



# REGULATORY SERVICES SUMMARY

Contact Graham L. Mills for more information at 416-276-9612.

## REGULATORY SERVICES – FLAT RATE

### PRODUCT APPLICATIONS

APPLICATION TYPE	FLAT RATE (\$ CDN)
<b>PRODUCT CLASSIFICATION</b>	
Drug NHP Cosmetic Medical Device or Consumer Product	\$350
<b>OLD DRUG<sup>i</sup> APPLICATIONS</b>	
Admin DIN	\$4750
DINA no QOS-CE	\$5500
DINF (Category IV/Labelling Standard)	\$5900
<b>PRODUCT LICENCE APPLICATIONS</b>	
Compendial (NHPD monograph)	\$7300
Non-traditional (Food-like, NHPD monograph)	\$9100
Non-traditional (without TPD monograph)	\$19000
Non-traditional (with TPD monograph)	\$9100

DATE APPROVED: 27 JULY 2010

9-6975 Meadowvale Town Centre Circle  
Suite 410 Mississauga Ontario  
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## SITE LICENCE/DRUG ESTABLISHMENT LICENCE APPLICATIONS

APPLICATION TYPE	FLAT RATE (\$ CDN)
Drug Establishment Licence (DEL) <ul style="list-style-type: none"><li>- Application</li><li>- Renewal</li><li>- Amendment</li></ul>	\$1900 \$1900 \$950
NHP Site Licence (QAR not included)	\$2750
Quality Assurance Report (QAR) <ul style="list-style-type: none"><li>- Manufacturer</li><li>- Importer</li></ul>	\$9000 \$8000
Medical Device Establishment Licence	\$1000

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## REGULATORY SERVICES – OTHER

### PRODUCT APPLICATIONS

APPLICATION TYPE	
<b>NEW DRUG APPLICATIONS</b>	
New Drug Submission (NDS <sup>ii</sup> )	Please contact Graham Mills for information.
Veterinary New Drug Submission	Please contact Graham Mills for information.
Abbreviated New Drug Submissions (ANDS <sup>iii</sup> )	Please contact Graham Mills for information.
Supplements NDS and ANDS	Please contact Graham Mills for information.
QO-CE DINAs	Please contact Graham Mills for information.
Notifiable Changes	Please contact Graham Mills for information.
Level III Changes	Please contact Graham Mills for information.

<sup>i</sup> For a drug and any similar products that are not new and are listed on the Drug Product Database, only a DIN application is required if sold in Canada. Products may include prescription and non-prescription pharmaceuticals, disinfectants, and sanitizers with disinfectant claims.

<sup>ii</sup> For a new drug not listed on the Drug Product Database, the product requires a new drug submission (NDS), which will be regarded as an application for a DIN. This is handled through submissions in the Common Technical Document (CTD) format.

<sup>iii</sup> For a new drug listed on the Drug Product Database, the product requires an abbreviated new drug submission (ANDS), which refers to a submission for a generic product that is compared to a Canadian reference product already on the market.

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