DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Ste. 200
Maitland, Florida 32751

Telephone: (407) 475-4700
FAX: (407) 475-4769

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-06-32

August 14, 2006

Mr. Ronald I. Wells
Black Henna Ink, Inc.
9861 West Sample Road #196
Coral Springs, Florida 33065

Dear Mr. Wells:

This letter concerns your firm's sale and distribution of your product "Super Black Henna Powder" (also referred to on your Internet web site, www.blackhennausa.com, as "Black Henna Tattoo Powder"). According to statements on your website, your product is sold for use as a temporary tattoo; that is, it is intended to temporarily color the skin in a decorative fashion. This product meets the definition of a cosmetic in section 201(i) of the Act because it is intended to be applied to the human body for "cleansing, beautifying, promoting attractiveness, or altering the appearance." This product is in serious violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on the FDA website at www.fda.gov.

Your product is adulterated under section 601(e) of the Act [21 U.S.C. 361(e)], in that it is a cosmetic and it bears or contains a color additive that is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. 379e]. Recently, FDA collected a sample of your product. FDA analysis found the product contains approximately 28% of the color additive p-phenylenediamine (PPD). A color additive is deemed to be unsafe within the meaning of section 721(a) unless there is in effect, and the additive and its use are in conformity with, a regulation listing the color additive for such use. There is no regulation listing the color additive p-phenyenediamine as safe for use in coloring the skin.

We request that you take prompt action to correct these violations. Failure to properly correct these violations may result in enforcement action without further notice. The Act provides for the seizure of illegal products and injunctions against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure

that similar violations will not recur. Include any documentation necessary to show that correction has been achieved. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the attention of Shari H. Shambaugh, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,

Emma R. Singleton
Director, Florida District