

FRANCESCO  
INTERNATIONAL

May 24, 2000

Ms. Patricia L. DeSantis  
Center for Drug Evaluation  
& Research (HFD-2)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857  
Ph: 301-594-5406

Dear Patricia,

As discussed, attached are:

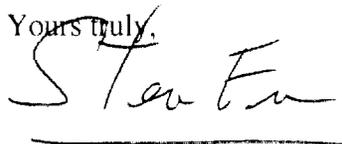
1. A basic statement of my company's credentials, as well as a company brochure.
2. A rough outline of the subjects in which I believe you will be interested. I have followed the six-point format used in the meeting announcement. Also, I have added more information on the international switch scene, and made some recommendations on changing the paradigm structurally.
3. Two recent SWITCH newsletters. For copyright reasons, I would appreciate it if you would keep these two newsletters to yourself for now.

Our company's mission is the "responsible enhancement of self-medication." We work 100% of our time on Rx-to-OTC switches on a global basis. Therefore, we have a huge amount of information and a lot of experience. In the Public Meeting setting, we could never reveal all our learning and beliefs.

Accordingly, we respectfully ask that we be accorded only 90 minutes. Moreover, given the broad overview we can provide, we are particularly suited to present early in the meeting.

We look forward to hearing from you around June 5. Of course, if you have any questions, please do not hesitate to call.

Yours truly,



Steve Francesco

**OON-1256**

**APE 55**

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Visit us on the web at [www.RxToOTCSwitch.com](http://www.RxToOTCSwitch.com)

# FRANCESCO INTERNATIONAL

Steve Francesco, President and founder of Francesco International, formed the company in 1994 as a consulting and publishing venture dedicated

"to the responsible enhancement of self-medication."

The company is uniquely positioned in the Rx and OTC industry for its independent and innovative thinking and knowledge of international healthcare systems. Francesco International provides quality information and guidance on whether or not to switch and, if so, how and when.

Consistent with its goal of enhanced public well-being through self-medication, Francesco International has previously proposed US legislation that would increase the number and kinds of drugs that could be considered for OTC status without sacrificing safety considerations.

Mr. Francesco is Editor and Publisher of SWITCH®, a monthly newsletter established six years ago, which focuses exclusively on international Rx-to-OTC switches and switch-related issues in the eight major OTC global markets. The publication currently has subscribers in 24 countries.

Recognized for its objectivity and thorough analysis of the complex issues in the switch field, Francesco International has a successful consulting practice to the pharmaceutical industry. Francesco International has championed the concept of Dual Status (simultaneous Rx and OTC existence) for drugs and has developed economic models in support of Dual Status. It has developed its own proprietary software, "Max the Molecule", to assist in Rx-to-OTC switch decisions.

Mr. Francesco is a frequent speaker and writer on international OTC issues. He has been a guest speaker in virtually all major markets and contributed to numerous text books and periodicals.

Mr. Francesco has more than 15 years of management and marketing experience in the field of international Rx and OTC medicines. Prior to founding Francesco International, he headed up the International OTC division of Schering-Plough for six years and before that the OTC division of Sterling Drug for four years. He also served as the US Director of Product Management for a US OTC division of Sandoz.

Mr. Francesco has traveled extensively, has lived in France and speaks fluent French as well as German. He is a Dean's List graduate of Columbia University, where he earned his B.A. and M.B.A.

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## Proposed Outline for the June 28/29 US FDA OTC Meeting

### **1) The global Rx-to-OTC switch scene**

- a) rate of switches 1995-1999
- b) products & indications available in leading markets outside the US but not in the US
- c) efforts to accelerate switch and the role of cost cutting
- d) the declining 3<sup>rd</sup> class of drugs

### **2) The criteria FDA should consider for making decisions on OTC availability**

- a) current system: safety obsession, then efficacy, self-diagnosis (self-recognition)
- b) what level of risk is acceptable as measured by patient outcome in controlled tests.

### **3) The classes of products, if any, that are not currently available but should be made available as OTC's.**

Mild Asthma	Osteoporosis
Arthritis	Hypercholesterolemia
Hypertension	Incontinence
Migraine	Benign Prostate Hyperplasia
Infections (viral)	Emergency Contraception

### **4) How the Agency can make sure consumers understand issues relating to OTC availability of drug products.**

- a) clinical trials, usage studies
- b) test markets (tightly controlled)

### **5) How rational treatment decisions are affected by coexisting prescription and OTC therapies for a given disease.**

- a) international experience
- b) high/low dose drugs
- c) modified indications (chronic vs acute, etc)
- d) additional monitoring and compliance

### **6) Whether the current structure for marketing products in the US is adequate**

Dual Status incentives

### **7) The FDA's role in switching products from prescription to non-prescription status.**