



September 26, 2013

SUBSTANTIALLY EQUIVALENT

FDA Submission Tracking Number (STN): SE0001698

HBI International
Michael R. Sneberger, Esq., General Counsel
3315 West Buckeye Road, #4
Phoenix, Arizona 85009

Dear Mr. Sneberger:

The Food and Drug Administration (FDA) completed review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for the following tobacco product:

Applicant:	HBI International
Tobacco Product Name¹:	Elements Aficionado 1 and 1/4
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Rolling paper and paper tips
Package Size:	50 papers and tips
Package Type:	Box

Based on our review of your SE Report, we find the new tobacco product specified above substantially equivalent to a tobacco product commercially marketed in interstate commerce as of February 15, 2007.

Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you opted not to provide an adequate summary of any health information related to the new tobacco product with your application, but stated that such information will be available upon request by any person. Consistent with the requirements of Section 910(a)(4), you may wish to consider providing the following when information is requested:

¹ Brand/sub-brand or other commercial name used in commercial distribution

- A. A copy of your final SE Report upon which our order was based, redacted only to the extent necessary to exclude patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR § 20.61 and 20.63 and;
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]”.

Alternatively, you may provide the following when information is requested:

- A. Description of the new tobacco product;
- B. Description of the predicate tobacco product;
- C. List of all differences in characteristics between the predicate and new tobacco products;
- D. Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health; and
- E. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]”.

There may be other accurate, complete and not false or misleading ways to satisfy the requirements of Section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of 910(a)(4), submit a meeting request to FDA.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA “approved” the new tobacco product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act.

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. A review of labeling and advertising was not conducted as part of this substantial equivalence review. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

Center for Tobacco Products
Food and Drug Administration
Document Control Center, Rm 020J
9200 Corporate Boulevard
Rockville, MD 20850-3229

We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Laila Noory, M.P.H., Regulatory Health Project Manager, at (301) 796 – 9280.

Sincerely,

Digitally signed by David Ashley -S
Date: 2013.09.26 11:05:33 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science
Center for Tobacco Products