DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/07/2010 - 01/05/2011* FEI NUMBER 1640689

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David J. Calver, Supply Director

FIRM NAME	STREET ADDRESS
Reckitt Benckiser, Inc.	14801 Sovereign Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Worth, TX 76155-2645	Human Drug 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:

QUALITY SYSTEM

OBSERVATION 1

Each lot of components is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

a. Your procedures allow for the release of raw materials, to include Active Pharmaceutical Ingredients (API's), for use in production prior to testing and release by the Quality Control Unit (QCU).

b. Raw materials, to include Active Pharmaceutical Ingredients, are routinely released for use in production prior to testing and release by the QCU.

i. The percentage of API batches released to production prior to testing and prior to release by the QCU out of all API batches used from 3/17/10 to 11/1/10 is as follows;

API	Number of API batches released to production prior to testing and release by the QCU from 3/17/10 to 11/1/10	Total number of API's used by production from 3/17/10 to 11/1/10	Percentage of API batches released to production prior to testing or release by the QCU from 3/17/10 to 11/1/10
Pseudoephedrine HCl, USP	6	(b) (4)	(b) (4)
Dextromethorphan HBr, USP	5	(b) (4)	(b) (4)
Guaifenesin, USP	11	(b) (4)	(b) (4)

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Scott T. Ballard, Investigator
Robert D. Tollefsen, Investigator
Jodi M. Gatica, Investigator

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ii. The specific API batches released to production prior to testing and prior to release by the QCU from 3/17/10 to 11/1/10 are as follows;

API	API Batch #	Date released to production	Date release by QCU	Number of days between release to production and release by QCU
Pseudoephedrine HCl, USP	01001875	(b) (4)	(b) (4)	3
	01001876	(b) (4)	(b) (4)	3
	01002385			1
	01002386			1
	01002387			1
	01002742			1
Dextromethorphan HBr, USP	01001757			8
	01002020	(b) (4)	(b) (4)	6
	01002245			2
	01002246			2
	01002247			2
Guaifenesin, USP	01002005			5
	01002006			6
	01002007			6
	01002008			6
	01002009			5
	01002193			4
	01002278			4
	01002279			4
	01002280			4
	01002282			4
	01002326			3
	01002327			3
	01002328			3
	01002329			3

iii. The following is one example where an API batch was used by production in manufacture of a finished drug product packaging batch prior to testing and prior to release of the API batch by the QCU;

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- Guafenesin API batch 01002007 was issued to production on 9/29/10 and used in the manufacture of Mucinex SE 1200mg 28ct Blister batch WO00473786 on 10/1/10. This was 4 days prior to the 10/5/10 release by the QCU of Guafenesin API batch 01002007. Mucinex SE 1200mg 28ct Blister batch number WO00473786 was later approved by the QCU on 10/18/2010.

OBSERVATION 2

In-process materials are not tested for quality and purity and approved or rejected by the quality control unit during the production process.

a. Your procedures allow for the release of in-process batches to include granulation batches, blend batches, and bulk tablet batches for use by production prior to testing and prior to release by the QCU.

b. In process materials, to include granulation batches, blend batches, and bulk tablet batches are routinely released for use in production prior to testing and release by the QCU. The following chart identifies examples where packaging batches were manufactured using in-process batches that were not tested or approved by the QCU prior to their use in subsequent significant manufacturing steps;

Date Packaging batch Released for Distribution	Product Description	Package Batch Lot Number	Bulk Tablet Lot Number	Tablet Batch Used under conditional release	Blend Lots used under condition al release	Granulation Lots used under conditional release
10/8/2010	Mucinex SE 600mg 20ct Blister	WO00465058	WO00466999	Yes	0 of (b)(4)	4 of (b)(4)
9/27/2010	Mucinex-D 1200mg 24ct Blister	WO00466411	WO00468282	Yes	0 of (b)(4)	0 of (b)(4)
11/3/2010	Mucinex SE 1200mg 14ct Blister	WO00466417	WO00471764	Yes	2 of (b)(4)	0 of (b)(4)
10/14/2010	Mucinex D 600mg 18ct Blisters	WO00476488	WO00475411	Yes	3 of (b)(4)	0 of (b)(4)
Destroyed	Mucinex D 600mg 36ct Blisters	WO00472027	WO00475413	No	2 of (b)(4)	0 of (b)(4)

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9/13/2010	Mucinex DM 1200mg 14ct Blisters	WO00466385	WO00469142	No	1 of (b) (4)	6 of (b) (4)
7/1/2010	Mucinex DM 600mg 20ct Blisters	WO00460184	WO00452062	No	1 of (b) (4)	0 of (b) (4)

c. Your ERP (Enterprise Resource Planning) system used to maintain the status of materials (e.g.; Quarantine, Release, Hold) in your warehouse and processing areas has been set by default to place all granulation batches and all blend batches to a status of released for use in production as soon as they are manufactured. Additionally, you have failed to implement controls to maintain the status of these granulation batches or blend batches while stored in the processing areas or in the WIP (Work-in-Progress) storage area of the Warehouse (i.e.; these materials are not physically identified or segregated as to their status).

OBSERVATION 3

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

a. The (b) (4) is an in house developed electronic record reportedly relied upon by Quality Assurance release staff as a control tool for determining that all Exception Reports and Lab Investigations have been closed out and as a control for determining that all conditionally released raw material batches and all conditionally released in-process batches used in manufacture of a packaging batch have been approved before final sign off for approval to release a packaging batch. Concerns regarding the (b) (4) include;

- No procedure defines that this electronic record is used as part of batch release.
- No procedure defines how QA release staff access this electronic record as part of batch release. No alternative control system is used by the QA release staff to verify the information provided to them in the (b) (4)
- No procedure defines how data from Exception Reports, Lab Investigations, conditionally released raw material batch status, or conditionally released in-process batch status is manually populated by QA release staff into this electronic record.
- No procedure defines what data is required to be populated into this electronic record or how this data, once populated into the record, is to be maintained. Older data populated into this electronic record is overwritten as newer data is input with no record of the older data being maintained.
- There are no established requirements, no established design controls or version controls, and there has been no validation or qualification established for this electronic record called the (b) (4) The (b) (4) is a (b) (4) document file stored on a shared directory that is reportedly accessed, populated, and used electronically by QA release staff.

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b. Mucinex D 600mg tablets blister batch WO00476488 in 18 count blister packs was approved by the Quality Control Unit on 10/6/2010 allowing for final release of this finished drug batch even though there existed an open and unresolved deviation related to its manufacture. Specifically;

- During the filling of tablets for Mucinex D 600mg tablets blister batch WO00476488, tablets from one of the (b) (4) bulk tablet containers plugged up the production equipment. The plug up of the equipment was identified to be due to an increased tablet thickness for some of the tablets observed in bulk tablet container (b) (4) The fill was ended and bulk tablet container (b) (4) was isolated and was not used. Exception Report ER-10-210 was generated in response to this issue but this Exception Report with its documented investigation was not signed off as approved by the Quality Control unit until 11/11/2010, over 1 month after Mucinex D 600mg tablets blister batch WO00476488 had been approved for release by the Quality Control Unit.

c. The Review Checklist form (referred to as a "traveler form") is a check list reportedly used by QA release staff when reviewing production records for batch release. This form includes check offs to include; All pages of the batch record are present, All Pre-Run Release checks are completed, verify all weight tags are completed and accurate, all additional reports included, Lab Results Received and Acceptable, and Pending Corrections or Investigation. Concerns regarding this control include;

- No procedure defines that this production record review checklist is used as part of batch release.
- The review checklist form is not reviewed or approved by the Quality Control Unit and is not maintained under document control.
- This review checklist form, once completed, is reportedly destroyed and not maintained after the production records have been reviewed and a batch released.

OBSERVATION 4

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the quality of drug products.

Specifically, the Quality Control Unit has failed to adequately control the recent piping and equipment expansion of the distribution loop on the Purified Water (PW) system that included addition of point-of-use ports in the (b) (4) (b) (4) and in the (b) (4) This modified distribution loop was first used by production in the *manufacture of commercial batches starting on or* ***about July 19, 2010*** *and has been in continual use since that time.* Concerns regarding change control for this Purified Water system include;

1. To date, the Quality Control Unit has not reviewed the contractor's documentation to ensure that the contractor's records include sufficiently detailed "as built" or "isometric" drawings or other alternative records with sufficiently detailed design

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specifications necessary for verification of: equipment specifications (e.g.; gauges, valves, pumps, etc.), piping welds, piping dimensions, piping slopes, or process piping and valve arrangements are correct and are free of dead-legs. Additionally, the Quality Control Unit has failed to ensure that any other group at your firm has reviewed the contractor's records which are reportedly the source for the detailed design specifications for this modification to the Purified Water system.

2. To date, the Quality Control Unit has not approved the change control documentation required to release the PW distribution loop for use following the modifications. Change Management record CM#10-078 has never been signed off for Final Approval by Quality Assurance or by any other organizational unit at your company. Change Management Request CM# 10- 078 was identified as the record controlling this change. CM #10-078 requires that; *"Product SHALL NOT be Released until AFTER the Final Approval is complete. A new/updated room SHALL NOT be utilized until AFTER the Final approval is complete."*

3. To date, the Quality Control Unit has never approved Qualification report TR10-107 entitled "Installation and Operation Qualification of the Purified Water Systems New Section of Distribution Loop, Flow Meters and Recirculation Pump" that was generated to qualify the use of the Purified Water distribution loop after it had been modified. The objectives reported in the Purpose section of Qualification report TR10-107 are defined, in part, to; *"...present the documentation collected in support of the installation and operation qualification of the new section of the distribution loop, flow meters and recirculation pump installed on the Purified Water System..."*. Additional issues regarding this report include:

- Report TR10-107 is dated December 8, 2010, over 4 months after the modified distribution loop was first used by Production in manufacture of commercial batches

- Report TR10-107 concludes, in part, that; *"...The new section of distribution loop, the new pump, and the new flow meter is installed and operates according to design specifications..."* However, the design specifications for this change which are included in the contractor's documentation have not been reviewed, verified, or approved by the Quality Control Unit or by any other organization in your company. Even though report TR10-107 was not signed off by the Quality Control Unit it has been signed off by both the Operations group and by Technical Services group.

4. The stated objectives identified in report TR10-096 entitled "Revalidation of the Purified Water System after Modifications to the Distribution Loop" include; *"...to provide confirmation that the Purified Water System Distribution Loop continues to operate within its design specifications and is delivering Purified Water of acceptable quality and within USP and EP limits..."* and concludes; *"...the changes made to the Purified Water System Distribution Loop had no effect on the loop's ability to deliver Purified Water of acceptable quality."* Regarding this report;

- Report TR10-096 was not signed off by the Quality Control Unit until October 25, 2010 which is over 3 months after the modified distribution loop was first used by Production in manufacture of commercial batches.

- The Quality Control Unit reviewed and approved report TR10-096 even though it lacks complete information to support its conclusions regarding organisms recovered from the Purified Water system during the testing interval. Qualification report TR10-096 reports the following water born Gram negative bacillus were recovered from the Purified Water system during the test interval; (b) (4) and (b) (4)

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(b) (4) and concludes that these organisms are not objectionable. However, there is no information included in this report or any other report defining what rationale was used in determining that these organisms are not objectionable. Additionally, the microbiologist responsible for this conclusion in report TR10-096 explained her reasoning that these (b) (4) organisms were not considered objectionable was based exclusively upon the fact that all of them are organisms that one might expect to find in water.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm does not always fully investigate deviations or create exception reports when raw materials are accepted without full QCU review. For example:

1. An exception report was not generated by your firm for tablet lot WO00466999 compressed between 8/15/10 and 8/17/10 which had a super sack containing (b) (4) kg of Mucinex SE 600mg tablets with failing friability in-process results during in-process inspection which was rejected and destroyed as indicated in Material Hold Notice MH10-170 dated 8/20/10.

2. An investigation was not initiated by your firm specific to the root cause determination of tablet thickness of package lot WO00476488 of Mucinex D 600mg tablets packaged between 10/01/10 and 10/05/10 which had "thick" tablets failing to fit through the blister packaging machine during packaging. This led to a tablet lot WO00475411 hold (MH10-241 dated 10/12/10) awaiting further disposition and "remediation".

3. There was no investigation or exception report generated for the Conditional release of raw materials and subsequent use in manufacturing. This has occurred ten separate times without full analysis and quality unit review between 3/17/10 - 11/1/10 for the following APIs: Guaifenesin, Dextromethorphan, and Pseudoephedrine. See the chart in Observation #2 for further details of lot numbers and release dates.

OBSERVATION 6

The quality control unit lacks responsibility for approving or rejecting drug products manufactured and packed under contract by another company.

Specifically, obligations defined in your contract with (b) (4) in (b) (4) a third party human drug manufacturer, are not being met with respect to quality control operations governing the surveillance of manufacture of the following products packaged in 4 fluid ounce plastic bottles: Mucinex Children's Multi-Symptom Cold (Very Berry Flavor); Mucinex Children's Liquid Cough (Cherry Flavor); Mucinex Children's Liquid Cold (Mixed Berry Flavor); Mucinex

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Children's Liquid (Grape Flavor); Delsym Adult Nighttime Cough & Cold (Cherry Flavor); Delsym Adult Nighttime Multi-Symptom (Honey Lemon Flavor); and Delsym Children's Nighttime Cough & Cold (Grape Flavor). We reviewed four batch production records (Lot numbers: 0G247, 0K278, 0J272, and 0L234) used by (b) (4) in the manufacture of three of these products manufactured between July 2010 and November 2010 for your firm.

a. Your quality agreement with (b) (4) specifies your company is responsible for reviewing and approving original master batch records for the drug products manufactured for you under contract by (b) (4) However, batch record review identified (b) (4) use of production activity master forms which have not been reviewed or approved by your firm. These include, but are not limited to:

i. (b) (4) document FRM-QA-007-01 entitled "Record Review and Product Disposition Form" effective 10/20/10

ii. (b) (4) Work Instruction *WI-ADM-0009* revision C entitled "Lot Approval Report" effective *3/22/10*

iii. (b) (4) Work Instruction WI-QC-0007 revision A entitled "Production Line Clearance Form" effective 3/22/10

iv (b) (4) Work Instruction WI-PM-0123 revision A, Attachment A identified as "LPKG-2 Cleaning Checklist" effective 11/05/10

v (b) (4) form FM-PM-0094 revision E entitled "Machine & Transfer Line Cleaning and Sanitization Record-General" effective 7/01/10

vi. (b) (4) Form FM-MFG-0121 revision C entitled "Operator Control Chart - LP2 (Bottled Products)" effective 11/12/10

vii. (b) (4) Form FM-QC-0218 revision A entitled "In-Process Checks for LP-2 Reckitt Products" effective 9/07/10

viii. (b) (4) Form FM-QC-0219 revision A entitled "Finished Goods Inspection Checks- LP-2 Reckitt Products Carton" effective 9/07/10

ix. (b) (4) Form FM-QC-0219 revision B entitled "Finished Goods Inspection Checks - LP-2 Reckitt Products Carton" effective 11/19/10

b. Your quality agreement with (b) (4) specifies your company is responsible for approving process validation protocols and process validation reports for the drug products manufactured for you under contract by (b) (4) However, review of three protocols and two final reports exhibit discrepancies to include, but not limited to:

i. Significant portions of the scanned copies of the validation protocols and final reports received by your firm from (b) (4) for approval are not legible. However, they are signed and dated as approved by your firm's Quality Assurance (QA) Manager and/or QA Engineer.

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ii. On 9/10/10, your firm's QA Manager approved a process validation protocol deviation initiated by (b) (4) which indicated it was not necessary to revalidate the manufacturing process of Mucinex Children's Liquid Cough (Cherry Flavor) after major equipment additions of a (b) (4) and a (b) (4) were made to (b) (4) Tank (b) (4) after validation batches 1 (Lot 0H260B) and 2 (Lot 0H261B) were manufactured, but before validation batch 3 (Lot 0H262B) was manufactured.

iii. On 9/14/10, your firm's QA Engineer approved the Master Batch Formulation Validation Final Report for Mucinex Children's Liquid Cough (Cherry Flavor) regardless of the fact equipment used (b) (4) gallon Tank (b) (4) varied from equipment specified (b) (4) gallon Tanks (b) (4) and (b) (4) in the Master Batch Formulation Validation Protocol for this product which was approved by your QA Engineer on 8/27/10.

c. Your quality agreement with (b) (4) specifies your company is responsible for reviewing and approving all deviations, failures, and out of specification (OOS) reports generated by (b) (4) for the drug products manufactured for you under contract by (b) (4) However, your firm has no system or procedure in place to account for OOS reports, deviations, and non-conformance reports (NCRs) generated by (b) (4) which are to be submitted to your firm's review and approval. For example:

i. After multiple requests we made between 12/17/10 and 12/21/10 for copies of all (b) (4) investigations your firm reviewed and approved (to include OOS reports, deviations, and NCRs), copies of NCRs and OOS reports were not provided to us by your firm. However, during our batch record review we observed two of the four batch records (Lots 0G247 and 0K278) include OOS reports and one of four batch records (Lot 0K278) includes an NCR.

d. Your quality agreement with (b) (4) specifies your company is responsible for releasing product to the market; however your firm lacks procedures regarding batch record content review to allow the release of product such as, but not limited to:

i. Lot 0L234 of Mucinex Children's Multi-Symptom Cold (Very Berry Flavor) includes Revision A (Effective 9/07/10) and Revision B (Effective 11/19/10) of (b) (4) form FM-QC-0219 "Finished Goods Inspection Checks-LP-2 Reckitt Products Carton". The forms were used on 11/20/10 and 11/22/10, respectively. Your Quality Assurance Releaser signed and dated form CMFG-002 "Final Release of Product for Distribution" Revision 2 (Effective 5/12/09) for this lot on 12/16/10.

ii. Lot 0G247 of Delsym Adult Nighttime Cough & Cold (Cherry Flavor) manufactured by (b) (4) in July 2010 has two versions of production documents FM-04-248 "Finished Goods Analysis and Approval" Revision B within the "Master Batch Formula and Mixing Instruction" Revision B. Varied content within these forms includes, employee who prepared the form prior to use, batch number row, and issue and effective dates. This batch record also includes pages 24 and 25 of Revision C of form 04-248-4000 "Master Batch Formula and Mixing Instructions" (Effective 9/07/10).

iii. Lot 0G247 of Delsym Adult Nighttime Cough & Cold (Cherry Flavor) packaged in July 2010 is missing a pertinent page of the batch record from (b) (4) "Production Work Order" Revision B (Effective 7/15/10) which is used to document line filling and packaging information such as, line package used, fill weight specification, amount of retains needed, and bill of materials (e.g., bottles, caps, and labels).

OBSERVATION 7

Written procedures are not reviewed and approved by the quality control unit.

Specifically, various uncontrolled written instructions for performing specific processing activities were observed available to operators in the different processing areas each lacking revision number, date, signature of review, or signature of approval by the QCU. For example:

1. On 12/7/10, we observed a laminated placard in the (b) (4) compression room with instructions for inputting values into the parameter file used to control the automated (b) (4) tablet press during processing operations. Further evaluation determined the parameter values identified on this uncontrolled placard were not consistent with the parameter settings in use.

2. On 12/7/10, we observed placards for both of the automated (b) (4) series tablet compression machines with instructions for how to change the (b) (4) air filters on these presses.

3. On 12/7/10, we observed a placard for the automated (b) (4) tablet compression machine with instructions for double checking the correct configuration (i.e.; parameter file settings) have been entered.

4. On 12/8/10, we observed placards on blister packaging line (b) (4) that include instructions for how to deal with faults detected by the automated blister packaging equipment.

5. On 12/8/10, we observed placards on blister packaging lines (b) (4) with instruction for how to set up the vision systems used on these packaging lines for detection of defects in foil labeling, carton code, and tablets (i.e.; correct tablet, broken tablet, missing tablets).

6. On 12/8/10, we observed placards on blister packaging lines (b) (4) with instructions for visual inspection of blister packs to verify that all labeling on the back of the blister packs is properly aligned.

PRODUCTION SYSTEM

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OBSERVATION 8

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, bottle packaging line operators do not change or sanitize gloves between handling tablets, equipment, utensils, records, and other materials.

On 12/8/10, we observed a bottle line operator did not change or sanitize her gloves during the approximate two (2) hour period we observed the bottle filling/packaging process of Mucinex SE 600mg (lot #WO00472191). During this period of time, the bottle line operator (b) (7)(C) was observed using her gloved hands to alternate between operations which included her manually handling various pieces of equipment (e.g.,(b) (4) filling machine,(b) (4) Counter, and a printer), paper batch records and writing utensil, packaging components (e.g., labeling, interior of bottles placed back on the packaging line, cotton, bottle caps, and corrugated cardboard boxes), and tablets which were recovered and staged for placement back into the(b) (4) filling machine.

Additionally, procedure "Reject Recovery" (PKG-128) (Revision 2/Effective date 8/31/10) instructs operators to use "clean gloves" while handling recovered tablets and does not describe or give instructions for the sorting of tablets and does not describe criteria by which tablets can be sorted.

On 12/8/10, during packaging for Mucinex SE 600mg (lot #WO00472191) described above, the production line was stopped and material hold notice #10-329 was initiated by the QCU due to "Product contamination. A total of 39 shippers and 468 bottles were affected which resulted in production to cease."

OBSERVATION 9

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

Specifically, procedures describing production and material handling practices are not always followed. For example:

a. Procedure MFG-017 "COMPONENT WEIGHING" approved by the QCU on March 25, 2010 requires that weigh tags used to document records of weighing of components (raw materials) are to be initialed and dated by the person weighing each component. However, personnel performing these activities routinely document their initials and dates on weight tags using an electronic system that provides no assurance that the initials are attributable to the persons performing the weighing activities and provides no assurance that the dates included next to the initials are accurate and verifiable.

b. Procedure MFG-017 "COMPONENT WEIGHING" approved by the QCU on March 25, 2010 requires that; *"All weigh tags shall be verified by a second qualified individual. The weighing activities (Form) must be verified by a second qualified individual."* However, component weight tags are routinely not verified by a second individual. Examples of commercially

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distributed packaging batches manufactured using component weight tags that were not verified by a second individual are as follows:

Date Packaging batch Released for Distribution	Product Description	Package Batch Lot Number	Bulk Tablet Lot Number
11/3/2010	Mucinex SE 1200mg 14ct Blister	WO00466417	WO00471764
10/14/2010	Mucinex D 600mg 18ct Blisters	WO00476488	WO00475411
9/13/2010	Mucinex DM 1200mg 14ct Blisters	WO00466385	WO00469142

FACILITIES / EQUIPMENT SYSTEM

OBSERVATION 10

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, your firm has failed to validate process operating parameters for manufacturing tableted Mucinex products. For example:

1. To date, the (b) (4) Tablet Press (OMF-2083) has not been validated to establish appropriate process parameters for manufacturing Mucinex DM 1200mg tablets. The following is a partial list of examples of compression parameters not validated.
   a. Target Fill Depth
   b. Target Force
   c. Speed
   d. Feeder Speed
   e. Tolerance Plus
   f. Tolerance Minus
   g. (b) (4)
   h. (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/07/2010 - 01/05/2011* FEI NUMBER 1640689

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: David J. Calver, Supply Director	
FIRM NAME Reckitt Benckiser, Inc.	STREET ADDRESS 14801 Sovereign Rd
CITY, STATE, ZIP CODE, COUNTRY Fort Worth, TX 76155-2645	TYPE ESTABLISHMENT INSPECTED Human Drug Manufacturer

The (b) (4) tablet press has been in service since 2006.

On 11/8/10, Mucinex DM 1200mg tablets (lot #WO00469142) were manufactured using the (b) (4) press and were later found to fail dissolution testing due to blend failures according to ER #10-118.

Additionally, the document titled "Equipment Commissioning and Qualification Guidelines" (rev 8, dated 1/16/2009, #GEN-043) in section 7.2.2 requires "Documentation of operational parameter settings" and "include the verification of switch settings, input and output settings, and operational set point values." As described above, the requirements of this procedure have not been met and there is no written document which describes which parameters are critical for process control.

Repeat Observation from previous inspection 2/10/2010.

OBSERVATION 11

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically, facilities and equipment used for the manufacturing of human drug products are not kept in a sanitary condition. For example:

1. On 12/07/10, we observed blue residue on the floor and vacuum hose in Compression Suite (b) (4) housing the (b) (4) (b) (4) where compression of Mucinex D 600mg tablets (lot #WO00486137) orange and white-colored bi-layer tablets, had taken place and the room was labeled "To Be Cleaned".

2. On 12/7/10, we observed residue accumulation on the mezzanine and white powder accumulation on air-handling vents in the Fluid Bed Suite (b) (4) Air handling vents and mezzanine are located above the input vacuum hopper for the (b) (4) White powder residue was observed on the upper surface of the (b) (4) and on the stainless steel table near the entrance door where employees handle documents and other utensils. This room was in a cleaned status as documented by the Cleaning Log for Fluid Bed Suite (b) (4) entry dated 12/7/10).

3. On 12/7/10, we observed white fibrous material on the surfaces of the (b) (4) tablet press in close proximity (within 12 inches) to the compression tooling within the equipment cabinet.

4. On 12/08/10, grey colored accumulation was observed on the ceiling and ceiling vents above the bottle filling line bottle hopper where clean open bottles are placed and above the conveyor lines where bottles filled with tablets are conveyed towards the bottle cottoner and capper. This room was in a cleaned status as documented by the Packaging Area Cleaning Checklist with entries dated 12/8/10.

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5. On 12/08/10, grey colored accumulations of what appeared to be dust was observed on the green overhead shipper conveyor line above the tablet feed area on Blister Package line (b) (4) where Mucinex D 600mg (lot# WO00484367) was being blister-packaged.

OBSERVATION 12

Buildings used in the manufacturing, processing, and packing of a drug product are not maintained in a good state of repair.

Specifically, facilities in the compression suites, granulation room, blending room, and packaging line areas show evidence of damage or deterioration in proximity to exposed in-process and tableted human drug products. For example:

1. On, 12/8/10 we observed damaged and missing sections of over-head ceiling tiles above the bottle packaging line.
2. On 12/8/10, we observed holes and gaps in section of overhead ceiling tiles above the Blister Packaging Line (b) (4) We also observed damaged and flaking paint and dry-wall on the East wall, in the vicinity of the Blister Packaging Line (b) (4) and along the South wall in the vicinity of the Blister packaging Line (b) (4)
3. On 12/7/10, we observed flaking paint and rust on the motor that drives the (b) (4) (#E-2084)

OBSERVATION 13

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm's equipment in the compression suites show evidence of damage and deterioration in close proximity to exposed and in-process human drug products. For example:

1. On 12/7/2010, we observed cracked and flaking (b) (4) accumulated fibers, gaps under rubber gaskets, and metal impact marks on the (b) (4) tablet compressor (OMF-2083).
2. On 12/7/2010, we observed gaps under rubber gaskets and metal impact marks on the (b) (4) tablet compressor (OMF-1820).
3. On 12/7/2010, we observed cracked and broken plexiglass covers on (b) (4) (OMF-1820) around fasteners securing these covers.
4. On 12/7/10, we observed a vacuum manifold in the (b) (4) tablet press that was occluded with clear tape as well as an adhesive sticker residue on the surfaces of the equipment within the equipment cabinet.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David J. Calver, Supply Director

FIRM NAME	STREET ADDRESS
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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Worth, TX 76155-2645	Human Drug Manufacturer

LABORATORY CONTROL SYSTEM

OBSERVATION 14

Laboratory records do not include a complete record of all data secured in the course of each test, including all graphs and charts from laboratory instrumentation, properly identified to show the lot tested.

Specifically, your firm does not maintain all documents and data generated during the testing and analysis of drug products. For example:

On 12/9/10, we observed the (b) (4) dissolution apparatus with its automated sampling equipment generate a printed document pertaining to the analysis of Mucinex DM 1200mg tablets batch #WO00486135. Data recorded on this printed document included; rotation speed, dissolution bath temperature, sampling date and times, sample rinse volumes, sample load speeds, sample dispensing speeds. Regarding this hard copy record of dissolution testing;

a. The Senior Lab Technician (b) (7)(C) stated that for commercial drug product this documentation printed from the dissolution system is typically not reviewed and is typically destroyed after packaged batches are reviewed and released by the quality unit. The Director of Quality Assurance (RL) later confirmed that these records of dissolution testing for commercial batches are typically printed out and are not reviewed and are typically not maintained.

b. The following batch is an example of a recently manufactured drug product batch in which this data had been printed out from the dissolution system was unavailable for inspection and therefore could not be verified and had been destroyed according to the Director of Quality Assurance (RL).

Date Packaging batch Released for Distribution	Product Description	Package Batch Lot Number	Bulk Tablet Lot Number
10/14/2010	Mucinex D 600mg 18ct Blisters	WO00476488	WO00475411

*** DATES OF INSPECTION:**
12/07/2010(Tue), 12/08/2010(Wed), 12/09/2010(Thu), 12/10/2010(Fri), 12/13/2010(Mon), 12/14/2010(Tue), 12/15/2010(Wed), 12/16/2010(Thu), 12/17/2010(Fri), 12/21/2010(Tue), 12/28/2010(Tue), 01/05/2011(Wed)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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