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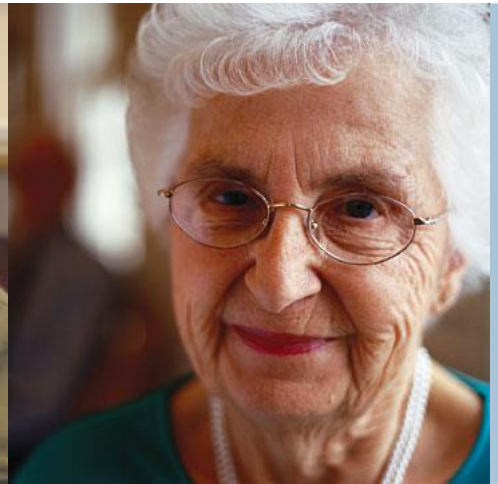
The Food and Drugs Act Liaison Office's New Role in Reconsideration Processes





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Purpose

- To provide an overview of the changes to reconsideration processes within the Health Products and Food Branch (HPFB).
- To describe the Food and Drugs Act Liaison Office's role in reconsideration processes beginning in January 2015.




Food and Drugs Act Liaison Office

As part of Health Canada's Communications and Public Affairs Branch, the Food and Drugs Act Liaison Office (FDALO):

- is an impartial resource for individuals, businesses, and organizations when they experience problems with the administration of the *Food and Drugs Act*;
- assists staff to manage difficult communications with stakeholders;
- offers confidential and voluntary services;
- has no decision-making authority over regulatory matters;
- serves as a reporting mechanism on issues that stakeholders face;
- champions openness and transparency in decision making.




Drivers for changing the current system

- In response to stakeholders' feedback, HPFB senior management requested that FDALO work with HPFB Directorates to enhance the impartiality, openness, and transparency of reconsideration processes.

- FDALO carried out a systems design study in 2013. Senior management selected the option presented here.

- The Therapeutics Product Directorate (TPD)accepted to be the first Directorate in HPFB to review, revise and implement a new process.

- HPFB senior management has agreed that changes made to the TPD process will eventually be rolled out Branch-wide.




TPD/BGTD Reconsideration Process

- The TPD reconsideration process was first launched in 2006 under the Guidance Document: Reconsideration of Final Decisions Issued for Human Drug Submission.

- It stipulates:

  "This formal dispute resolution process is intended for use when informal mechanisms fail to resolve issues between Health Canada and Sponsors over final decisions related to human drug submissions. "

- The Biologics and Genetic Therapies Directorate (BGTD) uses the same Guidance and process – the new process will also apply to BGTD.




OTCs and Disinfectants moved to NNHPD

In 2013, the regulation of non-prescription, over the counter (OTC) drugs and disinfectants was moved out of TPD into the Natural and Non-prescription Health Products (NNHPD) Directorate.

The rationale for this was to cluster the regulation of products with a similar risk profile under one Directorate, allowing for a more harmonized approach when assessing safety and efficacy.




Does the revised Guidance apply to OTCs?

- The TPD/BGTD Reconsideration Guidance was written in 2006 to cover all “Human Drugs” which included non-prescription and OTC drugs when they were regulated in TPD.
- Changes to the TPD/BGTD Reconsideration Guidance will not be applied to reviews done in NNHPD.
- For now, NNHPD will continue managing all reconsideration requests it receives using current practice.
- FDALO will work with NNHPD to carry out a review and revision of its reconsideration process in 2015-2016.




FDALO in the TPD/BGTD Process

- FDALO will become the administrative convenor for the Reconsideration Process for TPD and BGTD.
- In this new role, FDALO will carry out such tasks as:
  - Receive reconsideration request and sponsor's package;
  - Determine eligibility for a reconsideration;
  - Liaise with sponsor and directorate on procedural issues for the process;
  - Lead on recommendation to Directorate DG on approach for reconsideration and determination of expertise required for the process – based on input from sponsor and review bureau;
  - Liaise with internal or external reconsideration panel members to prepare them for the process;
  - Arrange and coordinate reconsideration meeting if one is required;
  - Present Directorate DG with recommendation for reconsideration decision - uphold or amend;
  - Ensure reconsideration decision is communicated to sponsor and review bureau in a timely way.




Moving Ahead

- Comments submitted during the consultation process for the TPD/BGTD Guidance Document will be analysed and the document will be updated and released in early December 2014.
- TPD/BGTD reconsideration requests received in January 2015 will follow the new process with FDALO as administrator.
- The implementation of the new process will be evaluated after 6 months.
- In 2015-2016 FDALO, in collaboration with a NNHPD working group, will begin the work of revising the reconsideration process for NNHPD.