

RCC Industry Panel – Consumer Products

Presentation to RCC Stakeholder Dialogue Session
June 20, 2013

Darren Praznik

*President & CEO, Canadian
Cosmetic, Toiletry and
Fragrance Association*

Elizabeth Turek

*Vice President, Regulatory Affairs North
America, Johnson & Johnson Consumer
Products*

Presentation Overview

- Organization Overviews
- Example of alignment opportunity – GMP requirements and inspections
- Quantification of benefit to industry, government and customers(retailers)/consumers
- Progress & Challenges Ahead

Canadian Cosmetic Toiletry and Fragrance Association (CCTFA)

- Lead Trade Association for Personal Care Products Industry in Canada (175 member companies who manufacture, distribute or retail personal care products as well as suppliers of goods and services to the industry)
- With US Personal Care Products Council, sponsored RCC Summit in Sept. 2012 (included 6 personal care & OTC industry associations from both sides of the border as well as RCC Secretariat, Health Canada & the US FDA)
- Personal Care Products Annual Wholesale Value:
Canada - \$5.6 Billion; US - Over \$60 Billion
- OTC Products Annual Retail Value:
Canada - \$4.8 Billion; US \$23.6 Billion

Johnson & Johnson Consumer Products

- One of 3 sectors in J&J (Consumer, Pharmaceuticals, Medical Devices & Diagnostics)
- *Consumer Sector* - Skin Care (NEUTROGENA®), Baby Care (JOHNSON'S®), Oral Care (LISTERINE®), Wound Care (POLYSPORIN®), OTC (TYLENOL®)
- \$14.4 Billion Worldwide Consumer sales (2012)
 - ~7100 Employees in North America
 - > 30 North American manufacturing sites and suppliers
- Interact with Federal Regulators in Canada and U.S.
 - Health (Health Canada, Food and Drug Administration)
 - Environment (Environment Canada, Environmental Protection Agency)

Alignment Opportunities

1. Alignment of Regulatory GMP Requirements & Inspections for Imported Products
 - Mutual Recognition of **GMP Documentation** and **Test Results for Product Release**
 - Mutual Recognition of **Facility GMP Inspections**
2. Establishment of harmonized Labeling and Packaging
 - Ingredient Nomenclature
 - Label Harmonization
 - Tamper-proof Packaging
3. Alignment of Environmental, Health and Safety Reviews and Ingredient Reviews
 - Eliminate Duplication of Science Based Environmental, Health and Safety Reviews
 - Coordination and Alignment of Ingredient Review Policies (to minimize issues in cross border market access)

Benefits from Alignment of GMP Requirements and Mutual Recognition of Inspections

Industry

- Avoid duplicative documentation, release testing, warehousing, HC fees, temperature monitoring, and stability testing
- Reduced supply chain complexity and delays

Government

- Avoid duplicative facility inspections
- Reduced administrative burden to develop, review and maintain separate standards

Customers(retailers)/Consumers

- Shortened product supply timelines
- Opportunity for broader product choice and increased market competition

A day at the beach without sunscreen...

What if a natural disaster near the current manufacturing plant created the need to source product from the other country?

Canada → U.S.	U.S. → Canada
Recent Health Canada inspection but no previous FDA inspection	Add U.S. site to Drug Establishment Licence (current evidence of GMP compliance required)
FDA inspection required	Product quarantined upon arrival in Canada
Random border screening and testing	Product retested for active ingredient and re-released in Canada
	Annual commitment lot for full testing annually



Cost Implications...

Estimated Year 1 Cost:
Import 1 Sunscreen
product to Canada:

**\$150,000 to
\$190,000**

- Warehousing
- Lab testing
- HC Fees-product, site
- Temperature monitoring
- Creation of Documentation
- Stability Testing







+ **SPF**



+ SPF =



Paperwork Implications...

Cosmetics:



Paperwork Implications...

Drugs:



Cost Implications...



Estimated Year 1 Cost:
Import 1 SPF Lipstick to
Canada:

\$170,000

- Warehousing
- Lab testing
- HC Fees-product, site
- Temperature monitoring
- Creation of Documentation
- Validations
- Stability Testing

Versus Cost Implications of a Cosmetic...

Estimated Year 1 Cost:
To Import a Cosmetic:

<\$1,000



*Detailed information on the cost work-up available upon request₁₅.

Progress and Challenges Ahead

Progress

- Health Canada making administrative changes in regulations of “consumer health products”
- Health Canada & FDA discussing how to recognize each other’s facilities inspections

Challenges

- Keeping up the momentum for regulators to be doing the required detailed work
- Integrating trade considerations & regulatory alignment into regulatory culture (RCC, TPP, Canada & US trade agreements with the EU, and the “Canary in the Coal Mine”)