

What Happen About Herbal Medicine in the World On 2006

PEFFOTS

Dr. Zhu Guo-Guang

USA FDA 2004

**Guidance for Industry Botanical Drug
Products**

EU EMEA March 31, 2004
2004/24/EC

The U.S. Food and Drug Administration (FDA) approved a special extract of green tea as a prescription drug for the topical (external) treatment of genital warts caused by the human papilloma virus (HPV). The new drug, called Veregen™ (Polyphenon® E) Ointment is the first prescription botanical (herbal) drug approved by FDA under the “new” drug amendments of 1962 that required drugs to be proven both safe and effective prior to being marketed in the U.S.

The active drug ingredient, Polyphenon E, represents a proprietary mixture of phytochemicals produced from a partially purified water extract of green tea leaves. Green tea, brewed from the leaves of the tea plant (*Camellia sinensis*), is one of the most popular beverages worldwide.

For FDA drug approval, the safety and efficacy of Polyphenon® E Ointment were studied in two prospective, randomized, double-blind clinical studies in nearly 400 adults with external genital and anal warts ranging in number from 2 to 30. Test subjects applied the ointment three times daily until complete clearance of all warts. In each of these clinical trials, the median time to clear warts completely was 16 weeks and 10 weeks, respectively.

“This is a regulatory breakthrough, said Mark Blumenthal, Founder and Executive Director of the nonprofit American Botanical Council. “It is the first time a complex herbal preparation has come to market as a prescription drug in the U.S. in more than half a century.”

FDA defines a “botanical” as a product that exclusively contains ingredients from plants, algae or fungi. In contrast to most conventional pharmaceutical drugs comprised of one single chemical, botanicals contain complex mixtures of naturally-occurring chemicals. In order to more appropriately evaluate herbal mixtures, in June 2004 the FDA published Guidance for Industry for Botanical Drugs, a new policy providing advice for potential botanical drug manufacturers, describing both the application process and providing recommendations as to how chemically complex products might satisfy the requirements of FDA’s rigorous “new drug” review process.

100ml Klosterfrau melisana®

乙醇 79%

Balm leaves (香蜂草叶) 0.536g

Scabwoof rootstalk (土木香) 0.714g

Angelica root (欧当归) 0.714g

Ginger root (生姜) 0.714g

Clove flowers (丁香) 0.285g

Nutmeg seed (肉豆蔻) 0.071g

Dried bitter-orange peel (枳壳) 0.714g

Cinnamon bark (桂皮) 0.321g

Cassia flowers (番泻花) 0.036g

Cardamom fruits (白豆蔻) 0.001g

Gentian rootstalk (龙胆根茎) 0.714g

Galangal rootstalk (高良姜) 0.285g

Black papper furits (黑胡椒) 0.071g

- **Nervous ailments**
- **Nervous headaches**
- **Stomach complaints based on nerves**
- **Sleep disturbance based on nerves**
- **Meteoropathy**
- **Colds**

Indications

Internal use: Effective against nervousness, states of tension and excitement, anxiety, difficulties in falling asleep, headaches, sensitivity to changing weather, non-organic heart ailments, painful menstrual cramps and during menopause, stomach-intestinal ailments like indigestion, fullness, no appetite. It is used to alleviate symptoms of a cold or flu.

Topical use: Painful nerves, pains after muscular exertion, lumbago, gingivitis, indisposition and exhaustion.

Contraindications

Should not be used in cases of stomach or duodenal ulcers.

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**The Medicines and Healthcare
products Regulatory Agency
(MHRA) has granted
the first UK product
registration under the
European Directive on
traditional herbal**

The first product to be registered is *AtroGel Arnica Gel*: an arnica gel traditionally used for the symptomatic relief of muscular aches and pains, stiffness, sprains, bruises and swelling after contusions. The product registration has been granted to Bioforce (UK) Ltd.

Professor Kent Woods, Chief Executive of the MHRA said:
“This first product registration is an important landmark. We hope that Atrogel Arnica Gel will be the first of many products to receive a traditional herbal registration .

***Our aim is to
enable those consumers who
wish to take herbal medicines to
make an informed
choice from a wide range of
products which have been made
to assured
standards of safety, quality and
patient information.***

Under the European Directive on traditional herbal medicinal products, all manufactured traditional herbal medicines placed on the market will now have to meet the requirements of the Directive. There is transitional protection until 2011 for products that were legally on the UK market before April 2004. The MHRA expects a progressive build up in the number of products registered as we move towards 2011.

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Thank you very much !

