

**Update on Canadian
Draft Guidelines for
Second entry metered dose inhalers**

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A g e n d a

- 1. Regulatory activities prior to 1992**
- 2. Draft guidelines issued in 1992**
- 3. Regulatory activities past 1992 and future of the Draft guidelines for**
 - Bronchodilator MDI'S**
 - Corticosteroid MDI'S**

Regulatory Activities Prior to 1992

- **1988/1989 Clearance of Two Generic Salbutamol MDI's**
- **1990 Preliminary Draft Guidelines**

The 1992 Draft Covered MDI'S for:

- **Bronchodilators (e.g. Salbutamol)**
- **Corticosteroids (e.g. Beclomethasone dipropionate)**
- **Antiallergics (e.g. Cromoglycate, Nedocromil)**

Slide 5 - diagram of “Bronchodilation Equivalence Protocol”

Slide 6 - diagram of "Diagnosis of Bronchoprotection Equivalence Protocol"

Slide 7 - Diagram of PC₂₀-Placebo Ratio

Consultation on Corticosteroid Models

- DIA, Toronto, October 1993
- Workshop, Seattle, May 1995
- CTS Workshop, Toronto, December 1995

CSPS Feb. 98

ISRT, May 1998

Guidelines
for
Corticosteroid MDI's

1. Safety

Serum cortisol AUC

2. Efficacy

A) Steroid Reduction Model (1992)

B) Allergen Inhalation Model (1992)

C) Uncontrolled Asthma Model (NEW)

Uncontrolled Asthma Model

Recommended Outcome Measures

- 1. Airway hyperresponsiveness**
AMP or Methacholine (PC₂₀)
- 2. Airway inflammation**
 - Induced sputum**
 - Eosinophil counts (PB)**
 - Exhaled nitric oxide**

Website for Environment Canada

<http://www.ec.gc.ca/ozone>