



Santé  
Canada Health  
Canada

*Votre santé et votre  
sécurité... notre priorité.*

*Your health and  
safety... our priority.*

**CAPRA Symposium  
March 1, 2010, Toronto**

# **The Challenge of Change: Working with the Post-NOC Guidance**

## **Update on e-Submission at Health Canada**

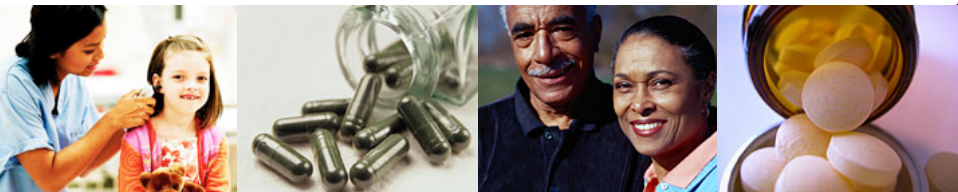
**I. Pastorekova  
Submission Information Policy Division  
Therapeutic Products Directorate**



**Canada** 

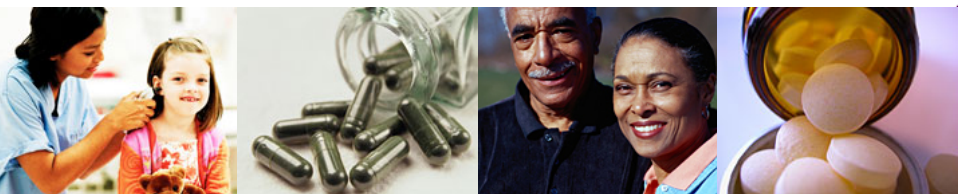
# Outline

1. Notice of Change (Level III) in eCTD format
2. Notice of Change (Level III) in non-eCTD electronic format
3. Reminders & Validation errors for submissions in eCTD format



# Notice of change (Level III) in eCTD format

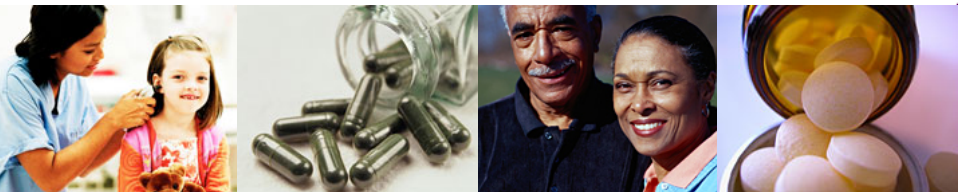
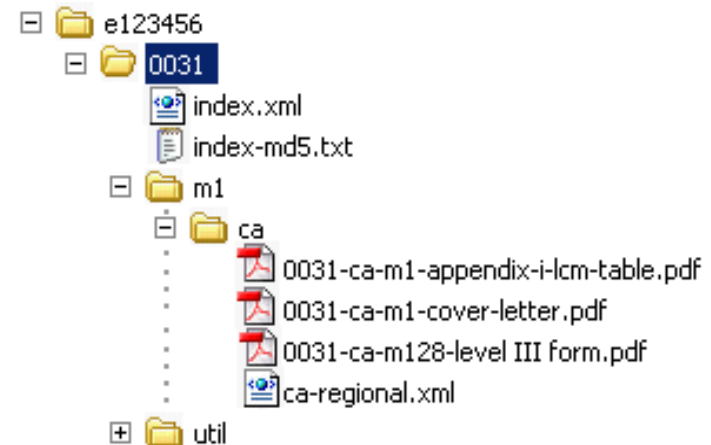
- **Level III is eligible to be filed in eCTD format,**
  - **When related to previously filed submissions in eCTD format**
  - **Annual basis**
  - **Supporting information should not be submitted**
  - **Paper copy is not required to be submitted**
  - **Many Drug Products per CD**
  - **Send to SIPD** (BGTD & TPD submissions) printed MD-5 checksum and CD at the same time you return the Annual Drug Notification
    - CD should be labelled as follow:
      - Sponsor name
      - “Protected B”;
      - Virus-free certification, the software used for the virus check, and the date of the virus definition file or files;
      - Month and year of the submission;
      - Disc number and total number of discs



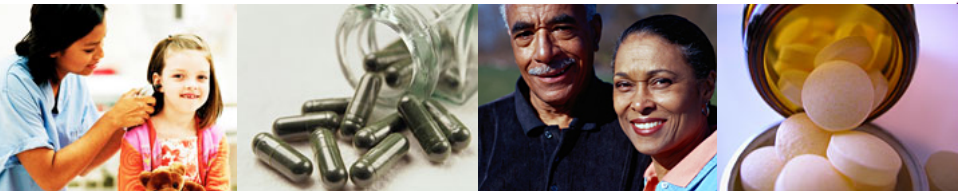
# Notice of change (Level III) in eCTD format (con't)

## ➤ Rules and Conditions

- **Form** completed, printed, signed and scanned
- **Placement** *m-1-2-8-other-application-information* subheading
- **Naming**
  - PDF file: e.g 0031-ca-m1-level III form.pdf
  - leaf title: Notice of Change (Level III)
- **Submission type** "ADMIN"

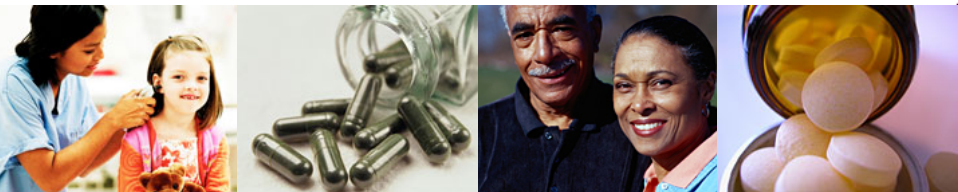


- The Yearly Biologic Product Reports (YBPRs) are eligible to be submitted in eCTD format when related to previously filed submissions in eCTD format
- The Annual Drug Notification Form, is company based and not product specific. Therefore, is not eligible to be submitted in eCTD format.



# Notice of change (Level III) in non-eCTD electronic format

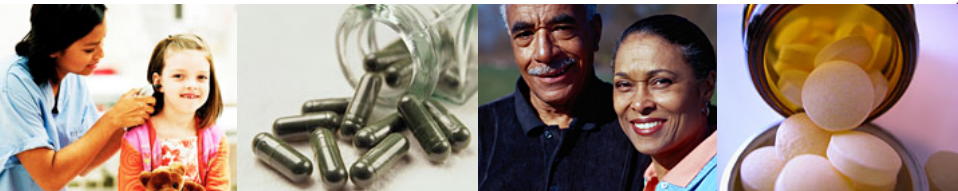
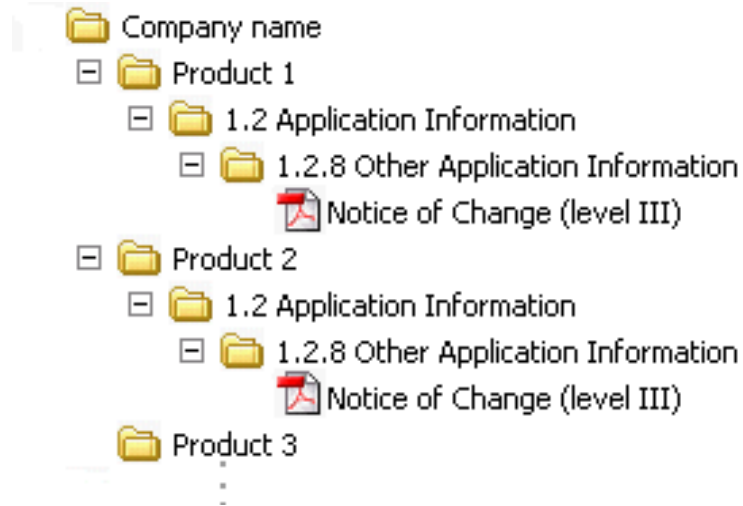
- **Strongly recommended to submit in electronic format as pdf files**
  - **Annual basis**
  - **Supporting information should not be submitted**
  - **Paper copy is not required to be submitted**
  - **Many Drug Products per CD**
  - **Send to SIPD (BGTD & TPD submissions) CD at the same time you return the Drug Annual Notification**
    - CD should be labelled as follow:
      - Sponsor name
      - “Protected B”;
      - Virus-free certification, the software used for the virus check, and the date of the virus definition file or files;
      - Month and year of the submission;
      - Disc number and total number of discs



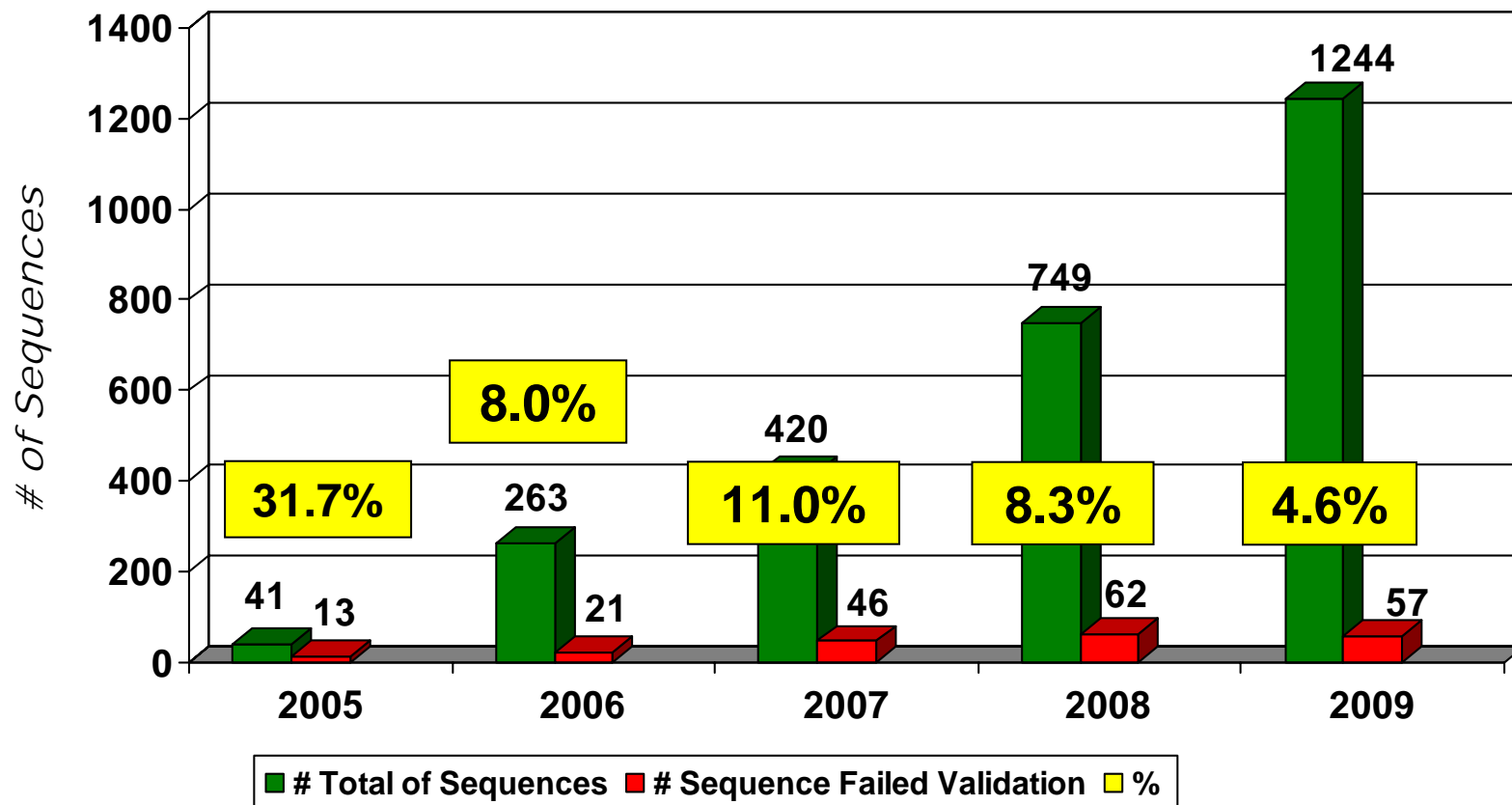
# Notice of change (Level III) in non-eCTD electronic format (con't)

## ➤ Rules And Conditions

- **Form** completed, printed, signed and scanned
- **Placement** *1.2.8 Other Application Information Folder*
- **Naming** PDF file: e.g. Notice of Change (level III).pdf



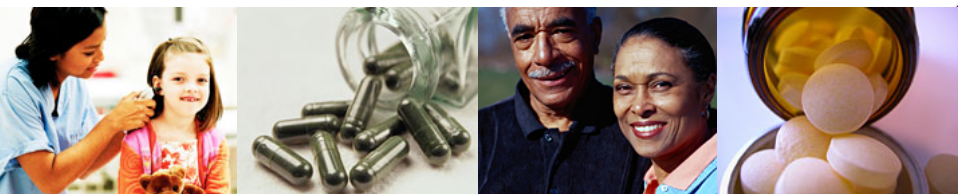
# Sequences that Failed eCTD Validation





# Reminders & Validation Errors for submissions in eCTD format

- **eCTD centralized processing by SIPD (BGTD & MHPD & TPD)**
- **Missing printed content of MD5-checksum or incorrect**
- **Attestation letter – missing or incorrect (signed & dated)**
- **Missing top level folder**
- **Disfunctional hyperlinks & bookmarks**
- **Unreferenced files**
- **Life Cycle Management – invalid file reference or no previous ID fond**



# Questions?

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