tylenol Caplets lot# BHA0001638, an incorrect granulation lot corresponding to Tylenol Rapid Release granulation lot# BHA0001437 was loaded in (b) (4) and used in the compression of tablets.

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One of the operators involved in the event confirmed that he was not physically present for the verification to ensure that the correct bin was placed on the (b) (4) He acknowledged that he was completing an unrelated task and relied on the other's operator performance to verify that the correct batch was being used.

B. On 06/07/10, while processing Tylenol Extra Strength Rapid Release Gels (ERG) lot BEA0002740 in the (b) (4) (b) (4) the operator inadvertently loaded bucket # (b) (4) containing another Tylenol (ERG) lot (b) (4) resulting in the mix of two different lots. A second operator checked the movement without detecting the discrepancy. The discrepancy was detected on 06/07/10 during the reconciliation process.

Subsequently, on 06/08/10, (b) (4) containing lot (b) (4) (already engraved) was loaded again into the engraving machine while processing Tylenol (ERG) lot (b) (4) The engraving machine rejected the product at the beginning of the process. Quality Notification (QN) # (b) (4) dated 06/08/10, identified as the root cause the lack of verification of the bucket identification against the batch record documentation by the operators. The impacted product was destroyed due to the lack of traceability.

C. On 04/07/10 during the granulation batch record revision of Motrin Ibuprofen lot BCA0000892, the operator detected that (b) (4) (Part no. (b) (4) used for Tylenol) was weighed instead of (b) (4) (b) (4) (Part No. (b) (4) On 04/08/10, the supervisor found that two additional lots, (b) (4) and BCA0001829, were also weighed using the same incorrect material. Quality Notification (QN) # (b) (4) dated 04/07/10, identified the root cause of the investigation as a human error, since the operators failed in execution and verification activities. Lots impacted by the event were destroyed.

D. On 01/27/10, during the coating process of Benadryl Allergy Ultratab (BAU) lot BBA0000746, the operator selected the Benadryl Allergy Kapgels formula instead of Benadryl Allergy Ultratab formula. On the same day, after running the product with the incorrect formula for (b) (4) a second operator detected the discrepancy and stopped the process for (b) (4) Your firm's Technical Group decided to continue the critical (b) (4) (b) (4) that were different between the formulas (b) (4) (b) (4) There is no documented evidence of QA approval for this change. Quality Notification (QN) # (b) (4) dated 01/27/10, identified human error as the root cause since the operator did not follow the instructions in the batch record. Lot BAA0000746 was released to continue processing and for commercial distribution based on acceptable results of statistical sampling.

There is no assurance that activities related to charge-in of components/containers are adequately executed, verified and/or supervised during manufacturing activities.

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OBSERVATION 6

Written procedures are not followed that describe the in-process controls, tests, and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

Our review observed a trend of events initiated from January 2010 to September 2010 that is related to failure to identify defects and out-of-specification values during routine in-process testing and deviations to critical processing parameters. For example:

OOS in in-process samples not identified/detected

A. On 06/13/10, during the verification of the compression batch record for Tylenol PM Geltabs (PMJ) lot (b) (4) the QA Technician found a hardness value out of specification (OOS). Quality Notification (QN) # (b) (4) dated 06/14/10, found that the operator did not detect the hardness OOS value and failed to segregate and identify the impacted portion of the lot. The affected portion of the lot was recommended for destruction. Your firm's investigation identified sixteen (16) similar events for the period of 06/26/08 to 06/26/10.

Defects not identified during routine in-process testing

B. On 05/28/10, during a packaging line QA audit of the Imodium A-D Caplet 24 NDA (IMK) Lot BEA191, the QA Technician detected that one (1) expiration date in the impression mat was incorrect causing the printing of an incorrect expiration date in 1 out of 16 blisters produced. The expiration date read 03/13ZZ instead of 03/13. Quality Notification (QN) report # (b) (4) dated 05/31/10, found that the defect was not detected during QA verification when received from the vendor; was not detected during mechanic verification before installation, neither detected by the second operator responsible to verify the expiration date in the impression mat according to procedure (b) (4) A total of thirty-four (34) in-process visual inspections performed during the packaging process did not detect the expiration date defect.

C. On 12/14/09, your Analytical Laboratory detected units of (b) (4) from lot (b) (4) with tiny white mottling spots (porous defect) and generated a QC Alert. On 01/12/10, the GQA Technician performed a statistical sampling to the Sudafed lot consisting of 1250 units with an acceptance (b) (4) and a (b) (4) The statistical sampling failed, detecting 950 units with porous product which can cause "tiny white mottling spots". However, the defect was not detected during routine in-process sampling. Quality Notification (QN) # (b) (4) initiated on 01/12/10 found that there were no clear instructions/visual aids to identify the defect. A visual

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aid was created and implemented on July 2010, but as of October 2010 the document was not part of a written and approved procedure.

Equipment/process critical parameters out of approved and written limits not identified during production

D. QN# (b) (4) and (b) (4) were initiated because on 02/16/10 and 02/17/10, during the compression process of Tylenol Extra Strength Rapid Release Gel lots BBA0001067 and BBA0001074, the Fette #22 was operated outside the velocity critical parameters (Maximum velocity: (b) (4) This discrepancy was not identified by the compression operator. In addition, on 02/17/10 the QA Document Review Technician audited and approved the batch record for lot BBA0001067 without detecting the out of parameter condition.

E. On 12/30/09, during the packaging process of RS Tylenol Tablet 100 Lot ASA275, the QA Technician audited (b) (4) and observed that the speed critical parameter of the (b) (4) was documented out of range limits (b) (4) (b) (4) Quality Notification (QN) # (b) (4) dated 01/11/10, found that the mechanic that performed the setting up of (b) (4) speed and the operator who verified the parameter on 12/29/10 did not follow the procedures for the execution of these tasks.

OBSERVATION 7

Established laboratory control mechanisms are not followed.

Specifically,

Laboratory Investigation (b) (4) was initiated on 08/11/2010 because during the product disposition process a QA specialist found that the product description and code reported in the Certificate of Analysis of lot BHA0001647 (Extra Strength Tylenol Tablet EZ) did not correspond to this lot number. Your investigation found the following:

- ❒ Lot (b) (4) was received from the manufacturing area and logged manually as an Extra Strength Tylenol Tablet EZ. However, it was logged in (b) (4) automated system that captures laboratory data) as a Tylenol Extra Strength Caplets lot.
- ❒ The lot was approved by the analytical laboratory on 07/28/2010 with an incorrect appearance product description and the error was not identified by the system and/or the verification steps described in your procedures.
- ❒ The QC Sample Receiving Clerk was not trained in the current SOP for product sample receiving, testing and disposition.
- ❒ The analyst (QC technician) that performed the assay was certified in the technique of assay test, but not trained in the current method specification.
- ❒ The (b) (4) templates (working sessions) that were used were those of an Extra Strength Caplet product instead of Extra Strength Tylenol Tablets - EZ Tablets product. Therefore, the lot BHA0001647 was incorrectly logged, analyzed and approved.

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- ☐ The sample was in the analytical laboratory six (6) days and the discrepancy was not identified by the receiving clerk, the two analysts that performed the finished testing and/or the approver that retrieved the electronic analytical report for review and approval. The investigation found about 8 deviations to your written and approved procedures.
- ☐ In addition, your laboratory investigation found the following events that occurred from 07/24/2010 to 08/21/2010:
  - Lot BHA0001641 (EZ Tab Product) was also approved by the analytical laboratory on 07/27/2010 with an incorrect product description.
  - Lot BHA0003572 was documented with an incorrect part number in SmartLab system. A domestic part number was used instead of (b) (4) part number.
  - Lot BHA0002870 was logged incorrectly in (b) (4)
  - The second granulation lot of TAR lot BHA0001705 was entered incorrectly in (b) (4)
  - Motrin IB granulation lot BHA0003485 was logged in (b) (4) as a compression lot number.

The investigation concluded that the root cause was related to "a laboratory error related to the lack of self-checking to ensure that the intended action is correct before it is performed". Corrective actions related to an assessment about the performance of analysts and improvements to the training process are still pending.

There is no assurance that other similar instances have been identified by your firm and that the current laboratory controls are adequate to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

OBSERVATION 8

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used, description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance, and instructions for protection of clean equipment from contamination prior to use.

Specifically,

The established procedures and controls for cleaning and maintenance may not be sufficient to prevent mix-ups and/or contamination during the manufacturing and packaging process as evidenced by the mix-up deviations, and incidents involving manufacturing and packaging operations. There is no assurance that the established procedures for the cleaning and verification of manufacturing and packaging areas and equipment are clear and specific for the intended purpose. Since January 2010 to September 2010 your firm reported about eight (8) mix-up event from which five (5) are related to human error, four (4) are related to method, and two (2) are related to equipment. For example,

a. On 07/09/10, during the packaging process of Extra Strength Tylenol PM Caplet for lot BHA046 in Line #2, the filler operator detected one (1) unit of Motrin IB Caplet (MIK). Investigation QN# 1003220426, dated 07/09/10, found that there are no instructions to disassemble (b) (4) and (b) (4) identified product trap point location within the equipment; and did not discard the human factor as a root cause.

b. On 04/07/10, after discharging the Motrin IB Caplet (MIK) lot BCA0001615 into the (b) (4) and

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466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787)-474-9500 Fax:(787) 729-6809 Industry Information: www.fda.gov/oc/industry	09/20/2010 - 11/02/2010*
	FEI NUMBER 2650141

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Delfin Lorenzo, General Manager

FIRM NAME	STREET ADDRESS
McNeil Healthcare, LLC	Rd # 183 Km 19.8 Bo. Montones
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Piedras, PR 00771	Manufacturer

during the minor cleaning of (b) (4) the operator detected one (1) coated Benadryl Ultra Tablet Bulk (BAU) unit in the bucket. Investigation QN# (b) (4) dated 04/07/10, concluded that the event was caused by human error; and found that there are no specific instructions on the use of the buckets for extraordinary activities.

c. On 03/27/10, during the clearance process of (b) (4) the QA Technician observed two (2) white tablets with (b) (4) (Tylenol Extra Strength Rapid Release), packaged on 03/26/10 and one (1) Motrin Tablet (MIT) packaged on 01/10/10. Additional product was found in the packaging traps, conveyor and floor. Investigation QN# (b) (4) dated 03/27/10, found that the cleaning procedures are not clear and specific, and identified difficult to reach areas in the equipment.

In addition, from January 2010 to September 2010 your firm generated approximately fourteen (14) cleaning investigations and twenty-seven (27) manufacturing cleaning "incident reports" (detected during verification).

Moreover, a total of forty-nine (49) mix-up related consumer complaints have been received by your firm for the same period. Your Quality Unit classified all the referenced mix-up complaints as isolated occurrences based on the fact that no prior complaints were reported for the specific lot number investigated, and that no quality-related issue could be identified.

There is no assurance that the corrective actions are adequate to prevent mix-ups and cleaning deviations at the site. This is a recurrent observation.

*** DATES OF INSPECTION:**
09/20/2010(Mon), 09/21/2010(Tue), 09/22/2010(Wed), 09/23/2010(Thu), 09/27/2010(Mon), 09/28/2010(Tue), 09/30/2010(Thu), 10/04/2010(Mon), 10/05/2010(Tue), 10/06/2010(Wed), 10/07/2010(Thu), 10/12/2010(Tue), 10/13/2010(Wed), 10/14/2010(Thu), 10/18/2010(Mon), 10/19/2010(Tue), 10/25/2010(Mon), 10/26/2010(Tue), 11/02/2010(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jose R. Lopez, Investigator Rebecca Parrilla, Compliance Officer/ Recall Coordinator	DATE ISSUED 11/02/2010