Health Canada Santé Canada

Health Products and Food Branch

Medical Devices Bureau
Therapeutic Products Directorate
Rm. 1605, Main Stats Canada Bldg.
Tunney's Pasture : AL 0301H1
Ottawa ON K1A 0L2

June 8, 2001

To: Medical Devices Stakeholders

Subject: Application Form for Custom-Made Devices and Medical Devices for Special Access

The attached revised application form entitled *Application Form for Custom-Made Devices and Medical Devices for Special Access* sets out the information requirements as outlined under Part 2, Section 71 of the Regulations for applying for authorization that would permit the importation and/or sale of a Class III or IV custom-made device or a medical device for Special Access. It is intended to replace the existing application and declaration forms published with the Therapeutic Products Directorate (TPD) guidance document entitled *How to Apply for Authorization to Obtain Custom-Made or Special Access Devices* dated March 25, 1998. For approval following a request for a batch release, health care professionals should use the updated declaration form as attached to notify the Bureau each time a device is used.

In order to improve the quality of applications received and to expedite the review process for Special Access, the accompanying document entitled *Instructions for Completing the Application Form for Custom-Made Devices and Medical Devices for Special Access* is provided to guide health care professionals and industry on the subject.

Effective immediately, health care professionals are requested to complete the attached new application form. Both the new and old forms which are available electronically on the Health Canada web site at http://www.hc-sc.gc.ca/hpb-dgps/therapeut under the Special Access Programme - Medical Devices along with the accompanying guidance documents will be accepted during the transition period. Health care professionals are encouraged to forward any comments that they may have for improvement of the forms and guideline.

The processing of Special Access requests is given a high priority within the Medical Devices Bureau and provided that the regulatory requirements of Part 2 of the Regulations are satisfied, requests are reviewed and processed in less than **three** working days. However, health care professionals are requested to apply to the Special Access Programme as soon as they are aware of a surgical procedure which requires Special Access. To avoid any requests for additional information and ensure that your application is processed within three working days, please ensure that your application is complete.

For more information on the Special Access Programme for medical devices, please contact:

Manager, Device Evaluation Division, Medical Devices Bureau
Phone: (613) 954-0297; Fax: (613) 957-9969
E-mail: sap_devices_mdb@hc-sc.gc.ca

Further comments and suggestions regarding this form or the TPD guidance document entitled *How to Apply for Authorization to Obtain Custom-Made or Special Access Devices* should be directed to:

Melinda Ché, Special Access Programme, Device Evaluation Division, Medical Devices Bureau
Phone: (613) 954-0172; Fax: (613) 957-1596
E-mail: melinda_che@hc-sc.gc.ca or sap_devices_mdb@hc-sc.gc.ca

original signed by
Beth Pieterson
Director
Medical Devices Bureau

Attachments