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	05/26/2009 - 05/28/2009* FEI NUMBER 3007187671

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Tim L. Clarot, Vice President R&D and Product Quality

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 I 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,

The firm does not classify and report anosmia (loss of smell) or loss of taste as a serious adverse event and therefore does not report these complaints to the Food and Drug Administration (MedWatch reporting system). The following three complaints were not reported to the Food and Drug Administration (MedWatch reporting system): AE09-000723, AE09-000736 and AE09-000886.

*** DATES OF INSPECTION:**
05/26/2009(Tue), 05/28/2009(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Timothy T Kapsala, Investigator Timothy T. Kapsala	05/28/2009