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	01/28/2013 - 02/14/2013* FEI NUMBER 1911445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Richard R. Lloyd, Region Head OTC Americas

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:

Products affected by the observations listed below (manufactured at your facility) include, but may not be limited to:

OTC:

Triaminic Syrups (entire product family)
Theraflu Syrups (entire product family)
Myoflex Cream (Trolamine Salicylate 10%)
Lamisil Cream (Terbinafine HCL 1%)
Nupercainal Cream (dibucaine)

RX:

Voltaren Gel (Diclofenac sodium 1%)

As of 2/13/13, you have distributed the following products and number of units which are currently within expiry:

Product	**Units:** (all sizes of product are included in total):
Lamisil	(b) (4)
Myoflex	(b) (4)
Nupercainal	(b) (4)
Theraflu	(b) (4)
Triaminic	(b) (4)
Voltaren	(b) (4)

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EMPLOYEE(S) SIGNATURE
Eric M. Mueller, Investigator
Susanna E. Ford, Investigator
Joseph R. Lambert, Investigator

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OBSERVATION 1

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.

QUALITY SYSTEM:

Specifically,

Your Quality Unit has conducted consumer complaints independently (without assistance from GMP consultants) by your newly trained NCH investigators since October 15, 2012.

Below are examples of problems identified with investigations since this time:

a) A review of consumer complaints revealed your newly trained group of consumer complaint investigators has reviewed and closed a total of 1,066 investigations since 10/15/12. Of these 1,066 complaint investigations, I randomly chose to review nine (10850645, 10870893, 10864337, 10895761, 10901820, 10850650, 10870681, 10862820 and 10905170) complaint investigations in detail. Nine of nine (100%) complaint investigations completed since October 15, 2012, failed to address all products potentially affected by the problem within the complaint. This is indicative of a pattern of problem at your firm.

LIQUIDS:

b) Your consumer complaint investigations into Triaminic "Child Resistant Packaging/Cap failed" have not documented the potential association of (at least) the below criteria.

For the Triaminic liquid family of products, since 2010 you have received approximately:

- 174 consumer complaints for the problem of "Child Resistant Packaging/Cap failed"
- 404 consumer complaints for "Leaking, Cracked, Broken Container"
- 62 consumer complaints for "Leaking, Cracked, Broken Closure"
- 59 consumer complaints for "Tamper Resistant Seal or Safety Seal Broken/Missing"
- 15 consumer complaints for "Appearance of Crystals/Precipitate/Particles in Liquid"

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Your consumer complaint investigations into the above complaints do not extend to other products you manufactured that may have similar problems (Theraflu liquids, Buckley's complete, Neo-Citran). Additionally, the potential association of the above complaint descriptions have not been documented.

A review during this FDA inspection of a Technical complaint summary (since 2010) revealed similar complaints for other products.

c) As an example of the above, your complaint investigation (10864786, into a 1 year old opening and drinking a half of bottle of Triaminic cold and cough), **opened 1/15/13 and closed 1/22/13**, is deficient. Specifically, this investigation fails to extend to all lots and products potentially affected by the problem.

During this FDA inspection, nine (9) recent complaints (10930710, 10937697, 10939781, 10922465, 10926714, 10939832, 10927793, 10795642, 10918608) were reviewed (for complaints such as crystals, leaks, tamper-seals) . Of these complaints, 9 of 9 (100%) investigations failed to investigate and associate the above potentially similar problems.

CREAMS/OINTMENT/GELS:

You have received 141 consumer complaints for the problem of "Lot/Exp legibility/location issue" and "Lot/Exp Date Missing from Packaging" for your drug product Voltaren Gel, since 2010. Complaint investigations have not associated this problem to other products with potentially similar issues (such as Lamisil Cream, Myoflex cream, Nupercainal, etc.).

d) Your consumer complaint investigation #10870681 (into expiration date legibility problems of Voltaren Gel 100 Gram), **opened 7/31/12 and closed 12/12/12,** is deficient. Specifically, this investigation fails to extend to all lots and products potentially affected by the problem identified in the complaint.

e) Your consumer complaint investigation #10905170, **opened 10/11/12 and closed 11/20/12,** into Lot/Exp legibility/location issues for Lamisil cream has not extended to all lots and products potentially affected by similar problems.

A review during this FDA inspection of a Technical complaint summary (since 2010) revealed similar

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complaints for other products manufactured at this site.

These examples are significant because the investigations were recently closed and are indicative of how your firm currently handles consumer complaints.

THIS IS A REPEAT OBSERVATION FROM PREVIOUS FDA INSPECTIONS AT YOUR FACILITY, DATED 8/29-9/10-07, 4/5-16/10, 6/13-7/8/11 AND 12/14/11-1/20/12.

OBSERVATION 2

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

QUALITY SYSTEM:

Specifically:

Your Quality Assurance review of deviations (Technical Complaint Investigation Reports) is not occurring in a timely manner according to your procedures.

A review of consumer complaint investigations closed by your site since October 15, 2012, indicates investigations are not occuring within 30 days as required procedurally. For example, a total of 1,066 investigations have been reviewed and closed since 10/15/12 and 429 of these investigations are closed outside of 30 days. (shows 40% of recent investigations are not closed in a timely manner).

Examples include:

a) **LIQUIDS:** You received a consumer complaint on 11/26/12 (for a 2 y.o child being able to remove a Triaminic child resistant cap with tamper evident seal). An Unplanned Deviation (No: 112688) was officially opened 01/7/13, roughly 6 weeks after the complaint was received. Also, this investigation remains open as of 2/13/13, which is outside of procedural requirements to close within 30 calendar days.

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Your Quality Assurance Associate Director recommended a recall assessment for this problem on 12/11/12. This recall assessment was not completed until 1/24/13 which confirmed the necessity for market correction of affected products.

This is significant because consumer complaints for this defect (and others possibly related) have been arriving to your firm since at least 2010 (see Observation 1 above for details).

b) CREAMS: Your investigation (10870681) into a consumer complaint on 7/31/12 (into illegible lot number/expiration date for Voltaren Gel 1%) did not occur in a timely manner. The complaint arrived to your firm on 7/31/12, and was closed 12/12/12. This is outside of your procedural requirements for closing an investigation within 30 days.

Also,

Your most recent unplanned deviations trend report for 3rd (July-September, due (b) (4)) and 4th (October-December, due (b) (4)) Quarters of 2012 have not been signed as reviewed by your Quality Unit as of 2/7/13.

The report also shows:

- A total of 86 of 133 Unplanned Deviations (65%) are not closed within 30 days as required in the 3rd Quarter of 2012.
- A total of 40 of 99 Unplanned Deviations (40%) are not closed within 30 days as required in the 4th Quarter of 2012.
- No justification exists as to why two Quarterly reports (Q3 and Q4 of 2012) are combined into one report. This shows that Quarterly review is not occurring as required procedurally (SOP QAD-063-04). Quarterly trends are required to be signed within (b) (4) of the previous quarter.
- There is no documented assurance contained within the report that Corrective and Preventative Action items for potential product weaknesses indicated by the trend report are addressed.

There is no justifcation for combining quarterly reports for (4th Quarter 2011, 1st Quarter 2012, and 2nd Quarter 2012) into one report.

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OBSERVATION 3

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

QUALITY SYSTEM:

Specifically,

Your investigation conclusions and recommendations are not always supported by evidence and known information.

For example:

LIQUIDS:

a) Your complaint investigation, 10964786, (into a 1 year old opening and drinking a half of bottle of Triaminic cold and cough), **opened 1/15/13 and closed 1/22/13,** fails to include numerous known facts/evidence at the time the investigation was closed.

The report reads "No actions are necessary at this time due to an unknown lot number and a downward trend in the Product Family". This statement is contradictory to known facts in your firm during this time such as:

- Retention samples for Triaminic had confirmed the issue on 11/30/12 for another related

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complaint (CRTS 10929825).

- A recall Assessment was recommended for the product on 12/11/12.
- On 12/14/12, your Quality Unit revealed a 100% confirmation (90 bottles in total) of defect on similar products.
- Several (at least five documented) Quality meetings from 12/14/12 to 1/17/13 had occurred in your firm regarding the issue of "failed child-resistant caps" on products you manufacture.

Despite these activities and known facts confirming the defect mentioned in the consumer complaint, your investigation (# 10964786) closed 1/22/13, failed to document the above mentioned details. This is also evidenced by the fact that on 1/31/13, your Quality Director does not agree with the conclusions drawn in the report.

b) Similar issues (as noted above) are contained in a consumer complaint 10926008, **opened 11/16/12 and closed 12/14/12**. The investigation documents a Triaminic Child Resistant Packaging/Cap failure complaint. This investigation also fails document information and facts (see above) known in your company at the time it was being investigated and closed.

CREAMS:

c) Your investigation into consumer complaint 10870681 (voltaren gel lot/exp legibility issues), **opened 7/31/12 and closed 12/12/12**, contains information that could not be confirmed on 1/31/13.

For example,

The investigation states the returned complaint sample was inspected by your employee and reads, in part, "The complaint sample confirmed the Lot# and Exp. Date were clearly legible".

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On 1/31/13, during a review of this same returned sample, 7 of 7 Novartis employees (different from the employee who reviewed the sample in the investigation) could not read the lot number correctly during this FDA inspection.

Your investigation (# 10870681) also identifies an escalating trend for this complaint, however, the summary inexplicably states "Long term product family suggests an upward trend in complaints for this subject description but cannot be fully considered an accurate representation of consumer activity." There is no justification for this statement.

d) Another example of similar problems as mentioned above can be seen in your consumer complaint 10869898, **opened 7/27/12 and closed 8/25/12** (closed after last FDA inspection)

THIS IS A REPEAT OBSERVATION FROM PREVIOUS FDA INSPECTIONS AT YOUR FACILITY, DATED 6/13-7/8/11 AND 12/14/11-1/20/12.

OBSERVATION 4

Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

QUALITY / PRODUCTION SYSTEMS:

Specifically,

Your most recent Annual Product Review (APR) for **Voltaren Gel (diclofenac sodium, review period 8/11-10/12)** contains information that is not confirmed by evidence.

Your Annual Product Review for this product from 8/11-10/12 reveals an increase in the number of complaints (lot/exp date missing) for this product (compared to prior review period).

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The report continues to read, in part, "In the rare cases where a return sample was received, the lot number and expiration date were verified to be visible on the crimp end of the tube as they should be indicating consumers had difficulty locating the lot/exp."

A review conducted on 1/31/13 (during this FDA inspection) of two returned samples of Voltaren Gel 1% (for legibility issues) revealed seven of seven people in your firm could not read and correctly identify the expiration date of the products.

This verifed fact (7 of 7 people not being able to verify the expiration date) is contradictory to information included in your Annual Product Review Report. **Additionally, as of 2/1/13, the report remains unsigned and was due to be completed 1/17/13.**

Annual Product Reviews (APR) for products such as Voltaren Gel, Lamisil Cream, Triaminic family of products, and Theraflu products fail to identify trends, interpret data and draw accurate conclusions from the data presented. This is evidenced by the fact that previous APR's failed to recognize and associate problems with your products for years (at least 2010, 2011, 2012).

THIS IS A REPEAT OBSERVATION FROM PREVIOUS FDA INSPECTIONS AT YOUR FACILITY, DATED 6/13-7/8/11 AND 12/14/11-1/20/12.

OBSERVATION 5

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically,

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

Your drug product Voltaren Gel 1% has received approximately 140 consumer complaints into issues such as "Lot/Exp legibility/location issue", and "Lot/Exp Date Missing from Packaging", since 2010.

Despite consistent signals indicating potential problems with your product, an NDA Field Alert was not submitted to the FDA until 2/1/13. NDA Field Alert submission is required procedurally by SOP

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"202335, OTC NDA Field Alert Reports"..

FAILING TO FILE 3 DAY NDA FIELD ALERTS IN A TIMELY MANNER IS A REPEAT OBSERVATION FROM PREVIOUS FDA INSPECTIONS AT YOUR FACILITY, DATED 6/13-7/8/11 and 12/14/11 - 1/3/12 .

OBSERVATION 6

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

QUALITY, PACKAGING AND LABELING SYSTEMS:

Specifically,

You have failed to follow established operating procedures.

Specifically,

The following are examples of employees in your firm failing to follow established procedures.

- Failure to conduct thorough, timely and meaningful Annual Product Reviews (Refers to liquid products such as Theraflu and Triaminic families, and cream/gel/ointment products such as Voltaren and Lamisil).
- Lack of timeliness for completing adequate complaint/deviation investigations
- Failure to extend investigations to all lots and products potentially affected by a problem
- Failure to draw investigational conclusions based on evidence and known problems
- Failure to identify root cause of known problems
- Failure to File NDA Field Alerts within 3 working days

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

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- Deviation Management, SOP QAP-013-13
- Handling of Customer Technical Complaints in OTC, SOP-202313
- Examination of Returned Customer Complaint and Retained Samples and Review of Batch Documentation for Complaint Investigations, SOP-203868
- OTC NDA Field Alert Reports, SOP-202335
- Management Escalation Process, SOP 203971
- Product Recall Assessment for Novartis OTC, SOP-202405
- Requirements for APR/PQR, SOP-202634
- Quality Trend Reports, SOP-QAD-063-04

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OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

LABORATORY SYSTEM:

Specifically,

Your stability protocols for Triaminic Day Time Cough and Cold, Project 1429; Buckley's Chest and Congestion, Project 1613; Theraflu warming Syrup Cold and Chest Congestion, Project 1650 do not include the requirement for storing stability samples either inverted or on its side.

Stability protocols are deficient in that the liquid solution is not in contact with the container closure system. Therefore the container closure system was not tested.

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OBSERVATION 8

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

LABORATORY SYSTEM:

Specifically,

Liquid products (manufactured at this site) are not stored either inverted or on its side in the stability chamber (b) (4) °C/ (b) (4) %RH.

Triaminic Cold & Cough Syrup, 1250-5366.80, 1250-5347.40

Buckley's Congestion Oral Solution, 1613-5312.31

Theraflu DT Sever Cold Warming Syrup, 1450-5312.13

Due to the storage of all samples in a vertical position, Novartis was unable to detect any problems with the container closure system. Container closure systems for Triaminic Cold & Cough Syrup, Buckley's Congestion Oral Solution, Theraflu DT Severe Cold Warming Syrup liquids may not provide adequate protection against external factors in storage that can cause deterioration or contamination of the drug product as evidenced by the fact that your firm has not stored stability samples inverted or on-side to demonstrate the appropriate selection of the closure system.

OBSERVATION 9

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

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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 conduct complete Annual Product Reviews, Failure to extend investigations of known problems to all lots potentially affected, Failure to file NDA Field Alerts in a timely manner and Failure to store retention/stability samples adequately).

This is also evidenced by numerous product recalls for similar problems over the last several years.

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*** DATES OF INSPECTION:**
01/28/2013(Mon), 01/29/2013(Tue), 01/30/2013(Wed), 01/31/2013(Thu), 02/01/2013(Fri), 02/04/2013(Mon), 02/05/2013(Tue), 02/06/2013(Wed), 02/07/2013(Thu), 02/08/2013(Fri), 02/13/2013(Wed), 02/14/2013(Thu)

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