DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	06/13/2011 - 07/08/2011* FEI NUMBER 1911445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Terence J. Walsh, Site Leader

FIRM NAME	STREET ADDRESS
Novartis Consumer Health	10401 Hwy 6
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lincoln, NE 68517-9626	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:

OBSERVATION 1

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

Specifically,

Your Quality Unit has failed in the responsibility and authority to monitor Quality Systems designed to assure the quality of drug products manufactured and packaged at your firm. This failure is evidenced in the Observations below (2-13), as well as continued NDA Field Alerts and recalls for similar problems over the last several years.

OBSERVATION 2

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically,

You have failed to open deviation investigations into numerous "critical" consumer complaints of foreign products found inside the drug products manufactured at your firm.

Specifically,

In the year 2010, you had 26 complaints where solid dosage form products (with confirmed mix-up complaints of Novartis Consumer Health "NCH"-Lincoln manufactured product) were returned to your

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site, by a customer, and no official investigation was opened.

In the year 2009, you had 13 complaints where solid dosage form products (with confirmed mix-up complaints of NCH-Lincoln manufactured product) were returned, by a customer, to your site and no official investigation was opened.

This is important because a total of 40 confirmed returned consumer complaint samples (containing mix-ups of NCH-Lincoln manufactured solid oral dosage form products) have not been adequately investigated by your firm.

Additionally,

You have failed to adequately investigate 166 complaint instances of foreign tablets in your drug products since 2009.

These instances refer to examples where the suspected solid dosage oral products were not returned by the complainant to the firm and no follow up was conducted by your Quality Unit.

Lastly,

Your Quality Unit's neglect to follow up with the complaint is a failure to follow Procedure SOP-202891, Conducting Deviation Investigations.

OBSERVATION 3

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

You have failed to extend investigations to all batches of product potentially affected by a problem.

For example,

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A) Your Quality Unit failed to extend the investigation to all lots/batches of product potentially affected for a recent mix-up complaint of Excedrin Migraine Tablets, Lot # 10087498, mixed with Excedrin Migraine Caplets. This complaint is associated with NDA Field Alert, dated 10/15/10.

Lastly, the conclusion of this investigation, reads in part, "it is not possible that the products were mixed within Novartis control." does not appear to be supported by the evidence in your investigation. The two products in the complaint sample were actually packaged on the same equipment within 4 orders of each other. Also, the investigation revealed several areas in the process where the two products could have possibly come into contact (compression, film coating, transport, packaging).

B) Your investigation of Unplanned Deviation PR, No: 88510, (opened March 2, 2011) investigating complaint 10656633 of mixed Excedrin Extra Strength caplets, Lot: 10099302 with Excedrin ES Gelcaps did not extend to all lots/batches of product potentially affected. In this instance, the two products were packaged on the same line b(4) consecutively.

These are just two examples of numerous instances in which your firm's deviation investigations do not extend to other lots/batches of product potentially affected by the problem.

THIS IS A REPEAT DEFICIENCY FROM THE PREVIOUS INSPECTION AT YOUR SITE, DATED 4/5-16/10.

OBSERVATION 4

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning an incident that caused a drug product or its labeling to be mistaken for another article.

Specifically,

You have failed to file NDA Field Alerts within 3 days of a problem being identified.

You have received numerous consumer complaints which were not submitted to the FDA as required by your firm's procedures:

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For example:

A) Since October of 2010 (a period in time where second person review of consumer complaints ceased at your firm), there have been 21 consumer complaints (for NDA products) that procedurally should have been reported as 3 day Field Alerts. A review of two individual Technical Complaint Investigation Reports for two of these NDA mix-up complaints (case 10642591 and case 10675854) revealed your investigation and conclusion (justification) for not submitting 3 day Field Alerts was inadequate. **Also, these two reports are indicative of a pattern of problem at your firm.**

It should be noted that this number was only verified beginning from October 2010, but is indicative of a problem for all consumer complaints received by your firm for mixed solid dosage form products on the market.

B) You have failed to file a 3 day Field Alert as required by your procedure, for complaint 10650826 regarding a mix-up of Excedrin Migraine Caplets, received on 1/26/11. The complaint sample was received by your firm on 2/14/11 and confirmed on 2/16/11. However, your initial 3 day Field Alert was not submitted until 2/22/11.

It should also be noted the conclusions drawn into the investigation of this mix-up did not appear to be supported by evidence gathered during the investigation. (See Observation 8-C)

C) You failed to file a 3 day Field Alert as required by your procedures, for complaint 10642060 regarding a mix-up of Excedrin Migraine Geltabs (lot: 10039449), received on 1/5/11. The complaint sample was received by your firm on 2/1/11 and confirmed on 2/4/11. However, your initial 3 day Field Alert was not submitted until 2/8/11.

Additionally, this complaint involves a mix-up of Excedrin Migraine Geltabs, Lot: 10096621, expires: 7/12 and Excedrin Migraine Tablets, Lot: 10039449, expires 7/10. The carton in question (Excedrin Migraine Geltabs, Lot: 10096621, expires: 7/12) was not reported as required by your 3-day Field Alert procedures (all lots potentially affected in the complaint were not addressed in the Field Alert, dated 2/8/11)

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A further review of your firm's complaint file revealed Excedrin Migraine Tablets, Lot: 10039449 (same lot as above) had a second mix-up complaint on 4/2/08 that appeared to have an unsupported conclusion.

Your firm's procedure, SOP-202335, OTC NDA Field Alert Reports, dated 7/31/09, reads in part, "Reports must be submitted to district FDA offices within three (3) days of a problem being identified. The three (3) day timing starts when the firm becomes aware of a reported problem (ie. complaints or internal testing)."

OBSERVATION 5

The batch records do not record the distinctive identification number, code, and name of equipment to identify major equipment to show the specific equipment used in the manufacture of a batch of a drug product.

Specifically,

You have failed to document the distinctive identification of the slats utilized on the (b) (4) tablet fillers during packaging operations on non-dedicated packaging Lines (b) (4) and (b)(4) (Lines (b) (4) and (b) (4) are used to package products such as Excedrin tablets, caplets, gel tablets, Bufferin, and No doz) (Line (b)(4) is used to package DEA schedule II products such as (b) (4) and (b) (4) solid dosage forms)

This is important because the dedicated slats are utilized as supporting evidence in two of your complaint investigations. These investigations (identified as Unplanned Deviation Report 74956 and 73243) state in part:

> "...The cavities in the slats are dedicated to a specific size product dose. The cavities in the slats used for Excedrin caplets are too small to hold Excedrin tablets. If Excedrin tablets had been in with the bulk caplets, they would have remained in the hopper. The packaging equipment used does not support this complaint."

This conclusion is based on knowing which dedicated slat was used in production (there are (b) (4) different sets of dedicated slats which can be utilized in packaging Lines (b) (4) & (b) (4). However, there was no documentation in the batch record of the dedicated slat used to package batch records 10074660 and 10066070, which are associated with Deviation Reports 74956 and 73243, respectively.

Furthermore,

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From 1/1/09 to 6/26/11, there have been (b) (4) bottles packaged on Line (b)(4), (b) (4) bottles packaged on Line (b) (4) and (b) (4) bottles packaged on Line (b) (4). According to a Novartis Quality Manager, none of these bottles have documented traceability to a particular set of slats.

OBSERVATION 6

Deviations from written production and process control procedures are not recorded and justified.

Specifically,

Your Quality Assurance review of critical foreign tablet complaint investigations (Technical Complaint Investigation Reports) is not occurring in a timely manner.

A review of foreign tablet complaint investigations, received by your firm, since 1/1/2009, revealed a total of **367 of 401** critical Technical Complaint Investigation Reports, have not been second-person reviewed within b(4) calendar days as required by your procedures.

There are approximately 138 reports that took over 100 days to review.

According to your procedures, closure (including QA review) of individual complaint investigations should be completed within b(days of receipt for all critical complaints (per Complaint Handling Procedure, SOP-202313).

OBSERVATION 7

Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

Specifically,

You have failed to identify the root cause of customer complaints for solid dosage form foreign tablets of products manufactured at your firm since at least 2009.

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Since 2009, you have received approximately 57 returned customer complaint, mix-up samples containing only NCH-Lincoln produced product.

Despite the continued evidence of solid dosage form mix-ups over these years, you have not determined a root cause of tablet/capsule/geltabs mix-ups.

As an example of the above,

A) You have failed to justify the root cause for a recent mix-up complaint of Excedrin Migraine Tablets, Lot # 10087498, mixed with Excedrin Migraine caplets.

The direct cause was identified as "Occurred outside Novartis Lincoln Control", however, there is no evidence to support your root cause. **This is just one example (showing a pattern) in which the root cause of the mix-up was determined to occur outside Novartis Lincoln control without documented justification.**

Lastly,

Your conclusion reads in part, "**based on this investigation, it is not possible that the products were mixed within Novartis control."

However, a review of the investigation into this problem revealed Excedrin Migraine Caplets were packaged on the same line (b) (4) four orders prior to Excedrin Migraine Tablets, Lot: 10087498, and immediately after.

B) You have failed to justify the root cause determination for a recent mix-up complaint of Excedrin Migraine Gel Tabs, Lot # 10072553, mixed with Excedrin TH Express Gels.

You have concluded, "The only possible way that the Excedrin TH Express gel caplets to have ended up inside the Excedrin Migraine GelTabs was for it to happen after the customer had opened the bottle." However, there is no documented evidence to support this root cause.

THIS OBSERVATION DEMONSTRATES A PATTERN OF PROBLEMS AT YOUR FIRM.

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OBSERVATION 8

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically,

Your Unplanned Deviation Reports are deficient in that conclusions drawn are not supported by the evidence in the reports.

For example,

A) The conclusion for Unplanned Deviation PR, No: 83756 (opened 10/20/10 and approved 10/22/10 for foreign tablets inside of Prevacid 24 hour packages) is not supported by evidence documented in the report.

The conclusion reads, in part, "Product pilfering is the most likely cause***Deliberate***Cause Verified". Additionally, the summary reads in part, "it appears the package was pilfered outside of Novartis' control." It also states, in part "it appears the carton was resealed/reglued and returned to the retailer for refund with Prevacid tablets being replaced with acetaminophen tablets. The suspect package was subsequently placed back on the shelf and purchased by the noted complainant."

A review of your investigation revealed there was no evidence to support the root cause (above) and conclusion that the sample was "pilfered".

B) Your conclusion for Unplanned Deviation PR, No: 88510 (opened March 2, 2011, investigates complaint 10656633 of mixed Excedrin Extra Strength caplets, Lot: 10099302 with Excedrin ES Gelcaps) is not supported by the information in the investigation.

Your conclusion reads in part "Based on all the supporting evidence above, there is a **very small to no possibility** that the foreign product was introduced through Novartis procedures and practices."

Further review of the information in the report indicated both products in the complaint (Excedrin Extra Strength Caplets and Excedrin ES Gelcaps) were packaged by NCH-Lincoln on the same equipment (line (b)(4) in the firm) consecutively, on the same day 10/4/10. This information does not support your summary.

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C) Your conclusion for Unplanned Deviation PR No: 87817 (opened 2/16/11, investigates complaint 10650826 of mixed Excedrin Migraine caplets, Lot: 10101757 with Excedrin Migraine Tablets) is not supported by the information in your investigation.

Your conclusion reads in part "This event occurred outside of Novartis control.", also "The incident is believed to have occurred outside of the manufacturing, packaging and holding operations at Novartis based on this investigation it is not possible that the products were mixed within Novartis control."

There is no documented investigational evidence to support your statement "This event occurred outside of Novartis Control". The product in the returned sample was packaged at NCH-Lincoln on line (b)(4) within 3 days of each other (11/17/10 and 11/20/10). Additionally, your investigation also revealed several areas in the process flow where the product could have come into contact (compression, film coating. Transport bins, packaging).

THE ABOVE EXAMPLES REPRESENT A PATTERN OF PROBLEM AT YOUR FIRM WHERE INVESTIGATION CONCLUSIONS ARE MADE WITHOUT JUSTIFCATION.

OBSERVATION 9

Written procedures describing the handling of complaints do not include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications, a determination as to the need for an investigation of any unexplained discrepancy, and explaining the reasons for the failure of the batch or any of its components to meet specifications.

Specifically,

Your Quality Assurance Unit has consistently failed to review critical complaints for drug products manufactured and packaged at your facility.

For example,

2011:
223 critical complaints have not been properly reviewed out of 223 critical complaints received by your firm.

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2010:
165 critical complaints have not been properly reviewed out of 587 critical complaints received by your firm.

Also, your Quality Assurance review of critical complaints ceased in mid-October of 2010. This deficiency was unnoticed by your Quality Unit until this FDA inspection.

Specific to Foreign Product Complaints:

Since October of 2010, a total of 88 consecutive critical complaints of foreign tablet complaints have not been adequately reviewed or investigated by your Quality Assurance Department.

In this instance, your Complaint Handling Procedure SOP-202313, and Quality Manual, Module N14.3 were not followed.

OBSERVATION 10

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically,

A) Your Quality Directive 2.1.01, Management Escalation Process, is routinely not followed.

For example, your site is procedurally obligated to report to Global QA "Any (critical) complaint or adverse event that may result in a potential 3 day Field Alert, BPDR, recall, correction or market withdrawal or may require non-routine regulatory reporting."

This procedure has not been followed, as Novartis corporate personnel was not aware (for a minimum of the last two years) of your critical complaints regarding complaint mix-ups until early June of 2011.

B) You have failed to send postage-paid mailing materials to customers complaining of foreign tablets (considered "critical" by your firm) as required procedurally by SOP, 203133, version 1, dated 1/22/10.

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In 2011, a total of 5 instances occurred where postage-paid materials were not sent to complaining customers when deemed necessary.

In 2010, a total of 13 instances occurred where postage-paid materials were not sent to complaining customers when deemed necessary.

This is significant, because neglecting to ship the postage-paid materials to the complainant expunges any attempt for the suspect product to be returned and properly investigated by your firm.

It is important to understand also that no person in Novartis was aware of this failure until the information was requested by the FDA on 6/16/11.

OTHER PROCEDURES CONSISTENTLY NOT FOLLOWED INCLUDE:

C) Complaint handling Procedure, SOP-202313, dated 5/09, was not followed in that critical complaints were not reviewed and investigations are not conducted as required.

D) Deviation Investigation Procedure, SOP-202891, dated 6/10, was not followed in that investigations were not always opened as required, all lots/batches of product potentially affected were not determined, conclusions were not justified and root cause was routinely not identified (regarding foreign tablet mix-ups).

E) Quality Manual for Handling of Consumer Complaints, Module N14.3, was not followed in that critical complaints were not reviewed or approved as required. Additionally, adequate corrective and preventative actions were not addressed and followed up (regarding foreign tablet complaints).

OBSERVATION 11

The number of qualified personnel is inadequate to perform and supervise the manufacture, processing, packing, and holding of each drug product.

Specifically,

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There are an inadequate number of personnel conducting and reviewing (at a minimum) complaint investigations occurring at your firm.

This was evidenced in your firm's lack of review of critical complaints as required procedurally.

This was also evidenced by the fact that once the deficiencies were discovered (during this FDA inspection), you brought outside assistance to conduct the reviews which should have originally been done by your Quality Assurance staff at NCH-Lincoln.

Also, you have one person (or designee in absence) conducting and closing initial complaint Technical Complaint Investigation Reports. This is inadequate as evidenced by failing to open (b) (4) investigations when needed, developing conclusions not supported by evidence, and consistently failing to follow up complainants when necessary.

OBSERVATION 12

GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically,

Training is inadequate in the Quality Unit at your firm.

This is evidenced by the problems documented: failure to open (b) (4) investigations when needed, investigational conclusions not supported with evidence, failures to satisfy 3-day Field Alert requirements, failure to escalate critical complaints to corporate personnel, failure to notify top management when Quality procedures are not being followed due to time constraints, and consistent failures to follow up with complainants when necessary.

Most importantly, a lack of training is evidenced by the fact that no person at NCH-Lincoln recognized the failures in the Quality Unit's Oversight (see Observations above) prior to this inspection.

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OBSERVATION 13

Written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs.

Specifically,

Your Use Sequence Log, used to document packaging activity on non-dedicated equipment (line (b)(4)), is not always completed by your operators assigned to verify packaging line clearance.

There is no operator signature in the Use Sequence Log for "Dates of Major (wet) clean only" indicating major cleans are conducted as required after a particular packaging run. Major cleans should have been documented on the forms after: Excedrin ES Tablets (6/10/09), Excedrin AFTH (6/11/09), Excedrin PM Capsules (6/18/09) however, this was not completed.

The example above is indicative of how your firm currently operates with regard to filing out line usage logs for all packaging lines.

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06/13/2011(Mon), 06/14/2011(Tue), 06/15/2011(Wed), 06/17/2011(Fri), 06/20/2011(Mon), 06/21/2011(Tue), 06/22/2011(Wed), 06/23/2011(Thu), 06/27/2011(Mon), 06/29/2011(Wed), 07/01/2011(Fri), 07/08/2011(Fri)

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