

# UPDATING THE REGULATIONS OF OTC DRUGS

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# Background

- The Monograph system was started to regulate existing OTC drugs to ensure safety and efficacy.
- The original structure of independent expert panels meeting and establishing proposed rules, went ahead and finished most the categories of drugs in about 6 years.

# What Happened Next?

- The concurrent review seems to drag on forever with no end in sight.
- At the same time, it became clear that the system was a major deterrent for progress, as there was no provisions for new drugs, except the costly and time consuming NDA method.
- This put new drugs at a competitive disadvantage and remains a deterrent for innovation and new science.

# The Old Solution

- Public hearings on OTC drugs in the late 90's lead to the FDA solution: the Time and Extent Application (TEA) process. (2002)
- Since then 14 have passed the first stage but nothing has gotten any further
  - 8 UV Filters
  - 3 Dandruff
  - 1 Internal use
  - 2 Triclosan applications

# A Possible Solution to The FDA Current OTC Situation

- The first thing to understand is that all OTC drugs must be divided into 3 distinct categories.
- Each has distinct and unique requirements for safety, efficacy and labeling.
- One size does not fit all!

# Most Important Category

- Ingested drugs with dose restrictions
- These require the FDA's attention and their top priority.
- If expertise is needed to add new drugs, change warnings and directions, doses etc., this could be obtained by re-establishing the expert panels. The FDA should be the reviewer, and not have 100% of the burden.

# Next

- Topically applied drugs with dose restrictions.
- These include :
  - Acne –up to 3 times a day
  - Antifungal-once or twice a day
  - First Aid Antiseptics-1-3 times a day
  - Healthcare Antiseptics (not consumer washes)
  - Corn & Callus Removers-1-2 times aday
  - Skin Bleaching-Twice a day
  - Topical Analgesics-3-4 times a day
  - Wart Removers-soak 5 minutes a day

# Finally

- Topical drugs without dose restrictions.
- These are regulated in most of the world as cosmetics.
- Most consumers consider them cosmetics.
  - Anticaries paste-at least twice a day
  - Healthcare hand washes-as needed
  - Antiperspirants-as needed
  - Dandruff-at least twice a week
  - Skin Protectants-as needed
  - Sunscreens- as needed

# What to do with the TEA's?

- Some of these have been submitted over 10 years ago with no action.
- All but 1 are topical's and most of these are without dose restrictions.

# The Process

- The first stage is a check list: you qualify or you don't. An intern can do this in an hour. It is not a good use of FDA's highly qualified staff to do this.
- The second stage is where everything currently is held up. The solution is to go back and re-established the expert panels to review the safety and efficacy data and than have the FDA oversight.

# Finally

- When the FDA asks for comments on anything, it should be a Federal crime to “spam” the FDA!

# Questions?

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**Thank You!**

