

# EU Cosmetics Dossier

**A Special Presentation for  
Natural Product & Cosmetic Companies  
Bringing Cosmetic Products to the EU**

Natural Clinical Trials Network  
[www.NaturalClinicalTrials.net](http://www.NaturalClinicalTrials.net)

[All information on these slides is also on the Web Page.]

Companies wishing to market cosmetics in the European Union are required to maintain certain records in the **Product Information File** (Dossier), in order to sell in the EU countries.

Among the requirements is the **Safety Assessment Certification** provided by third party consultants, such as those of the Natural Clinical Trials Network.

# Our Background

*Over 100 Years Total Experience ...*

The three principals of the Network are:

- **Robert M. Goodman, PhD**  
Biochemist & Science Researcher
- **Rima E. Laibow, MD**  
Medical Director of the Center & Environmental Physician
- **Ralph Fucetola, JD**  
International Counsel

# Natural Solutions Center

The Natural Clinical Trials Network  
of the Natural Solutions Center  
Volcan, Panama



# Services

- 1. Consultation regarding the required “description of the qualitative and quantitative composition.”
- 2. Confirmation of the required “physic-chemical and microbiological specification” as certified by the responsible person at the Company; the Confirmation Document attests that our search of the scientific literature supports the specification as reported.
- 3. Consultation regarding description of the SOPs for method of manufacture complying with cGMPs.
- 4. *Certified Assessment of Safety*; this Certification Document shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure, and shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended.

# Work Product

The work product provided for the Company's permanent records consists of four documents, with Dossier cover:

- 1. **Letter of Opinion** regarding the description of the qualitative and quantitative composition.
- 2. **Attestation** that our search of the scientific literature supports the physic-chemical and microbiological specification as reported.
- 3. **Letter of Opinion** regarding the Company's SOP for cGMPs [SOP recommendations are a separate service offered by the Network].
- 4. **Certified Assessment of Safety** that the generally safe toxicological profile of the ingredients are supported by reliable and competent scientific evidence, when taking into account chemical structure and level of exposure.

# Customer Information

- 1. Company name
- 2. Company address
- 3. Contact name
- 4. Contact email
- 5. Contact phone
- 6. Name of product(s)
- 7. General description of product(s)
- 8. Any "Look and Feel" claims currently being made in ads
- 9. Any "Look and Feel" claims currently on the label.
- 10. List of Ingredients and amounts or ratios (mark this "Proprietary")
- 11. Attach copy of label.

# Cost Analysis

The basic charge for the full Article 7a service package

- 1.The four letters, certifications & Dossier - \$1,200.00 + \$100 /ingredient > 3 ingredients
- 2.Standard Operating Procedures, from: \$1,000.00

# Article Seven Excerpts

**“... The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a) ...**

See the following panel for details.

# Article Seven - 2

**(a) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned;**

- The person responsible for manufacture or first importation into the Community must possess -**
  - an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation ..**

# Article Seven - 3

**(b) assessment of the safety for human health of the finished product.**

- **To that end the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure.**
- **It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended.**
- **There shall be *inter alia* a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene control criteria of the cosmetic product...**

# Contact Us

Please contact us through Dr. Goodman

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We look forward to your contact . . .

# Thank You!

