

Improvement to the OTC Monograph System

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With the implementation of the Monograph system for non-prescription drugs, the US FDA established a simple cost-effective way for producers of these drugs to enter the market place. By following the Proposed Rules, Tentative Final Monographs and Final Monographs, competition of finished drugs increased, as did the availability of self medication by consumers. These rules set out the procedure to follow for efficacy, label requirements and permitted active drugs.

This has been one major flaw in this entire system. There is need for a simple, transparent, inexpensive way for manufacturers of new actives, to have them permitted and added to the Monographs. Currently, the only avenue opened is to establish a relationship to a marketer of finished drugs who than would file a NDA. After clearing this time consuming and expensive hurdle, and after being used in the market place for a material time and extent, it is than possible to be considered for addition to a Monograph.

Because of these obstacles, the FDA has stifled development of new actives. For example, since this system started there has only been 1 new UV Filter (and that took close to 20 years) and no new antidandruff agents. To go through the costly process makes it impossible to price finished goods competitively to currently marketed drugs.

While attending the Mutual Understanding 2000 Conference, on global harmonization of cosmetic regulations, held in Malta this April, I heard the FDA being called "old fashion" and "out of step" with the rest of the way the world is moving to regulate cosmetics. Most of the attention was toward the European Union' methods of regulating these products. As I consider the EU system of regulation to be much more onerous than the US, why is this happening? The answer is very simple. In the EU the following products are regulated as cosmetics while they are drugs in the US: sunscreens, antidandruff, antiperspirant, antimicrobial cleaners, skin protectants and anti-aging products.

Of these products I wish to focus on the two that cause people to like the EU system over ours, namely sunscreens and antidandruff products. These are regulated by having the actives required to be pre-approved for safety (like our OTC system) and appear on Annex VI (preservatives) or Annex VII (UV filters).

For years many UV filters and biocides remained only provisionally allowed. Manufacturers of these ingredients were asked to submit safety data, but what? Finally, they published a model submission and the system became transparent. All of the provisionally allowed biocides and UV filters were moved to the permitted list as the necessary data was submitted and decisions were made. Currently there are about 6 UV filters and 2 antidandruff agents permitted in the EU which could be successfully used in the US. All are considered "new drugs" by the FDA.

As the FDA requires drugs to be safe and effective, we need to establish a better system for evaluating safety. Efficacy for these types of drugs is not an issue, as this is defined in the Final Monographs and must be run on the finished formulation, not the active.

I suggest that the FDA seriously consider allowing the Cosmetic Ingredient Review, to evaluate these "actives" for pre-market approval and subsequent addition to the Final Monograph. This would only apply to current OTC drugs without dose restrictions. This would be a very time efficient and cost effective procedure. As you are aware, a representative of the FDA is part of the CIR expert review panel. The FDA is the "biggest lion in the jungle". If the Agency objects at CIR meetings, their voice carries special meaning.

In conclusion, if the FDA adopted a simple, cost effective, transparent way of incorporating new UV Filters, Antidandruff agents and other similar OTC drug actives, to their Final Monographs, you would never hear that the Agency is "old fashion" and "out of step". Rather, you hear a ground swell to have the US be the model for Global Harmonization of Personal Care Regulations.