DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	10/05/2009 - 10/19/2009* FEI NUMBER 3007187671

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William Hemelt, President/CEO

FIRM NAME	STREET ADDRESS
Matrixx Initiatives Inc	8515 E Anderson Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Scottsdale, AZ 85255-5461	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

Serious adverse event(s) for a non-prescription drug used in the United States has not been reported to the Secretary.

Specifically,

Review of documents covering adverse events received by your firm noted the following examples of adverse events that should have been reported to the Food and Drug Administration as serious adverse events through the MedWatch Reporting system, which were not reported:

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 7/1/09 for a patient identified as (b) (6) year old male. The product/product description associated with this complaint identified the product as CLD/Nasal Gel Spray with the NDC/DIN "62750-003-10".

The documentation reviewed for this adverse event included the following information: The patient complained of a loss of taste and smell. Patient visited an MD and was subsequently referred to an ENT. The ENT prescribed Avelox (Antibiotic).

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 6/1/09 for a patient identified as (b) (6) year old female. The product/product description associated with this complaint identified the product as RPC/RapidMelts with Vitamin C with the NDC/DIN "62750-008-28".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Timothy T Kapsala, Investigator David P. Vanhouten, Investigator Kenneth Boehnen, Investigator	10/19/2009

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The documentation reviewed for this adverse event included the following information: The patient complained of hives from head to toe. Patient visited the ER and was subsequently prescribed the following medication: 20mg of prednisone to be taken 2 times a day for 4 days.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 5/24/09 for a patient identified as (b) (6) year old female. The product/product description associated with this complaint identified the product as MSN/Multisymptom Nighttime with the NDC/DIN "62750-023-10".

The documentation reviewed for this adverse event included the following information: The patient complained of Tachycardia (heart rate of 140), abdominal pain, chest pain and being flushed. Patient visited the ER and had the following tests performed: Tylenol level after one hour of ingestion, Tylenol level after four hours of ingestion, blood alcohol level, urine drug screen and metabolic panel.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 4/20/09 for a patient identified a (b) (6) ear old male. The product/product description associated with this complaint identified the product as RPC/RapidMelts with Vitamin C with the NDC/DIN "62750-008-28".

The documentation reviewed for this adverse event included the following information: The patient complained of dizziness, feeling like passing out and rapid heart rate. Ambulance was called and paramedics checked the patients vital signs.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 4/6/09 for a patient identified as (b) (6) year old female. The product/product description associated with this complaint identified the product as CLD/Nasal Gel Spray with the NDC/DIN "62750-003-12".

The documentation reviewed for this adverse event included the following information: The patient complained that her heart was skipping a beat for 4 days. Patient visited the ER and was provided a 24

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hour holter heart monitor. In addition the following tests/procedures were performed: CT scan and x-ray.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 3/10/09 for a patient identified as (b) (6) year old female. The product/product description associated with this complaint identified the product as ASW/Adult Nasal Gel Spray with the NDC/DIN "62750-003-20".

The documentation reviewed for this adverse event included the following information: The patient complained of abnormal vaginal bleeding and menstrual cramps. Patient visited the ER and the treating physician prescribed Tamiflu and Loratab 5.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 2/24/09 for a patient identified as (b) (6) year old male. The product/product description associated with this complaint identified the product as CON/Extreme Congestion Nasal Gel with the NDC/DIN "62750-005-10".

The documentation reviewed for this adverse event included the following information: The patient complained that he can't breath. Patient visited the ER and was treated by an ENT specialist with the following medication: Sudafed, ibuprofen, antibiotic and prescribed Rhinocort.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 3/6/09 for a patient identified as a male child. The product/product description associated with this complaint identified the product as AZP/All Zicam Products (no NDC/DIN number identified) "0000000".

The documentation reviewed for this adverse event included the following information: A voicemail was received from a consumer's father who reported (b) (6) (b) (6). The consumer's father did not leave any other information or a contact phone number where he can be reached at.

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Matrixx Case Number (b) (4)

This adverse event was received by your firm on 3/6/09 for a patient identified as (b) (6) ear old female. The product/product description associated with this complaint identified the product as CON/Extreme Congestion Nasal Gel with the NDC/DIN "62750-005-10".

The documentation reviewed for this adverse event included the following information: The patient complained of dizziness, feeling faint and that her heart was racing. Patient visited the ER and the hospital ((b) (6) located in (b) (6)) took blood and performed blood tests.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 12/31/08 for a patient identified as (b) (6) year old female. The product/product description associated with this complaint identified the product as RPC/RapidMelts with Vitamin C with the NDC/DIN "62750-008-28".

The documentation reviewed for this adverse event included the following information: The patient complained that she felt extremely dizzy, heart rate funny, cold and naseous. Paramedics took patient to the hospital after checking her blood pressure (163/90). Patient was examined at the hospital by an MD who administered medication to treat an ear infection.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 4/29/08 for a patient identified a (b) (6) year old male. The product/product description associated with this complaint identified the product as ASW/Adult Nasal Gel Swab with the NDC/DIN "62750-003-20".

The documentation reviewed for this adverse event included the following information: The patient complained that he had a grand mal seizure and a temperature of 104 degrees. The patient was taken to the ER in an ambulance. The following treatments were administered at the hospital: IV fluids, sedatives, Tylenol and antibiotic therapy.

Matrixx Case Number (b) (4)

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This adverse event was received by your firm on 1/24/08 for a patient identified as (b) (6) year old male. The product/product description associated with this complaint identified the product as ASW/Adult Nasal Gel Swab with the NDC/DIN "62750-003-20".

The documentation reviewed for this adverse event included the following information: The patient complained that he had excessive build-up of zinc in kidneys. Patient was extremely ill ("questionable that he would leave the hospital alive") required hospitalization at a (b) (6) hospital and was treated in an unspecified manner.

Matrixx Case Number (b) (4)

This adverse event was received by your firm on 1/16/08 for a patient identified as (b) (6) year old female. The product/product description associated with this complaint identified the product as CLD/Nasal Gel Spray with the NDC/DIN "62750-003-10".

The documentation reviewed for this adverse event included the following information: The patient complained of facial swelling and difficulty breathing. Patient visited MD who prescribed the following: prednisone, albuterol, antibiotic therapy and Sudafed.

* DATES OF INSPECTION:
10/05/2009(Mon), 10/08/2009(Thu), 10/14/2009(Wed), 10/19/2009(Mon)

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