

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

19701 Fairchild
Irvine, CA 92612
(949) 608-2900 Fax: (949) 608-4417
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

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

Matrixx Initiatives Inc

STREET ADDRESS

8515 E Anderson Dr

CITY, STATE, ZIP CODE, COUNTRY

Scottsdale, AZ 85255-5461

TYPE ESTABLISHMENT INSPECTED

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.

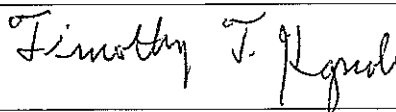
*** DATES OF INSPECTION:**

05/26/2009(Tue), 05/28/2009(Thu)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Timothy T Kapsala, Investigator



DATE ISSUED

05/28/2009