DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 07 2006

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rohit Tibrewala
Chief Executive Officer
Roha U.S.A., L.L.C.
5015 Manchester Avenue
St. Louis, MO 63110-2011

WARNING LETTER
CFSAN-01-06W

Dear Mr. Tibrewala:

On December 27, 2005, April 4, 2006, and May 2, 2006, the Food and Drug Administration (FDA) collected samples at food manufacturers of color additives certified to Roha USA and Roha Dyechem bearing the following six FDA certification lot numbers: AM7926, AM6366, AM4134, AM4054, AM9087, and AN1206. FDA analysis determined that the color additives sampled were substantially different from the material that Roha had submitted with its requests for certification of the batches that were certified under the above lot numbers. Because the color additives represented by certification lot numbers AM7926, AM6366, AM4134, AM4054, AM9087, and AN1206 require certification and are not certified, they are adulterated under section 402(c) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(c)], as these color additives are unsafe within the meaning of section 721(a)(1)(B) of the Act [21 U.S.C. § 379e(a)(1)(B)].

You can find the Act and FDA regulations at www.fda.gov.

In letters dated March 3, 2006, June 8, 2006, and June 16, 2006, FDA provided you with written notice of the expiration of certification for the following six previously-certified lots of Roha color additives:

1) **Color: FD&C Red No. 40, FDA Lot No. AM7926 [redacted] certified March 2, 2005)**

Finding: In the FD&C Red No. 40 sample collected [redacted] on December 27, 2005, Cresidine Sulfonic Acid (CSA) and Schaeffer's Salt (SS) were both found to be present at more than 10 times the level found in the certification sample from the subject batch (CSA: 0.57% vs. 0.04%, and SS: 0.71% vs. 0.04%). The values determined by our analysis exceed the limits for CSA and SS of 0.2% and 0.3%, respectively, set by 21 CFR § 74.340(b).

2) Color: FD&C Yellow No. 6, FDA Lot No. AM6366 [redacted] certified November 16, 2004)

Finding: In the FD&C Yellow No. 6 sample collected [redacted] on December 27, 2005, Higher Sulfonated Subsidiary (HSS) was found at more than twice the level found in the certification sample from the subject batch (6.3% vs. 3.0%, respectively). The values determined by our analysis exceed the limit of 5% for HHS set by 21 CFR § 74.706(b).

3) Color: FD&C Red No. 3, FDA Lot No. AM413[redacted] certified June 3, 2004)

Finding: In the FD&C Red No. 3 sample collected [redacted] on April 4, 2006, 2,4,5-Triiodofluorescein was found at more than 35 times the level found in the certification sample from the subject batch (7.11% vs. <0.2%, respectively).

4) Color: FD&C Blue No. 1, FDA Lot No. AM4054[redacted] certified May 28, 2004)

Finding: In the FD&C Blue No. 1 sample collected from an opened and in-use container[1] [redacted] on April 4, 2006, Manganese, a contaminant associated with the manufacture of this color additive, was found at more than 250 times the level found in the certification sample from the subject batch (5,000 Parts Per Million (PPM) vs. 18 PPM, respectively). The values determined by our analysis exceed the limits for Manganese in FD&C Blue No. 1 of 100 PPM set by 21 CFR § 74.101(b).

5) Color: FD&C Yellow No. 6, FDA Lot No. AM9087[redacted] certified May 9, 2005)

Finding: In the FD&C Yellow No. 6 sample collected [redacted] on May 2, 2006, Higher Sulfonated Subsidiary (HHS) was found at more than twice the level found in the certification sample from the subject batch (5.4% vs. 2.3%, respectively). The values determined by our analysis exceed the limit for HHS of 5% set by 21 CFR § 74.706(b).

6) Color: FD&C Yellow No. 5, FDA Lot No. AN1206[redacted] certified September 20, 2005)

Finding: In the FD&C Yellow No. 5 sample, 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt (Pyrazolone T) collected [redacted] on May 2, 2006, was found at twice the level found in the certification sample from the subject batch (0.36% vs. 0.18%, respectively). The value determined by our analysis exceed the limits for Pyrazolone T of 0.2% set by 21 CFR § 74.705(b).

[1] All other samples were taken from sealed containers.

You should respond in writing within 15 working days of receipt of this letter. Your response should describe the actions you have taken to determine how these color additives became adulterated and the corrective actions you have implemented to prevent recurrence. Your response should also describe the actions you have taken to ensure that these lots will not be used in the manufacture of FDA-regulated products. Your previous correspondence with FDA has failed to adequately address these areas. Your response should include documentation and other useful information that will assist us in evaluating your corrective measures.

The above violations are not intended to be an all-inclusive list of deficiencies. Other violations can also subject your firm and/or your products to legal action. It is your responsibility to ensure that all of your products are in compliance with all applicable statutes and regulations enforced by FDA.

You may address your reply to Compliance Officer Kristen Moe at the above address.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: B.J. Navalur
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