

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
555 Winderley Place, Suite 200
Maitland, FL 32751
407 475 4700 (Fax) 407 475 4768

DATE(S) OF INSPECTION
08/25-09/05/2008
FEI NUMBER
1047582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Raymond (NMI) Stadnick, Vice President, Quality Compliance

FIRM NAME
NBTY Inc., dba NBTY Rexall Sundown
CITY, STATE AND ZIP CODE
Boca Raton, FL 33487-3528

STREET ADDRESS
901 Broken Sound Parkway NW
TYPE OF ESTABLISHMENT INSPECTED
Dietary Supplement Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION #1

You did not make and keep documentation of the date of use, cleaning and sanitizing of the equipment used to prepare coating solutions for dietary supplement tablets.

Specifically, the last entry by the operator on the cleaning log for the Solution Prep Room was dated 7/26/2008. Coating solutions were prepared routinely in this room after 7/26/2008, for example as recent as 8/27/2008 (for Lot #239609).

OBSERVATION #2

Your batch production records did not include the actual results obtained during a monitoring operation.

Specifically, records for monitoring raw materials ("Raw Material Dispensing Sheet") in the Weigh Room do not include each partial raw material weight and the identification of the equipment used.

OBSERVATION #3

Your personnel did not use hygienic practices to the extent necessary to protect against contamination of dietary supplement ingredients.

Specifically,

a) Your personnel did not wear outer garments in a manner that protects against contamination of dietary supplement ingredients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Raymond Stadnick</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Raymond Stadnick, Vice President, Quality Compliance	DATE ISSUED 09/05/2008
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION #3 (CONTINUED)

Blending Room: On 8/26/2008 during your blending process of product ID 31-61621 associates touched drums, outer bags, and box cutters then filled the hopper touching raw material without refreshing gloves. An associate knelt down onto the raw material (without wearing protective clothing) and reached into the charge screen to push raw material through it into the hopper exposing the raw material to his bare arm and shirt sleeve (no sleeve protectors were worn).

Weighing Room: On 8/26/2008 an associate staging raw material for blending did not wear sleeve protectors while scooping bulk product RM 239550 into a container. Her shirt sleeve and arm came into direct contact with the raw material.

b) Your personnel used gloves that were not clean or stored in a sanitary condition. Blending Room: Gloves used by the associates were stored loose and unprotected on a table covered with raw material dust.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>[Signature]</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Marilyn E. Radick, QSC SUSAN WITKOWSKI, SCS	DATE ISSUED 09/05/2008
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