



Health Santé
Canada Canada

CTD Guidance and TPD Experience

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CTD Submissions received in TPD

	February 2003	May 2004
NDS	6	46
SNDS	6	86
SNDS-C	-	1
ANDS	16	113
SANDS	-	8
NC	(26)	(334)
CTA	-	(743)
CTA-A	-	(336)
Total	28 (26) = 54	254 (1413) = 1667

CTD Experience

- No major problems experienced with format and placement of information
- NCs
 - Sometimes sponsors include N/A tabs, which is not necessary
 - No need for duplicate Module 1 & 2
- NDSs / SNDSs
 - The overviews should not just be summaries of the summaries
 - Overviews should identify unresolved or controversial issues – sometimes buried in the submission

CTD Experience *cont'd*

- Volume numbering
 - sometimes still see 1 to X for the entire submission instead of starting each document at page 1
- TOC
 - Sometimes missing an overall TOC
- CTD numbering
 - Sometimes not followed