Energizer® Personal Care

Playtex®

Cost Impact of the Sunscreen Monograph

Banana Boat®

Hawaiian Tropic®

FDA and Industry Estimates Differ

- FDA estimated a total one-time incremental cost of the rule is $53 million
  - Estimate is based almost solely on costs of UVA testing and labeling
- Based on industry input, estimate is over $200 million
  - Testing and labeling costs are more than double what FDA estimates (PCPC estimates $124 - $190 million)
  - Consumer and HCP education costs, and inventory transition costs will be significant

FDA Estimate Avoided a Finding of "Significant Regulatory Action"

- FDA 's estimate was under $100 Million and avoided the application of Executive Order 12866
- FDA underestimated:
  - the number of products that would require testing,
  - the costs of such testing, and
  - the costs of relabeling.
- FDA failed to include:
  - consumer education to alleviate confusion created by the new UVA labeling requirement
  - costs for inventory transition

Costs Not Considered by FDA

- Consumer Education Costs
  - FDA did not assess costs to educate and alleviate confusion as to meaning of new UVA 'star rating system'
    - Without significant consumer education, star rating system will not promote public health
- Inventory Transition Costs
  - FDA assumed "no one-time costs associated with disposing of sunscreens already on the market" due to the 18 to 24 month implementation period

Consumer Confusion of Star Rating

- FDA did not assess whether star rating system achieves the objective of promoting public health
- System allows low SPF with high UVA star rating, and high SPF with low UVA star rating
  - Which product gives better protection?
- Industry and government will incur costs to address this confusion
- Public health will be negatively effected due to this confusion

Consumer Confusion

Which product offers the BEST protection?

Mock labels

4 Star

3 Star

2 Star

Inventory Transition Cost

- FDA assumption of "no one-time cost" is not correct
- FDA did not assess the reaction of the retail customers
- Retail customers will want compliance at the start of next season, regardless of phase in period
  - These inventory transition costs are estimated to be at least $112 million

Other Costs Not Considered by FDA

- Reformulated products will require additional testing costs for other product attributes
  - Hypoallergenic
  - "Tear Free"
    - May require additional clinical testing

Conclusions

- The one-time cost impact of the Proposed Final Monograph is greater than $100 million
  - UVA testing and relabeling costs will be greater than $53 million (FDA estimate)
  - Costs to educate and address consumer confusion of star rating system will be millions of dollars
  - Inventory transition costs will be greater than $112 million

Requests of OMB

- Require FDA to do an assessment of the Final Monograph:
  - On costs of consumer and HCP education on UVA labeling
  - On the efficacy of the star rating labeling system on consumer understanding
  - On the inventory transition costs due to the seasonality of the sunscreen business