COMPLIANCE SERVICES FOR THE ADMINISTRATIVE REGISTRATION OF COSMETIC PRODUCTS IN CHINA (*CHINA COSMETICS*)

Under the Chinese "**Regulation for Administrative Registration of Cosmetic Products**" (*SFDA [2009]856, published in China on 25 December 2009), companies seeking to place on the Chinese market a new raw material for use in the formulation of cosmetic products in China, or placing this raw material on the Chinese market as part of a product formulated outside of China must submit an application including administrative and technical information.

Companies applying for the administrative registration of cosmetics must submit an application including:

- Administrative information on the manufacturer of the raw materials
- A technical dossier on the new raw materials for which the application is made

The application will be reviewed and a license granted based on the outcome of the review process.

***Note as of March 2013, the National People's Congress of China formally changed the name of the State Food and Drug Administration (SFDA) to the China Food and Drug Administration (CFDA).**

CHINA COSMETICS REGISTRATION SERVICES:

- **Legal Representation in China: Non-Chinese companies cannot submit applications directly and must proceed via a registered regulatory representative (proxy) established in China.**
- **Preliminary raw materials evaluation**
  - Screening of registered raw materials, identification of raw materials considered as "new"
  - Determination of the compulsory regulatory schema
- **Initial assessment**
  - Information and data collection
  - Data analysis and evaluation
  - Data gaps assessment, qualifying documents for translation in Chinese language
- **Preparation of research and development report**
- **Preparation of manufacturing process description report**
- **Identification and generation of material quality and safety control requirements, including standards and testing methods**
- **Testing for missing data**
  - Cost effectiveness strategy, and testing planning
  - Testing for physicochemical, toxicological and eco-toxicological properties
    (**Note** : Toxicology testing must be performed by China based approved institutes)
- **Preparation of testing reports and relevant materials**
- **Preparation of safety evaluation on substance risk**
- **Preparation of report on effectiveness of components and their use, based on scientific literature**
- **Evaluation on toxicological safety**
- **Registration dossier generation, submission & follow up**
  - Registration process for **New raw materials**
  - Registration process for **Finished cosmetics products**
- **Translation and notarisation (Note: All documents must be submitted in Chinese language)**

B-Lands Consulting – World Trade Center, 5 Place Robert Schuman BP1516 - 38025 Grenoble - France
Phone : +33 (0) 476 230 627 - Fax: +33 (0) 476 295 870 - Email: europa@reach-compliance.eu

ADDITIONAL SERVICES RELATED TO *CHINA COSMETICS* COMPLIANCE:

- Classification and labelling for cosmetic products
- Assisting clients in readying for onsite inspections carried by enforcement authorities
- Regulatory and technical assistance
- Regulation monitoring and alerts for changes in legislation

Notes:

A toxicological safety assessment must be provided by supplying a number of full toxicological study reports. Studies generated outside of China may be accepted if they have been conducted in a laboratory with internationally accepted quality certification such as GLP, and translations of the full study reports are provided.

SFDA : *China's State Food and Drug Administration*

On February 2011, the SFDA (now CFDA) has officially approved 17 cosmetics testing institutes:

Effective on 1 June 2011, eleven institutes are approved to conduct the microorganism, sanitary chemistry and toxicity tests required in the cosmetic testing standard for the application of cosmetic administrative licences: (1) the Institute of Environmental Health and Related Product Safety (China Center for Disease Control -CDS-); **(2)** the Beijing, **(3)** Liaoning, **(4)** Shanghai, **(5)** Jiangsu, **(6)** Zhejiang, **(7)** Guangdong and **(8)** Sichuan CDCs; **(9)** Beijing institute for Drug Control; **(10)** Shanghai Institute for Food and Drug Control; and **(11)** the Guangdong institute for Drug Control.

Effective on 1 June 2011, six institutes are approved to perform the human safety and human sun block effect tests required in the standard: (1) the General Hospital of the Chinese People's Liberation Army Air Force; **(2)** Shanghai Skin Disease Hospital; **(3)** the third Affiliated Hospital of San Yat-sen University; **(4)** West China Hospital of Sichuan University; **(5)** the first hospital of China Medical University; and **(6)** the Kin Disease Hospital of Chinese Academy of Medical Sciences.

EU COSMETICS COMPLIANCE SERVICES (For the EU Market)

We provide currently registration services and regulatory assistance with respect to Council **Directive 76/768/EEC** of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (**EU COSMETICS**) and its subsequent amendments; along with transitional recommendations with regard to **Regulation (EC) No 1223/2009** of the European Parliament and of the Council of 30 November 2009 on cosmetic products, in force from 11 July 2013. With the exception of Article 15(1) and (2) applicable **since 1 December 2010**, as well as Articles 14, 31 and 32 to the extent that they are necessary for the application of those provisions.

Please contact our consultants, chemists or regulatory experts, if your seek assistance.

B-Lands Consulting World Trade Center 5 Place Robert Schuman - BP 1516 38025 Grenoble, France Website: www.reachteam.eu	Line 1 : +33 476 295 867 Line 2 : +33 476 295 869 Fax : +33 476 295 870 China office (Beijing) : +86 10 6789 1548 Email: services@reachteam.eu