

Posted: June 20th, 2008

2008 Annual Drug Notification

The Annual Drug Notification form is intended to assist you in complying with the Food and Drugs Regulations that require owners of Drug Identification Number (DIN) to confirm annually, before October, that all information previously supplied about the product is correct. If you have a DIN registration and have not received one of these packages you should investigate where it was sent and or confirm your DIN is still considered valid.

The annual fees apply to drug products that have a been assigned a DIN for which the Drug Notification Form (DNF) has been returned, notifying that sale of the product has commenced in Canada. If you qualify for a reduced fee, you must complete the fee reduction form and return it with your annual notification.

Please note that the 2008 Annual Drug Notification Form must be completed and returned by **August 8, 2008**. The forms need to be returned regardless of any changes have being made.

Annual fees WILL be charged even if the form has not been returned.

Notices included within the 2008 Annual Drug Notification Package:

Notice: Drug Product Information Form (DPIF)

For companies that have submitted the DPIFs to Health Canada, and have made subsequent changes to the product with respect to the information requested in the DPIFs you are requested to send in the revised Forms. Health Canada is also requesting those who have not yet submitted the DPIF for their DIN products to please do so.

Important Announcement:

Health Canada has revised the 3011 form, the new forms will soon be available online.

Notice: Important Information on approved Drug Products

Health Canada is committed to keep accurate information in all its databases therefore, in February 2009, they will be sending to all DIN holders a current listing of their approved drug product(s) that have been issued a DIN, but have not been notified as being marketed in Canada. Health Canada asks that you look over these lists, confirming and returning the lists.

Notice: Transitional DINs to NPNs

All Natural Health Products (NHPs) with Drug Identification Numbers must obtain a valid Product Licence Number (PLN)/Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) no later than December 31, 2009. Please note that after this date Health Canada will cancel all DINs that have not been transferred, but should have based on active ingredient and product use.

Notice: eCTD Projections

Health Canada is requesting that stakeholders please provide projections on the number of eCTD (Co-Submission or Hybrid) submissions that they plan to file in 2009.

