



Health Santé
Canada Canada

CTD Guidance and BGTD Experience

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Julie Clare, B.Sc.

A/Unit Head, Clinical Trial Applications

Submission Management Division, BGTD

Health Products and Food Branch

Direction générale des produits de santé et des aliments

CTD Submissions Received in BGTD

	February 2003	May 2004
NDS	4	11
S/NDS	2	23
DIN-B	0	7
NC	1	121
CTA	0	210
CTA-A	0	215
Total	7	587

CTD Experience

- Overall, no major problems with formatting.
- NDS and S/NDS
 - Facility diagrams in 3.2.A.1 should be paginated
 - Majority of the NDS filed received a Screening Deficiency Notice for lack of cleaning validation data
 - Additional sections should not be placed in the submission; incorporate documents into an existing section
- NCs
 - Tabs do not have to be included for N/A sections