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	12/14/2011 - 01/20/2012* FEI NUMBER 1911445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Brian J. McNamara, Region Head OTC Americas, Novartis Consumer Health

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.

QUALITY SYSTEM:

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 described below: (Failure to adequately investigate consumer complaints, Failure to assure your processes remain in a current validated state, Failure to conduct complete Annual Product Reviews, Failure to train employees within your operations and quality systems, Failure to extend investigations of known problems to all lots potentially affected, Failure to file adequate NDA Field Alerts in a timely manner and Failure to have an adequate number of trained personnel in your Quality Unit).

This is also evidenced by continued incorrect/incomplete/untimely NDA Field Alerts and numerous product recalls for similar problems over the last several years.

Products affected by this lack of overall Quality oversight include, but are not limited to:

OTC:	RX:
Excedrin (Entire Product Family)	Endocet

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Bufferin (All Strengths)
NoDoz
Gas X
(b) (4)
Prevacid

Percocet
Morphine Sulfate ER
Opana
(b) (4)
(b) (4)

THIS IS A REPEAT OBSERVATION FROM THE LAST FDA INSPECTION AT THIS SITE, DATED 6/13-7/8/11.

OBSERVATION 2

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

Specifically,

QUALITY SYSTEM:

Your Quality Assurance review of critical and major complaint investigations (Technical Complaint Investigation Reports) is not occurring in a timely manner according to your procedures.

As of 12/12/11, your firm is overdue (untimely) with adequately conducting approximately 1,360 investigations you have received from consumer complaints (1332 are major, 31 are critical). This backlog of overdue complaints has been over 1,000 in number since at least 8/30/11.

Complaints requiring review include, but are not limited to: foreign products in container, suspected tampering, foreign object, missing label, discolored product, partial tablet, chipped/cracked and crumbled product, etc.

Untimely review of critical and major complaints is a Quality Unit failure to follow Procedure SOP-202313, Complaint Handling Procedure. Critical complaints are procedurally required to be closed within (b) (4) calendar days from the date of receipt. Major complaints are required to be closed within (b) (4) calendar days. For the above instances, the critical and major complaints are not completed in a timely manner.

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Examples of the above include, but are not limited to:

Recent NDA Field Alerts (FAR's) submitted from your site since the last FDA inspection dated 6/13/11-7/8/11, have deviation investigations that are not occurring in a timely manner.

Some examples of critical complaints (for NDA products) not closed within (b) (4) calendar days as required procedurally:

- Initial FAR dated 8/11/11, Excedrin Migraine Tablets Lot number 10086758: (investigation opened 8/9/11 and closed 10/18/11, referring to a complaint of Excedrin Migraine Tablets also containing Excedrin caplets)
- Initial FAR dated 8/23/11, Excedrin Migraine Geltabs Lot number 10114662: (investigation opened 8/19/11 and closed 10/25/11, referring to two complaints of Excedrin Migraine Tablets in a carton of Excedrin Migraine Geltabs and Regular Strength Aspirin in Excedrin Migraine Geltabs Carton)
- Initial FAR dated 8/25/11, Excedrin Migraine Caplets Lot: 10089925: (investigation opened 8/22/11 and closed 10/28/11 into a mixed tablet complaint)
- Initial FAR, dated 8/30/11, Excedrin Migraine Caplets, Lot: 10102533: (investigation opened 8/26/11 and closed 11/2/11 into foreign tablets found in bottle complaint)
- Initial FAR dated 9/6/11, Morphine Sulfate 200 mg, Lot (b) (4) (investigation opened 9/8/11 and closed 10/25/11 into foreign object found in bottle)
- Initial FAR dated 11/11/11, Voltaren Gel, Lot: 10113483: (investigation opened 11/9/11 and closed 1/13/12 into a complaint regarding outside container and tube having different lot numbers)

As of 12/21/11, your firm also currently has approximately 360 customer returned complaint samples of various products (major and critical complaints) that have not been thoroughly reviewed by your Quality Unit. These are currently considered "open" by your firm as of

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December 2011.

Descriptions of these problems requiring investigation include, but are not limited to: foreign product, foreign object, suspected tampering, chipped/cracked/crumbled tablets, broken/missing seal, etc.

Also,

Your firm is outside of procedural timeframes for completing approximately 340 open Corrective and Preventative Action requirements (CAPA's), and 48 deviation (laboratory and unplanned) investigations.

THIS IS A REPEAT OBSERVATION FROM THE PREVIOUS FDA INSPECTION AT YOUR FACILITY, DATED 6/13-7/8/11.

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.

SYSTEMS: QUALITY, PRODUCTION, PACKAGING AND LABELING:

For example:

a. Your investigation into various tablets found on Line (b) (4) after line clearances (from 6/30/11-7/18/11), fails to identify all products potentially affected by the problem of inadequate cleaning on your packaging line (b) (4). This refers to Unplanned Deviation PR, No: 93070, **opened 6/30/11, and closed 7/21/11.**

These "various" tablets are indicative line clearance practices at your site do not consistently remove all tablets/capsules from packaging lines (in this instance Line (b) (4)) after a major clean.

The investigation details tablets were located (after major cleans) in areas such as: base of a filler dust collector, capper base, oil catch under capper, ledge of dust collector, base of filler, in an electrical cable

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tray, below the filler, underneath electrical box on the floor, inside check-weigher frame, filler start/stop proximity sensor bracket, and troughs, etc.

Packaging line (b)(4) is dedicated to the following products: Endocet, Percocet, Morphine Sulfate ER (MSER), Opana ER, Oxymorphone IR, Zydone and Opana.

This report details a total of (b)(4) various solid dosage forms (Excedrin tablets as well as "28 assorted tablets found in these troughs", Oxycodone ER, Opana, MSER, Percocet, etc.), a group of various tablet chips, 1/8th of tablet and one pamphlet were found during the cleaning, Autonomous Maintenance, inspection and re-inspections of line (b)(4) between 6/30/2011 and 7/18/2011.

Additionally, this investigation fails to address how "28 assorted tablets" (some not packaged in the room, such as Gas X, Soft Gels, (b) (4) , etc.) could have entered a room dedicated to packaging other products.

This investigation attributes the root cause of "Human Error" and "Failure to Follow Procedure". The investigation fails to document which personnel were responsible for this error, and there is no documentation of which procedure was not followed.

b. Your investigation into various tablets identified on line (b)(4), fails to identify all products potentially affected by the problem of inadequate cleaning on your packaging line (b)(4) This refers to Unplanned Deviation PR, No: 92770, **opened 6/23/11, and closed 7/14/11.**

A total of 14 tablets (Opana ER 20 mg and 30 mg, (b) (4) mg, and one unidentified tablet and two fragmented capsules) were found on line (b)(4) after a major clean was performed.

This investigation attributes the root cause of "Human Error" and "Failure to Follow Procedure". The investigation fails to document which personnel were responsible for this error, and there is no documentation of which procedure was not followed.

MORPHINE SULFATE ER 30 MG:

c. Your investigation, **opened 11/18/11 and closed 12/16/11,** into a complaint for "12 extra tablets",

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found by a pharmacist after opening a sealed bottle of Morphine Sulfate ER 30 mg, Lot: (b) (4) is deficient:

For example:

- This investigation fails to document whether the defect of "12 extra tablets" could have occurred at your site and possibly affect other products and/or lots.
- This investigation fails to document a root cause for the defect. Also, there is no conclusion as to whether the complaint is justified or valid.
- The 12 extra tablets in the complaint have not been identified by your firm.
- There are no documented preventative measures within the investigation to ensure this type of problem does not continue.

This is important because this consumer complaint was recently closed and is indicative of how your firm is currently investigating consumer complaints.

BUFFERIN RS/ES PARTIAL/INCOMPLETE TABLET/CAPLETS:

d. Your most recent consumer complaint **(opened 12/16/11 and closed 12/20/11)** into Bufferin RS Tablets, Lot: 10095189, for partial/incomplete tablet caplets, does not address all lots of product potentially affected by the problem of over-compressed tablets identified as the root cause. This is significant because it shows a recent example where your firm continues to close Complaint Investigations without addressing all possible lots affected by the problem.

This report documents this lot of Bufferin RS has received 80 consumer complaints in the past for this known problem.

Your firm was aware of Partial/Incomplete Bufferin tablets/caplets issues since at least 2009, yet a Medical Safety Assessment Report was not released until 10/14/11. There is no justification or explanation for the approximate 2 year delay in obtaining this report.

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MIXED PRODUCT COMPLAINTS (Excedrin family of products, (b) (4) Prevacid, Bufferin)

e. You have failed to extend the investigation to all lots/batches of product potentially affected by associated consumer complaints regarding mixed product complaints received from January 2009 to the present.

Specifically, your Deviation Investigation PR 93054, evaluating a total of 398 foreign product complaints from January 1, 2009 to June 13, 2011, does not address all lots and products potentially affected by the problem being investigated (mixed Novartis manufactured tablets). **This Deviation Investigation was closed 11/21/11.**

This investigation is limited to lot numbers and products that have received consumer complaints, rather than reviewing all lots and products that may be associated with the problem.

Your firm has been aware of multiple mixed product complaints since at least 2009, yet a complete market correction (due to this problem) was not executed until 1/8/12, which occurred during the course of this FDA inspection.

PREVACID 15 MG CAPSULE, PACKAGED ON LINE (b) (4)

f. Your investigation into a mixed tablet/capsule complaint failed to extend the investigation to all lots/batches of product potentially affected by mixed tablet/capsule complaints. This refers to case file number: 10668501, opened 3/9/11 and closed on 3/15/11.

Additionally, the foreign tablets in the complaint were not identified and the customer was not contacted during the investigation to assure all information was complete and accurate.

There is no root cause identified for the foreign tablets potentially in a Prevacid 15 MG Capsule container.

This complaint is similar to Case Number 10528132, closed 3/11/10, which did not address a root cause,

other lots/products affected, and adequate corrective actions.

These are 2 examples of complaint investigations for Prevacid 15 MG Capsules that fail to identify the root cause and fail to extend to other lots of all products potentially affected. These are indicative of how your firm handles consumer complaints for this product, as well as other products.

You have had 35 mixed tablet/foreign products for Prevacid 15 mg Capsules since 2009.

(b) (4) **MG TABLETS PACKAGED ON LINE** (b) (4).

g. Your investigation into a mixed tablet/capsule complaint failed to extend the investigation to all lots/batches of product potentially affected by mixed tablet/capsule complaints. This refers to case file number: 10508059, opened 1/12/10 and closed on 5/27/10.

Additionally, there is no root cause documented explaining how the identified foreign tablets could have been in the same container.

This is significant because a review of similar complaints for this product reveals 4 other complaints where the same foreign tablets ((b) (4) printed on the tablet) were found mixed with your (b) (4) tablets.

EXCEDRIN MIGRAINE TABLETS:

h. You have failed to extend the investigation to all lots/batches of product potentially affected for a recent mix-up complaint of Excedrin Migraine Tablets, Lot # 10086758, mixed with Excedrin Migraine Caplets. This complaint is associated with NDA Field Alert, dated 8/11/11.

The deviation investigation, **opened 8/9/11 and closed 10/18/11**, documents no justification for not associating this problem with other lots of product that may be associated with similar problems.

This complaint appears to be very similar to an NDA Field Alert mentioned in the previous 483 at this firm (see below).

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"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."

Despite the apparent similarities of the two examples above, as well as 15 other lots in recent product recalls at your firm, your investigations have failed to review other lots of potentially affected product.

EXCEDRIN MIGRAINE GELTABS:

i. Your Deviation Investigation PR # 95185, **opened 8/19/11 and closed 11/7/11,** (into a complaint of "white tablets" Excedrin Migraine Geltabs for Lot: 10113309) fails to review and document a list of products or systems affected by the deviation.

The root cause of the investigation reads "(b) (4) (b) (4)"

Other products (Excedrin ES/Migraine Bulk, Excedrin AFTH GT) you manufacture receive a similar b(4) process, however there is no assessment of how many products could be affected by this deviation (the b(4) process failure).

The "Statement of Impact" for this investigation reads "Due to the limited information available for this investigation, no statement of impact is possible." This statement can not be justified by your firm's Quality management.

Also, a review of similar complaints of this nature revealed this has occurred at least six other times since 2009 for this product, without mention of the impact on the product.

ENDOCET 10/325 MG:

j. The Technical Complaint Investigation, **opened 10/18/11 and closed 12/15/11,** is deficient in that it does not address other lots of products potentially affected by the problem in the complaint for "one extra tablet" in a 100 count Endocet 10/325 mg bottle.

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Additionally, the closed investigation fails to identify and confirm the extra tablet in the complaint.

These are just a few 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.

It is important to understand because of your firm's failure to adequately and thoroughly conduct investigations, it is difficult to determine how widespread the problems are at your firm (into the continued problem of NCH-Lincoln produced drug products as well as the observations shown below).

THIS IS A REPEAT DEFICIENCY FROM PREVIOUS INSPECTIONS AT YOUR SITE, DATED 8/29-9/10/07, 4/5-16/10, AND 6/13-7/8/11.

OBSERVATION 4

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

Specifically,

Your packaging line clearance operators failed to adequately clean packaging lines (and areas around packaging lines) during your "major" cleaning efforts of this equipment as evidenced by:

OCTOBER 2011:

a) Foreign tablet/tablet (s) were found in packaging areas on seven (7) occasions in October 2011. These were located by line clearance auditors after major cleans were conducted by line clearance operators at your site.

NOVEMBER 2011:

b) Foreign tablet/tablet (s) were found in packaging areas on twelve (12) occasions in November

2011. These were located by line clearance auditors after major cleans were conducted by line clearance operators at your site.

DECEMBER 2011:

c) Foreign tablet/tablet (s) were found in packaging areas on fifteen (15) occasions in December 2011. These were located by line clearance auditors after major cleans were conducted by line clearance operators at your site.

These foreign tablet/tablet(s) were located on or near your packaging lines (b) (4) and (b) (4)

Review of your line (b) (4) usage sequence log dated 10/12/11 through 12/19/11 confirmed foreign tablets were found during line clearance inspections. These foreign tablets found are not necessarily indicative of the tablet(s) from a previously run batch.

Your Comprehensive Site Assessment Update, dated January 11, 2012 submitted to the FDA, indicates inconsistency in line clearance practices.

OBSERVATION 5

Written procedures are not followed for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product.

SYSTEMS: QUALITY, PRODUCTION:

Specifically,

BUFFERIN:

a. Your most recent Annual Product Review (APR) for **Bufferin Extra Strength Tablets and Bufferin Regular Strength Tablets** (2010) is incorrect.

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- Your 2010 APR for Bufferin Regular Strength Tablets describes one complaint (Discolored/Spotted/Lightened Product) received for this product from 10/09-9/10. Further review of actual complaints for the time period of 10/1/09-9/30/10 reveals there are a total of 43 complaints for Bufferin RS Tablets. Included in the actual complaints are: Foreign object, chipped/cracked product, shortfil, etc.

- Your 2010 APR for Bufferin Extra Strength Tablets reads "There are no complaints for this material at this time." Further review of actual complaints for the time period of 10/1/09-9/30/10, reveals there were 11 complaints for this product. Included in these complaints are indications your firm's new formulation of this product (which you started manufacturing in 8/09) were "Chipped, Cracked, Crumbled".

Additionally, these reports fail to identify potential product weakness as required by your Annual Product Procedure, QAD-037-13.

The above complaints were inaccurately reviewed and placed in the incorrect Annual Product Review reports (for Bufferin ES and Bufferin RS 2010 "old formulation"). No justification exists for this error.

These complaints appear to be early indications of poor product performance of your Bufferin ES and Bufferin RS Tablets, however, your Annual Product Review failed to recognize these complaints. These products were included in your recall in January 2012 due to "delamination issues" which means cracking of tablets.

EXCEDRIN EXTRA STRENGTH EXPRESS GELS:

b. Your most recent 2011 Annual Product Review for **Excedrin Extra Strength Express Gels** (Acetaminophen 250 mg, Aspirin 250 mg and Caffeine 65 mg), approved 5/27/11, is deficient.

The report fails to document the consistent trend of complaints received by your firm for "Product Chipped, Cracked, Crumbled" and "Partial/Incomplete Tablet/Caplets" regarding this product.

This report documents you have received:

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- Approximately 550 complaints for these types of problems from 3/10-2/11
- Approximately 430 complaints for these types of problems from 4/09-2/10
- Approximately 212 complaints for these types of problems from start of manufacture to 3/09

The conclusion in the summary is inadequate in that there is no statement identifying potential product weakness as indicated by the consistent consumer complaints. Also, there is no justification for the statement "Based on data reviewed no changes in the manufacturing process are required."

This is a failure to follow Annual Product Review Procedure QAD-037-14, dated 5/26/11.

Additionally, your 2010 Annual Product Review for this product from 4/09-2/10 reveals an increase in the number of complaints for this product. It also shows complaints for chipped and incomplete tablets was a known design issue and placed on an R&D (research and development) project improvement list to correct.

Your firm has been aware of "Product Chipped, Cracked, Crumbled" and "Partial/Incomplete Tablet/Caplets" for this product (Express Gels) since at least 2009, yet a complete market correction (due to this problem) was not executed until 1/8/12, which occurred during the course of this FDA inspection.

EXCEDRIN PM EXPRESS GELS:

c. The conclusion in your most recently completed 2011 Annual Product Review for **Excedrin PM Express Gels** is not supported by the information within the report.

Specifically, the report reads "Chipped tablet complaints have been identified as an issue with the product. b(4) [redacted] (b) (4) [redacted] "

Despite this fact that a (b) (4) [redacted] is necessary to correct the problem of chipped tablets, the report concludes "Based on the data reviewed, no changes in the manufacturing are required."

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There is no justification for this conclusion that no changes are required.

Your firm has been aware of "Product Chipped, Cracked, Crumbled" and "Partial/Incomplete Tablet/Caplets" for this product (Express Gels) since at least 2009, yet a complete market correction (due to this problem) was not executed until 1/8/12, which occurred during the course of this FDA inspection.

EXCEDRIN TENSION HEADACHE EXPRESS GELS:

d. The conclusion in your most recently completed 2011 Annual Product Review for **Excedrin Tension Headache Express Gels** is not supported by the information within the report.

Specifically, the report documents approximately 130 consumer complaints for "Product Chipped, Cracked, Crumbled, Partial/Incomplete Tablet Caplet" during the timeframe of the review. It also documents 195 complaints for similar issues for a review period of 4/09-2/10 and 121 complaints for similar issues during the review period of start to 3/09.

Despite this fact that consumer complaints are indicating a problem with the product, your report concludes "Based on the data reviewed, no changes in the manufacturing are required. The manufacturing process remains in a validated state."

There is no justification for this conclusion that no changes are required.

Your firm has been aware of "Product Chipped, Cracked, Crumbled" and "Partial/Incomplete Tablet/Caplets" for this product (Express Gels) since at least 2009, yet a complete market correction (due to this problem) was not executed until 1/8/12, which occurred during the course of this FDA inspection.

BENEFIBER PLUS CALCIUM POWDER:

e. The conclusion in your most recently completed 2011 Annual Product Review for Benefiber Plus Calcium Powder, signed as acceptable on 6/27/11, is not supported by the information in the report.

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Specifically, the report documents 390 complaints for "Doesn't Dissolve in Liquid" during the timeframe for review, 2/10-1/11.

Your recommendation reads "Due to the amount of complaints received for this product, it was discontinued b(4) [redacted]

Your conclusion reads "Based on the data reviewed, no changes in the manufacturing process are required." This statement is not justified based on your recommendation.

Additionally,

Your 2010 Annual Product Review for Benefiber Plus Calcium is deficient in that your report fails to address approximately 760 consumer complaints received by Novartis Product Supply QA. In 2010, none of the 760 consumer complaints (for complaints such as "Doesn't dissolve in liquid, abnormal consistency, Lot/Exp legibility, insect in product", etc.) were described or evaluated in the report as required procedurally.

The failure by your firm to conduct accurate and thorough Annual Product Reviews is a pattern of problems at your facility.

The problems identified in your preliminary compliance assessment, dated 12/11 (leading to a recall of several products), have been known problems at your site and should have been captured in Annual Product Reviews and reviewed by your Quality Unit.

OBSERVATION 6

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

SYSTEMS: QUALITY, PACKAGING:

Specifically,

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11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax: (913) 752-2111 Industry Information: www.fda.gov/oc/industry	12/14/2011 - 01/20/2012* FEI NUMBER 1911445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Brian J. McNamara, Region Head OTC Americas, Novartis Consumer Health

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

MIXED-PRODUCT COMPLAINTS:

a. You have failed to document the root cause, and implement effective corrective and preventative actions regarding product mix-up complaints for solid dosage form foreign tablets of products manufactured at your firm since at least 2009. (Referring to products such as: Excedrin family products, Prevacid, narcotic products, etc. manufactured on lines (b) (4) and (b) (4))

Your foreign product recall assessment, dated 10/17/11, states you have received approximately 70 confirmed, returned customer complaint, mix-up samples containing only NCH-Lincoln produced product. **In total, there have been 400 complaint cases of this type since 2009.**

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

For example,

EXCEDRIN MIGRAINE TABLETS, PACKAGED ON LINE (b) (4) :

b. Your firm received a consumer complaint on 6/6/11 for a bottle of Excedrin Migraine tablets that also contained Excedrin Migraine caplets inside the bottle.

A review of the investigation **(opened 8/9/11 and closed 10/18/11)** into this problem revealed Excedrin Migraine Tablets, Lot: 10086758 were packaged on line (b) (4) on 3/18/10 at Novartis Consumer Health. The previous product packaged on line (b) (4) was Excedrin Migraine Caplets, 250 count. These are the same two solid dosage forms contained inside the returned complaint sample.

This investigation was **closed on 10/18/11** without a root cause identified. This is significant because this complaint-type is similar to others received by your firm for approximately 2 years, yet no identifiable root cause has been determined.

Also,

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

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Examples include, but are not limited to:

PREVACID 24HR 15MG CAPSULE, PACKAGED ON LINE (b) (4):

c. Your conclusion for Technical Investigation Report 10676709, **opened 3/31/11 and closed 11/18/11,** is not supported by the evidence in the report. This consumer complaint refers to a consumer complaint describing a bottle of Excedrin in a Prevacid carton.

The report concludes, in part, "The most likely root cause for this foreign object consisting of a bottle of Excedrin with a Prevacid carton is the mix-up most likely occurred from the distribution or retail level." There is no evidence to support this conclusion.

Additionally, the investigation reads "The 200 cc and 315 cc bottles do not fit into Prevacid cartons." There is no information in the report verifying the actual size of the bottle in the complaint.

EXCEDRIN MIGRAINE CAPLETS, PACKAGED ON LINES (b) (4) and/or (b) (4):

d. Your Unplanned Deviation report 95236, **opened 8/22/11 and closed 9/30/11,** into a complaint of Excedrin Migraine Caplets, lot: 10111614 concludes in part, "the most likely root cause for this foreign product found in the container complaint is a mix-up at the consumer level."

This statement is not supported by the evidence in the report. Specifically, there is no evidence documented within the report to support this conclusion.

Drawing conclusions without documented evidence to support the statement is a recurring problem at this firm (regarding handling complaints of "foreign tablets").

The above examples are indicative of investigations, closed since the last FDA inspection, that are deficient.

THIS IS A REPEAT OBSERVATION FROM THE PREVIOUS INSPECTION AT THIS SITE, DATED 6/13-7/8/11.

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OBSERVATION 7

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 and applied to another article.

SYSTEM: QUALITY

Specifically,

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

For example,

a. Your firm received a consumer complaint on 6/6/11 for a bottle of Excedrin Migraine tablets that also contained Excedrin Migraine caplets inside the bottle. The FDA Field Alert for this problem was not submitted until 8/11/11.

It should also be known that the cover letter for the NDA Field Alert into Excedrin Migraine Tables, lot: 10086758, submitted to the FDA on 11/23/11, was incorrect. Specifically, the letter reads that the consumer called Novartis on 8/9/11 instead of 6/6/11.

b. Your firm received consumer complaints for apparent product mix-up of Excedrin Migraine Geltabs lot: 10114662, on 7/25/11 and 7/27/11. The FDA Field Alert for this problem was not submitted until 8/23/11.

c. Your firm received a consumer complaint for a foreign product in Excedrin Migraine caplets, lot: 10103157, on May 2, 2011. The FDA Field Alert for this problem was not submitted until 12/19/11.

FAILING TO FILE 3 DAY NDA FIELD ALERTS IN A TIMELY MANNER IS A REPEAT OBSERVATION FROM THE PREVIOUS FDA INSPECTION AT YOUR FACILITY, DATED 6/13-7/8/11.

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OBSERVATION 8

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

SYSTEMS: QUALITY, PACKAGING AND LABELING:

Specifically,

There are numerous recent instances of employees in your firm failing to follow your established procedures.

For Example:

- Failure to conduct thorough, timely and meaningful Annual Product Reviews
- Failure to follow Major Clean Line Clearance Inspection Procedures (Packaging Lines (b) (4) (b) (4))
- Lack of timeliness for complaint/deviation and laboratory investigations
- Failure to extend investigations to all lots potentially affected
- Failure to document required procedural questions for consumer complainants
- Drawing conclusions in investigations without documented evidence to support statements
- Failure to identify root cause of known problems
- Failure to File NDA Field Alerts within 3 working days when the issue is identified

Specific procedures not followed include, but are not limited to:

- Major Clean Line Clearance Inspection Procedures, FAD-312-02
- Annual Product Review Executive Report Summary and Coordination of APR/PQR Process
- Potential Field Alert Assessment, Tracking and Filing, Job Aid - 0116
- Conducting Deviation Investigations, SOP -202891, QAP-013-10
- Complaint Handling Procedure, SOP-202313

Additionally,

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Your firm's interim control for the complaint center "Scripts for Technical Complaints", dated 9/23/11, is recently not followed initially by your call center personnel.

For example,

Key initial questions to be asked by the complaint call center include, but are not limited to:

1. Is this the first time you have used the product?
2. Where did you purchase the product?
3. When did you purchase the product?

These questions were not initially documented in deviation 98385, into a mix-up with Voltaren Gel, lot number 10113483. This information is critical for conducting a thorough investigation, but is not documented at the time of the consumer complaint. This is an example of what appears to be a recurring problem at your firm.

OBSERVATION 9

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

QUALITY UNIT:

Specifically,

There is an inadequate number of Quality Unit personnel in your firm to conduct timely, correct and thorough reviews of the products you manufacture.

This is evidenced by the fact that as of 12/12/11, there are approximately 1,360 consumer complaints that currently have not been adequately reviewed and closed in a timely manner.

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Additionally, there are approximately 340 overdue Corrective and Preventative Actions that need review, and 48 unplanned deviation and laboratory Investigations that are overdue (past 30 days).

The delays in closing complaints, investigations, and corrective actions contributed to a shutdown in production of your facility (12/11) in order to rectify these issues.

This is also evidenced by the fact that once these (and similar type) deficiencies were discovered and reported (during the last FDA inspection), you needed outside assistance (consulting firms) to assist in conducting the reviews which should have originally been done by your Quality Assurance staff at NCH-Lincoln.

Your firm's management confirmed this fact several times throughout this inspection via discussions regarding why these observations exist and continue at your firm.

THIS IS A REPEAT OBSERVATION FROM THE LAST FDA INSPECTION AT THIS SITE, DATED 6/13-7/8/11.

OBSERVATION 10

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

SYSTEM: QUALITY UNIT, PACKAGING:

Training is inadequate in the Quality Unit at your firm as evidenced by the problems documented during the last two inspections at your firm.

Employees consistently not executing established procedures are indications training is a problem at your firm (See above observations for details).

Also,

Your line clearance operators have incomplete and ineffective training as evidenced by:

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a. Two recent investigations attributed the cause of leftover tablets/capsules to be human error, and failure to follow procedures. Unplanned Deviation PR No: 97687 **(opened 10/19/11, and closed 10/31/11)**, and Unplanned Deviation PR No: 99014 **(opened 11/30/11, and closed 12/30/11)** from line clearance tracking results for October and November, 2011 for line b(4 detail foreign tablet(s) found during QA audit post major cleans of packaging equipment.

For example,

Unplanned Deviation 97687 **(opened 10/19/11, and closed 10/31/11)** identified the root cause as human error and failure to follow procedure. The employees consisted of (b) (4) operators (b(6) b6 and (b) (4) line clearance auditor b(6)). b(6) (operator) has no training records (training module FSU-010-02 General Changeover, cleaning, and operations) on line cleaning. b(6) (operator) training (training module FSU-010-02 General Changeover, cleaning, and operations) is incomplete (filler parts cleaning, secondary equipment cleaning and taking samples) without explanation.

Unplanned Deviation 99014 **(opened 11/30/11, and closed 12/30/11),** identified the root cause as human error and failure to follow procedure. There were (b) (4) operators, (b) (4) facilitators, and (b) (4) line clearance auditors, involved in this deviation, for the packaging of (b) (4) different products and (b) (4) different lots, for period from 10/20/11 to 11/29/11. b(6) (operator) training was not signed of in three sections and continued to perform inadequate line cleaning for line as evidence by deviations 99014 and deviation 97687. b(6) (operator) training was not signed as acceptable (training module FSU-010-02 General Changeover, Cleaning, and Operation presented to me was unsigned/blank).

Additionally,
b. Your line clearance auditors b(6) have documented training, yet still do not conduct adequate line clearance audits as evidence by foreign or extra tablets found post line clearance audits on (b) (4) and (b) (4) (see unplanned deviations PR No: 97687 and 99014).

For example,

Your line clearance auditor b(6)) trained on (b) (6) and conducted line clearance audit for line (b) (4) on (b) (4) . This line clearance audit failed to clear the line as evidence by two partial (b) (4) tablets found on b(4) by a different line clearance auditor b(6) .

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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These are just a few examples of what appears to be a problem at your firm.

THIS IS A REPEAT VIOLATION FROM THE PREVIOUS INSPECTION AT YOUR FIRM DATED 6/13-7/8/11.

*** DATES OF INSPECTION:**
12/14/2011(Wed), 12/15/2011(Thu), 12/16/2011(Fri), 12/19/2011(Mon), 12/20/2011(Tue), 12/21/2011(Wed), 12/22/2011(Thu), 12/23/2011(Fri), 12/27/2011(Tue), 12/28/2011(Wed), 12/29/2011(Thu), 12/30/2011(Fri), 01/03/2012(Tue), 01/04/2012(Wed), 01/05/2012(Thu), 01/06/2012(Fri), 01/09/2012(Mon), 01/10/2012(Tue), 01/11/2012(Wed), 01/12/2012(Thu), 01/20/2012(Fri)

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