



# **REGULATORY CHALLENGES OF IMPORTATION OF API AND FINISHED DRUG PRODUCT**

**Presented To: Joint CVG / TPD**

**2006 International Convention and Exhibition**

**October 6, 2006**

**Tom Barker**

**GMP Unit Manager**

**Ontario Operational Centre**

**Health Canada**



**Santé  
Canada**

**Health  
Canada**



# OVERVIEW

- Food and Drugs Act & Regulations
- Establishment Licences
- Procedures
- Policies
- Guidelines
- Future
- Questions





# FOOD AND DRUGS ACT & REGULATIONS

## Act

- Section 8 to 15
- Section 37

## Regulations

- A.01.040 & A.01.044
- C.01.004.1
- Division 1A
- Division 2



# SECTIONS 8 to 15



Section 8	Prohibited sale of drugs
Section 9	Deception, etc regarding drugs
Section 10	Drug standards (prescribed, trade, no standard)
Section 11	Unsanitary manufacture of drugs
Section 12	Drugs not to be sold unless safe manufacture indicated (Sch C or D drugs)
Section 13	Drugs not to be sold unless safe batch indicated (Sch E)
Section 14	Samples
Section 15	Sch F drugs not to be sold





## **SECTION 37**

- Drugs fabricated in Canada
- Labelling
- Export Certificate as Prescribed





## **A.01.040**

Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.





## A.01.044

- Labelling
- Must inform prior to import
- 90 days to correct labelling





## C.01.004.1

- Need Canadian person responsible for sale of drug in Canada
- Name and address of principal place of business in Canada of person responsible for its sale (inner & outer label)





## DIVISION 1A

# Establishment Licences (EL's)

All foreign sites that conduct licenceable activities must be listed on an EL.

For requests for foreign inspections please contact:

[Louise\\_Jodoin@hc-sc.gc.ca](mailto:Louise_Jodoin@hc-sc.gc.ca)

For more please visit:

[www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index_e.html)





# DIVISION 2

## Good Manufacturing Practices

Section	I (non- MRA)	I (MRA)
Personnel C.02.006	√	√
Manufacturing Control C.02.011 & C.02.012	√	√
Quality Control C.02.013 - C.02.015	√	√
Finished Product Testing C.02.018	√	√
<b>Finished Product Testing C.02.019</b>	√	
Records C.02.020 – C.02.024	√	√
Samples C.02.025 & C.02.026	√	√
Stability C.02.027 & C.02.028	√	√



## **GUIDANCE**

- SOP's
- Policies
- Guides





## SOP's

- 0052 Request and Assessment of GMP Compliance for Foreign Drug Establishments in Non-MRA countries
- 0128 Process for the Request and Receipt of GMP CoC from MRA countries
- 0254 Compliance Verification and Investigations Relating to the Importation and Sale of API's for Veterinary Use
- 0326 Process for Foreign Sites Assessed as NC





# POLICIES

- 0013 Conditions for Acceptance of Foreign Inspection Reports
- 0018 Policy for the Importation of Sale of API's for Veterinary Use
- 0019 Policy on Importation of Drugs for Human Use Including NHP's



# GUIDELINES

- 0057 Guidance document on the Commercial Importation and Export of Drugs in Dosage Form under the FDA
- 0067 Conditions for Provisions of Packaging/Labelling Services for Drugs under Foreign Ownership
- 0069 Guidance for Temperature Control of Drug Products during Storage and Transportation





# FUTURE

- Revised GMP Guidelines

[www.canadagazette.gc.ca/part1/2006/20060930/html/regle4-e.html](http://www.canadagazette.gc.ca/part1/2006/20060930/html/regle4-e.html)

- GMP Guidelines Annex for NHP's
- GMP for API Manufacturer
- GMP for Manufacturer of Drugs for Clinical Trials





**?? QUESTIONS ??**

**[www.hc-sc.gc.ca/dhp-mps/index-e.html](http://www.hc-sc.gc.ca/dhp-mps/index-e.html)**

**(links to drug products, compliance and enforcement, and much more)**



Santé  
Canada

Health  
Canada

# Acknowledgements

I wish to acknowledge the assistance of Tara Arena, Compliance Officer, Drug Inspection Unit, in the preparation of this presentation.



**THANK YOU !**

**TOM BARKER**

**416.973.1475 /**

**Tom\_Barker@hc-sc.gc.ca**



Santé  
Canada

Health  
Canada