DIN - patent

BGTD_ORA <bgtd_ora@hc-sc.gc.ca> Tue, Oct 19, 2010 at 8:30 AM
To: artfraserh@gmail.com
Cc: opml_bmbl@hc-sc.gc.ca

Dear Ms. Fraser,

This is in response to your email dated October 15, 2010 originally sent to the Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Health Canada.

The only instance where a vaccine may be administered to Canadians without a DIN, is where an investigational vaccine is being administered through a Health Canada authorized clinical trial.

The approval process for the reconstitution of (i.e. mixing of) Act-HIB with DPT Polio Adsorbed involved the filing of a Supplemental New Drug Submission (SNDS), by the manufacturer, to the Act-HIB previously authorized New Drug Submission (NDS) . This SNDS included appropriate data to support safety and effectiveness of the Act-HIB vaccine reconstituted with the DTP Polio Adsorbed vaccine. As already communicated to you in previous emails, this SNDS was reviewed by Health Canada and authorized on January 14, 1994. As part of this authorization, a Notice of Compliance (NOC) was issued along with a revised Product Monograph. The approved Product Monograph has also been provided to you in previous emails and the information appearing on the NOC is available on the Health Canada website via the NOC database.

Although the combination of these two vaccines was advertised by the manufacturer as the Penta vaccine in Canada, and as explained to you in previous emails, the mixing of these two vaccines was performed by a health care practitioner, such as doctor or nurse, immediately prior to injection. This is clearly detailed in the Product Monograph approved on January 14, 1994. As a result the Penta vaccine does not have an associated DIN of its own and was not sold by the manufacturer in Canada as a single syringe (or needle) containing the Act-HIB and DTP Polio Adsorbed vaccines premixed as implied by the comments in your email.

Sincerely,

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