Health Canada / Santé Canada

February 17, 2005

NOTICE

Our file number: 05-104120-52

The revised version of this Health Canada guidance document *Drug Submission Status Requests: Therapeutic Products Directorate* is now available. The guidance document has been updated to provide current contact information for the Therapeutic Products Directorate's Regulatory Project Management Division. The intent of the document remains unchanged.

This and other Guidance documents are available on the **Therapeutic Products Directorate Website** (**http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/**).

Should you have any questions regarding the content of the guidance, please contact

Regulatory Project Management Division
Office of Business Transformation
Therapeutic Products Directorate
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Ottawa, Ontario
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Canada

Health Canada Santé Canada

GUIDANCE FOR INDUSTRY

Drug Submission Status Requests: Therapeutic Products Directorate

Published by authority of the
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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	HPFB's Mandate is to take an integrated approach to the management of the risks and benefits to health related to health products and food by: • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Available in Canada through
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Également disponible en français sous le titre : Demandes de statut des présentations de drogue: Direction des produits thérapeutiques

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidances.

The following outlines the process drug submission sponsors should follow when making inquiries to the Therapeutic Products Directorate (TPD) about the status or progress of their human drug submissions.

This guidance is part of TPD's ongoing activities to streamline administrative processes and expedite drug submission review. In particular, it will prevent reviewers' time from being eroded by repeated calls from submission sponsors.

Regulatory Project Managers have been assigned to each review bureau, and will serve as the primary points of contact between the review bureau and the submission sponsor. Sponsors with questions about the status or progress of their submission are requested to contact the Regulatory Project Manager (RPM) servicing the relevant review division, or the Senior Regulatory Project Manager (SRPM) servicing the relevant review bureau.

Review Bureau	Review Division	Telephone Number	Fax Number
Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)	SRPM servicing BCANS	(613) 941-1049	(613) 941-1668
	RPM servicing Central Nervous System Division (psychiatry, antiemetics and anorexiants)	(613) 941-0572	
	RPM servicing Central Nervous System Division (neurology, anaesthesiology, and pain management)	(613) 952-2006	
	RPM servicing Allergy and Respiratory Drugs Division	(613) 941-1382	
	RPM servicing Cardio-Renal Division	(613) 941-0937	
Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)	SRPM servicing BGIVD	(613) 941-6071	(613) 941-1183
	RPM servicing Division of Anti-Infective Drugs	(613) 946-7004	
	RPM servicing Gastroenterology Division	(613) 952-8172	
	RPM servicing AIDS and Viral Diseases Division	(613) 941-0775	
	RPM servicing Disinfectants Unit	(613) 941-0775	

Review Bureau	Review Division	Telephone Number	Fax Number
Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)	SRPM servicing BMORS	(613) 954-6734	(613) 941-1365
	RPM servicing Division of Anti-neoplastic Drugs	(613) 954-6503	
	RPM servicing Metabolic and Musculoskeletal Drugs Division	(613) 941-4814	
	RPM servicing Reproduction and Urology Division	(613) 941-0900	
Bureau of Pharmaceutical Sciences (BPS)	SRPM servicing BPS	(613) 941-1666	(613) 957-3989
	RPMs servicing BPS	(613) 948-9237 (613) 948-9238 (613) 941-0680 (613) 948-9236	
Senior Medical Advisory Bureau	SRPM servicing Non-Prescription Drug Evaluation Division	(613) 941-2510	(613) 954-4474