Natural Health Products Directorate (NHPD)
Progress on the 53 Recommendations
of the Standing Committee on Health

Recommendations re: DEFINITIONS
1. Health Canada, in conjunction with a new separate Natural Health Products Expert Advisory Committee (EAC), set out an appropriate definition of natural health products (NHPs) and amend the *Food and Drugs Act* accordingly. Status: a. The NHP definition was developed by NHPD with the assistance of the EAC. b. The definition takes into consideration various concerns and suggestions expressed during consultations held by the NHPD. c. NHPs are defined in the Regulations to include traditional medicines, homeopathic medicines, vitamins and minerals, herbal remedies , probiotics, amino acids, plant isolates and essential fatty acids (like Omega-3). NHPs are also defined to exclude prescription drugs, drugs administered by puncturing the skin and substances that are regulated by the *Tobacco Act or* scheduled under certain other regulatory schemes like the *Controlled Drugs and Substances Act*.
2. Health Canada, in conjunction with the new NHP Expert Advisory Committee, examine the status of bulk herbs for legislative purposes. Status: a. The NHPD, in conjunction with the EAC, is examining the regulatory status of bulk herbs. b. The NHPD conducted a consultation session on bulk herbs in February 2002, and is proposing an administrative list of herbs that, for health or safety reasons, are considered NHPs regardless of the form in which they are sold. c. NHPD is considering having a follow-up consultation session on this issue, once the draft administrative list of herbs is available. d. This list is being developed with the assistance of the EAC.

Recommendations re: Expertise and Regulatory Structure

3. The government give consideration to the advisability of creating a new regulatory authority for NHPs that reports directly to the Assistant Deputy Minister of the Health Protection Branch.

Status:

a. The Office of Natural Health Products was created to be a new regulatory authority for NHPs, reporting directly to the Assistant Deputy Minister of the Health Protection Branch.
b. On July 1, 2000, Health Canada underwent a realignment and the newly formed Health Products and Food Branch was created. At that time, the Office of Natural Health Products became the Natural Health Products Directorate.
c. The NHPD will be the new regulatory authority, created specifically for natural health products.
d. The NHPD reports directly to the Assistant Deputy Minister of the Health Products and Food Branch.

4. The structure for this new regulatory authority be established within the next six months and be permanently staffed by individuals with expertise and experience in the field of NHPs.

Status:

a. The NHPD is staffed with a core group of experts with knowledge and experience in different areas of natural health products, such as herbal remedies, homeopathic medicines, traditional remedies, etc.
b. The NHPD consists of the Director General's office, the Bureau of Product Review and Assessment, the Bureau of Policy Development and Regulatory Affairs, the Bureau of Promotion, Liaison and Development and the Bureau of Research and Science.

5. The selection of personnel be agreeable to both government and NHP stakeholders.

Status:

a. The NHPD has been staffing positions in line with the Public Service Commission rules. As well, stakeholders have been asked to participate in other selection processes for key staff in the office.
b. The selection committee for the position of the Director General was composed equally of public servants and stakeholders. This position was staffed through an external competition.
c. External competitions are posted on the Health Canada website.
d. The NHPD ensures that positions are staffed with employees with knowledge, skills and abilities appropriate to the various positions within the NHPD. Staff include Naturopathic Doctors, homeopaths, herbalists, experts in traditional remedies, and experts in the study and evaluation of these products.

6. When necessary, working groups reflecting the various segments that make up the NHP category be set up to advise the new regulatory authority.

Status:

a. The NHPD has developed the regulatory framework in an open and transparent manner. Working groups have been, and continue to be, asked to provide advice.
b. The Expert Advisory Committee (EAC) was formed to provide expert/scientific advice on key issues in developing and operationalizing the regulatory framework. The EAC also utilizes working groups to address specific issues.
c. The NHPD has established a series of working groups and committees to address other issues, including the interim Industry Liaison Committee (ILC) and the Good Manufacturing Practices (GMP) Working Groups.
d. Working group members typically consist of industry stakeholders, professional associations, academics and consumer representatives.

7. All relevant inspection personnel be provided with training specific to NHPs.

Status:

a. The NHPD intends to hold joint training sessions for industry and inspection personnel in Fall 2003.
b. This also meets industry concerns that inspection personnel and industry stakeholders have the same interpretation of the regulations.

8. The necessary process to amend the *Food and Drugs Act* not delay in any way the implementation of the regulatory and administrative changes that can proceed at this time.

Status:

a. The *Food and Drugs Act* applies to health products, such as drugs, medical devices, foods and natural health products.
b. The *Natural Health Products Regulations* fall under the *Food and Drugs Act*. These Regulations were published in *Canada Gazette,* Part II, in June 2003.
c. The NHPD continues its efforts to ensure consistency between the renewal of the *Food and Drugs Act* and the NHP regulatory framework.

9. An Expert Advisory Committee be established immediately to assist Health Canada in the general and specific tasks necessary to design a new NHP regulatory environment.

Status:

a. In line with this recommendation, the ONHP (Office of Natural Health Products) Transition Team was formed and composed of 17 members, 14 of which were external stakeholders, with the mandate of facilitating the establishment of the new ONHP (now the Natural Health Products Directorate) and the NHP regulatory framework. They also had the mandate of identifying broad policy directions to assist Health Canada in implementing the 53 recommendations made by the Standing Committee on Health.
b. They first met in June 1999, and presented their final report to the Minister of Health on March 31, 2000.
c. Four members of the Transition Team continued their activities as members of the Transition Advisory Team, which was then expanded to include more members and became the Interim Industry Liaison Committee (ILC). This committee continues to meet regularly with the NHPD.
d. An Expert Advisory Committee (EAC) was also established, and their first meeting was held on May 25, 2000.
e. The EAC assisted NHPD in developing the NHP regulatory framework and continues to meet regularly with the NHPD, more precisely on the technical and scientific issues.
f. The EAC's Terms of Reference and minutes of the last meeting can be found in Appendix A. This and other information on EAC activities are available on the website, at http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/eac_e.html.

10. This Expert Advisory Committee review the re-establishment options for an NHP section with research and laboratory capacities and report its findings to Health Canada.

Status:

a. In developing its research program, the NHPD is now in a position to support both original research and capacity building. Much effort has been focussed on determining research priorities and building partnerships with other funding agencies, ensuring the Directorate's ability to support scientific and research projects.
b. Over the next year, the NHPD will be working to support partnerships between scientists working both within the department and in the community at large, ensuring that any future NHP research initiatives are inclusive, sustainable and have long term objectives.
c. A new Director of Research, Dr. Robin Marles, has recently joined the NHPD. One of his responsibilities is to further explore what role internal laboratory capacity will have in supporting the Directorate' s primary mandate. Any proposals will be considered and reviewed by the EAC.

11. The selection of members for the Expert Advisory Committee be agreeable to both NHP stakeholders and Health Canada.

Status:

a. The EAC members were chosen by a committee with equal representation from NHP stakeholders and Health Canada.

Recommendations re: SAFETY

12. The new regulatory authority assume primary responsibility for assessing safety of products.

Status:

a. The mission of the NHPD is to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.
b. Once the NHP Regulations come into force on January 1, 2004, they will be administered by the NHPD. As such, the NHPD will be responsible for assessing the safety of NHPs before they are available for sale.
c. During the fall of 2002, the NHPD conducted a series of consultations on Standards of Evidence across the country. Standards of Evidence (SOE) refer to evidence that a product licence applicant needs to provide to Health Canada to support the safety and efficacy of a NHP before it can be made available for sale.
d. Consultation comments are being reviewed and evaluated and will soon be posted on the Health Canada website.
e. A guidance document on the SOE will also be published before January 1, 2004, when the NHP Regulations come into force.

13. General safety protocols be developed by the Expert Advisory Committee based on EAC judgements of reasonable evidence.

Status:

a. Standards of Evidence (SOE) refer to evidence that a product licence applicant needs to provide to Health Canada to support the safety and efficacy of the NHP.
b. The Standards of Evidence framework has been developed through consultation with the Canadian public, with stakeholders, and with the EAC.
c. This framework will be published before January 1, 2004, when the new Regulations come into force.

14. When necessary, this regulatory authority establish appropriate working groups to assess the safety of specific products.

Status:

a. NHPD intends to utilize working groups, in addition to working with the EAC, as a means to advise on the safety, efficacy or quality of specific products, when needed.
b. The new NHP Regulations were published in June 2003, and they will come into force on January 1, 2004, with the exception of the 60-day disposition clause which will come into force on July 1, 2004. The NHPD will receive and evaluate applications for specific products after January 1, 2004, when the new Regulations come into force.
c. In developing monographs for specific NHP ingredients, the NHPD is working with the EAC, working groups within the EAC, and working groups of industry stakeholders.

Recommendations re: QUALITY/GOOD MANUFACTURING PRACTICES

15. Health Canada, in collaboration with the NHP industry, establish appropriate GMP guidelines reflective of the different nature of NHPs.

Status:

a. Working groups were formed in March 2001 to assist the NHPD in developing a Good Manufacturing Practice (GMP) guidance document appropriate for the different categories of NHPs, for example, vitamins and minerals, traditional medicines, homeopathic medicines, and botanical and herbal medicines.
b. Working group members included industry stakeholders, practitioners, academics and consumer representatives.
c. Recommendations were presented to the NHPD by the working groups in May 2001.
d. The NHPD conducted national GMP consultations sessions in Halifax, Montreal, Toronto, Winnipeg, Edmonton and Vancouver during the summer of 2002. Comments have been reviewed and evaluated, and are reflected as appropriate in the GMP guidance document.

16. GMP standards for NHPs include specific quality control and testing for herbal products.

Status:

a GMPs for natural health products (including herbal products) consist of provisions specific to: specifications (product), premises, equipment, personnel, sanitation program, operations, quality assurance, stability, records, sterile products, lot or batch samples, and recall reporting.
b. GMPs must be employed during the whole manufacturing process of NHPs.
c. It is the responsibility of the manufacturer to ensure that the NHP meets the specifications assessed by Health Canada.

17. Manufacturers, packagers, importers and distributors of NHPs, whether located in Canada or abroad, be obliged to hold valid establishment licenses.

Status:

a. The proposed NHP Regulations pre-published in Part I of the *Canada Gazette* outlined requirements for manufacturers, packagers, labellers, importers and distributors of NHPs in Canada to obtain site licences. Comments were received from industry through the Business Impact Test that the distributors should not be required to hold a site licence given that their activities are usually limited to the handling of a finished, packaged product and do not involve manufacturing, packaging or labelling. Based on a risk assessment, the activities of distributors were felt to be more in line with retailers and to be of extremely low risk of product interaction and adulteration. Accordingly, it was decided that, while good manufacturing practices and record requirements need to be followed, the site licensing provisions do not apply to distributors. Therefore, a site licence is only required for importers, manufacturers, packagers and labellers of NHPs.
b. The NHPD will not issue a site licence to foreign sites but will instead issue a foreign site authority number, after receiving evidence that GMP compliance has been met.
c. Evidence of Canadian GMP equivalence will be needed to ensure the quality and safety of NHPs.
d. Applicable international agreements will also be considered.

18. Inspection activities be performed consistently and on a regular basis by inspectors knowledgeable about the products.

Status:

a. The NHPD is developing an inspection strategy for NHPs. The goal of the strategy is to ensure an appropriate level of oversight for these products, and consistency in its application.
b. The NHPD will develop educational tools for inspection staff and industry. During the transition period, the NHPD will hold good manufacturing practices training sessions for inspectors and industry and look at effective ways to communicate with the stakeholders on the new requirements.

Recommendations re: EFFICACY

19. NHPs be allowed to make health claims, including structure-function claims, risk-reduction claims and treatment claims.

Status:

a. The Regulations define NHPs as products manufactured, sold or represented for use in:
   i. the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans;
   ii. restoring or correcting organic functions in humans; or
   iii. modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.
b. NHPs are, as recommended by the Standing Committee on Health, permitted to make structure-function, risk reduction and treatment claims. In addition, the NHPD has proposed a fourth claim type, 'nutritional support', based on comments received during consultations with consumers, practitioners and industry. Claims in this category would relate to the established function of a particular nutrient(s) in normal physiology (e.g. 'Calcium helps to build strong bones'). Claims can also be made for the source of an essential nutrient (e.g. 'Source of folic acid').

20. Claims be assessed to ensure that there is reasonable evidence supporting the claim.

Status:

a. With a view to ensuring that reasonable evidence is sought in support of claims, the NHPD conducted a series of cross-country consultations on Standards of Evidence during the fall of 2002. Standards of Evidence refers to evidence that a product licence applicant must provide to Health Canada in order to support the safety and efficacy of a NHP before offering the product for sale.
b. Consultation comments are being reviewed and evaluated.
c. A guidance document on the Standards of Evidence will be published before January 1, 2004, when the new Regulations come into force.
d. Prior to sale, all NHPs will be assessed to ensure there is reasonable evidence to support the claim and safety of the product.

21. The evidence not be limited to double-blind clinical trials but also include other types of evidence such as generally accepted and traditional references, professional consensus, other types of clinical trials and other clinical or scientific evidence.

Status:

a. The NHPD is developing the Standards of Evidence guidance document, which outlines that evidence such as traditional references, conclusions of reputable regulatory agencies, peer-reviewed published reviews, expert committee reports and clinical trials, be considered when evaluating claims associated with NHPs. The Standards of Evidence guidance document will be available on the NHPD website before January 1, 2004, when the NHP Regulations come into force.

22. The evidence required vary depending on the type of claim being made, with different evidence being required for structure-function claims and risk-reduction claims for minor self-limiting conditions than for therapeutic or treatment claims.

Status:

a. The level of required data varies depending on the type of health claim and the health risk associated with the product.
b. As an example, the NHPD requires that traditional products that have a long history of safe use, for which traditional claims are made, be supported by two (2) traditional references.

23. The label indicates clearly the type of evidence used to support the claim.

Status:

a. The NHPD previously proposed that the label indicate the type of evidence that was provided to support the claim. Following the consultation on Standards of Evidence, the NHPD has revised its requirements so that only the label of a product supported solely by traditional references include a statement such as “traditionally used as .....”.

Recommendations re: PRODUCT LICENSING

24. The new product licensing framework be based on a risk management approach that emphasizes the margin of safety associated with a particular product.

Status:

a. The mandate of the NHPD is to assess NHPs prior to market with respect to safety, efficacy and quality.
b. A pre-market review by the NHPD will be required for all NHPs before being made available on the Canadian market.
c. The NHPD is developing a Compendium of Monographs for natural health product ingredients that are considered to be low-risk or for which it has prior knowledge (e.g. through traditional use, clinical trials, other supporting evidence, or other regulatory bodies).
d. There are two product licencing review streams that take into consideration the health risk associated with the NHPs and history of use:
   1) applications which cite a monograph contained in the Compendium of Monographs as the sole information supporting safety and claims, and
   2) applications which provide evidence other than a monograph found in the Compendium of Monographs to support the safety and claims of the product.

25. Health Canada, in conjunction with the Expert Advisory Committee, establish categories within the NHP class to determine what level of regulation is appropriate for a particular product.

Status:

a. The Product licensing framework is based on a risk management approach. For this reason, there are two product licencing review streams, such as :
   1) applications which cite a monograph contained in the Compendium of Monographs as the sole information supporting safety and claims, and
   2) applications which provide evidence other than a monograph found in the Compendium of Monographs to support the safety and claims of the product.
b. The NHPD held consultations on the Standards of Evidence in Fall 2002, which refers to the information that a sponsor is required to provide to the NHPD in support of the safety and the efficacy of a NHP before being available on the Canadian market. Consultation sessions were held in Halifax, Montreal, Toronto, Saskatoon, and Vancouver.
c. The Standards of Evidence guidance document proposes that different types of supporting data will be required for different levels of NHP claims. As an example, certain claims will have to be supported by traditional references, while others will need to be supported by clinical trials data. The Standards of Evidence guidance document will be available on the NHPD website before January 1, 2004, when the NHP Regulations come into force.

26. A product licensing system based on monographs be used when they are available. Such a system should rely on a pre-market approval process and the regulator should have a short period of time (for example, 30 days) to review the application.

Status:

a. The NHPD is developing a Compendium of Monographs for natural health product ingredients that are considered to be low-risk or for which it has prior knowledge (e.g. through traditional use, clinical trials, or other regulatory bodies). The Compendium will be updated regularly and available on the NHPD website.
b. If the Compendium of Monographs is used as a reference for a licence application, no additional information on safety or claims needs to be submitted.
c. A 60-day disposition clause has also been included in the Regulations, which requires that the NHPD commit to review licence applications which conform with a NHPD monograph within this timeframe.

27. Health Canada, in conjunction with the Expert Advisory Committee (EAC), establish procedures to create new Canadian monographs based on work already accomplished in other countries.

Status:

a. The NHPD Compendium of Monographs is under development by the NHPD. These monographs are being developed based on internationally recognized references, such as the monographs published by the World Health Organization (WHO), the European Scientific Cooperative on Phytotherapy (ESCOP), and others, as well as advice received from the EAC.
b. The EAC has contributed to the development of the format and template used in the development of the monographs and the content of the NHPD monographs.

28. Manufacturers of products that do not have monographs be required to provide evidence to Health Canada before a product is marketed. The level of evidence would be consistent with the margin of safety associated with the product.

Status:

a. With a view to ensuring that reasonable evidence is sought in support of claims, the NHPD conducted a series of cross-country consultations on Standards of Evidence during the fall of 2002. Standards of Evidence refers to evidence that a product licence applicant must provide to Health Canada in order to support the safety and efficacy of a NHP before offering the product for sale.
b. The level of evidence required to support a claim for a NHP is based on the level of claim and any safety concerns about one or more ingredients in the NHP. The Standards of Evidence guidance document will be available on the NHPD website before January 1, 2004, when the NHP Regulations come into force.

29. The level of post-market monitoring be based on the margin of safety associated with the product and include a NHP adverse event reporting system for industry and an adverse reaction hotline for practitioners and the general public.

Status:

a. The NHPD is developing an adverse reaction reporting system for post-market monitoring.
b. Product licence holders are required to notify the NHPD within 15 days of any serious adverse reactions occurring in Canada, and any serious, unexpected adverse reaction occurring outside of Canada.
c. NHPD is also working with the Marketed Health Products Directorate, which has the responsibility of the post-market monitoring of products, and any associated adverse reactions.
d. NHPD recognizes that an outreach program is required to educate the public, product licence holders, Canadian distributors, and health care providers as to what constitutes an adverse reaction, and how the reporting system should be used.

30. Certain lower safety products be made available to consumers with appropriate warnings and other lower safety products only be made available with practitioner intervention.

Status:

a. A product's label can be a risk management tool. In many cases, potential health risks can be addressed with complete label information such as cautions, warnings, contra-indications or possible adverse reactions associated with a NHP.
b. The proposed NHP Regulations pre-published in the *Canada Gazette*, Part I, allowed for the possibility that a NHP be available on prescription.
c. It is the provinces and territories who licence practitioners, such as medical doctors, dentists, and doctors of veterinary medicine. These practitioners are authorized to write prescriptions.
d. Based on comments received through consultations, the NHPD has taken the approach that the NHP Regulations only apply to NHPs which are available to consumers without a prescription. In fact, the NHP Regulations, as published in Canada Gazette Part II , now state that: "For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if it is a substance the sale of which under the *Food and Drug Regulations* is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations." This clearly distinguishes prescription drugs from NHPs.

31. The new framework be phased in over a period of months to allow sufficient time for the stakeholders and the regulator to review the current DIN system and conform to the new regulations.

Status:

a. The proposed Regulations pre-published in Part I of the *Canada Gazette* indicated that stakeholders would have a period of two years from the date the NHP Regulations come into force to comply with the Regulations.
b. Following publication of the NHP Regulations in *Canada Gazette*, Part II, the product licence provisions, except section 6 related to the 60-day disposition clause, will come into force on January 1, 2004 with a six year transition period (for products with a Drug Identification Number "DIN") ending December 31, 2009. The 60-day disposition clause will come into force on July 1, 2004. Once the product licence provisions come into force, all new products that fit the NHP definition must comply with the NHP Regulations and undergo a full application process. In the case of products that already have DINs, they will be able to submit an abbreviated application which will include an attestation to safety and efficacy during the transition period. The sale of all natural health products must comply with the Regulations by January 1, 2010. The transition period for good manufacturing practices (GMPs) and site licensing remains two years as proposed in CGI.
c. This transition period will be coupled with an education program to assist industry to come into compliance.

Recommendations re: LABELLING

32. Health Canada consult with its new separate NHP Expert Advisory Committee to determine what information is to be included on the labelling, consisting of, at a minimum, the items recommended by the Advisory Panel on Natural Health Products.

Status:

a. The Expert Advisory Committee, the Transition Team, stakeholders, professional groups and the public have made recommendations regarding minimum requirements for NHP labels.
b. The NHPD recognizes that product labels should assist consumers in making informed choices with respect to NHPs.
c. Labels should assist in selecting products that meet individual needs and expectations, as well as the merits and limitations of products.
d. Labels should allow consumers and others to fully understand how products are to be used and stored to ensure their maximum benefit, and to be aware of any adverse reactions or other risks associated with the use of the product.

33. NHP labelling provide consumers with all relevant information needed to make informed choices.

Status:

a. Under the NHP Regulations, the required labelling information includes all of the following:
   - the brand name;
   - the product number (issued with the product licence);
   - the dosage form;
   - if the NHP is sterile, the notations “sterile” and “stérile”;
   - the net amount of the NHP in terms of weight, measure or number;
   - the name and address of the product licence holder;
   - if the NHP is imported, the name and address of the importer (and the product licence holder);
   - the common name of each medicinal ingredient and its proper name. In the case that the proper name is a chemical name, only the common name should be indicated;
   - a list by proper name, or by common name if the proper name is the chemical name, that sets out the quantity of each medicinal ingredient per dosage unit, and if any, the authorized potency.
   - a qualitative list of all non-medicinal ingredients (preceded by the term ‘non-medicinal ingredients’);
   - the recommended use or purpose;
   - the recommended route of administration;
   - the recommended dose and, if any, the duration of use;
   - the risk information relating to the NHP, including any cautions, warnings, contra-indications or known adverse reactions associated with the use of that NHP;
   - the recommended storage conditions, if any;
   - the lot number;
   - the expiry date;
   - a description of the source material of each medicinal ingredient that the product contains (for example, when the ingredient is a plant or plant material, the source material is the species and the tissue/part).

34. NHP labelling be standardized to provide clear and consistent product information.

Status:

a. NHP labelling requirements apply to all NHPs, therefore clear and consistent product information will be available to consumers. Recognizing that many NHPs are usually sold in small containers and that label space is limited, the Regulations include a provision for small package labelling.
b. Products on store shelves will be easier to compare.
c. Please also refer to recommendation #33

Recommendations re: SECTION 3 AND SCHEDULE A OF THE *FOOD AND DRUGS ACT*

35. Health Canada immediately initiate a review of the diseases listed in Schedule A to ensure that only appropriate diseases are included and, where relevant, specific diseases be exempted by regulation from the broad terms found in Schedule A.

Status:

a. In 1999, Health Canada established an internal Schedule A Committee with representation from departmental programs.
b. The Schedule A Committee developed a guidance document, which clarified the intent and scope of the current application of section 3 and Schedule A.
c. The committee recommended that Health Canada convene an external working group to review the Schedule A list of diseases.
d. On February 14, 2003 it was announced on the Health Canada website that the Working Group on Schedule A to the *Food and Drug Act* is being established.
e. The Working Group's mandate is to make proposals in respect to the criteria that could be used for determining which diseases ought to be included in Schedule A and on possible modifications of the Schedule.

36. Health Canada, subsequently, conduct a study with the participation of representatives from consumer groups, the food, natural health products and pharmaceutical industries, and health practitioners to determine whether subsections 3(1) and (2) of the *Food and Drugs Act* or all of the diseases listed in Schedule A should be deleted.

Status:

a. The Working Group is comprised of individuals representing various interested parties such as consumer groups, patient groups, health professional associations, academia, industry and Health Canada.
b. Health Canada will consider all proposals made by the Schedule A Working Group and its report will form the basis for broader public consultations.
c. The Working Group's mandate includes making proposals on the criteria that could be used for determining which diseases ought to be included in Schedule A and modifications to the Schedule.
d. In addition, the Working Group may consider whether certain products or classes of products should be exempted from the application if section 3 of the *Food and Drugs Act*.

Recommendations re: IMPORTATION OF HUMAN-USE DRUGS FOR PERSONAL USE

37. When the new regulatory framework is implemented, the personal importation policy be reviewed by Health Canada and the Expert Advisory Committee to determine if it is still appropriate and to outline permissible changes.

Status:

a. The Directive allows for personal importation of up to a three-month supply of a drug for an individual's personal use unless prohibited by law, and is comparable to policies in other countries.
b. The *Human-use Drugs for Personal Importation Directive* applies to many categories of products, such as medical devices, biologics, drugs and NHPs. For ease of reference, a copy of the policy in included in Appendix B.
c. Part of the rationale for the policy relates to Canadians travelling outside of the country, where upon their return they are permitted to import a three-month supply of a drug that they may have begun taking while out of the country.
d. Due to the broad application of this policy, it has been referred to the Legislative Renewal Initiative for consideration.

Recommendations re: COST RECOVERY

38. Health Canada conduct a review analysing the impact of the overall cost recovery policy on the different segments of the NHP industry.

Status:

a. The NHPD has committed to conduct separate consultations specific to cost recovery. This will allow for a detailed analysis of potential impacts on different segments of the NHP industry. Appropriate measures to mitigate negative impacts can then be developed.

39. The NHP industry stakeholders be consulted in the establishment of the most appropriate fee structure and amount.

Status:

a. An analysis of the impact of the current cost recovery system on the NHP industry will be a part of separate consultations specific to cost recovery.

40. As a result of this review, the existing fee levels be re-examined if necessary.

Status:

a. The fee levels will be established after full consultation on cost recovery.

Recommendations re: APPEAL PROCESS

41. As part of the immediate process for NHPs, Health Canada work with stakeholders to establish appropriate, accessible and effective appeal processes for relevant policies and possible inclusion into a revised regulatory and legislative framework.

Status:

a. The NHP Regulations include provisions for an appropriate appeals process for dispute resolution.
b. To allow for transparency, the process will be developed with full consideration of input received from stakeholders, the public, and professional groups.
c. In addition, the NHPD will implement a series of alternate dispute resolution mechanisms to try and resolve issues prior to initiating any formal appeals processes.
d. A guidance document is being developed to provide additional details about the process and will be available on the NHPD website before January 1, 2004, when the NHP Regulations come into force.

Recommendations re: INFORMED CHOICE

42. Health Canada immediately utilise existing formats and forums for more open and transparent communication on NHPs with the broader public and practitioners.

Status:

a. The NHPD has already widely consulted on the regulatory framework and continues to meet regularly with various consumer, industry, professional or practitioner groups.
b. The Health Canada website is another tool used to keep Canadians up- to-date with developments within the NHPD.
c. The NHPD has also developed an electronic newsletter, and sends electronic updates and messages to anyone who has provided us with their e-mail address.
d. Health Canada issues documents such as “Warnings” and “Advisories” to inform Canadians about certain issues.
e. The NHPD is committed to operating in an open and transparent manner on an ongoing basis.
f. The NHPD will hold public education and outreach sessions to inform Canadians about the new regulatory framework for natural health products.

43. Communication efforts include details about decisions and actions regarding NHP products (removal from market, change of status, etc.).

Status:

a. The NHPD will continue to operate in an open and transparent manner, including in situations where decisions about the status of some products have changed.

44. Relevant consumer, industry and practitioner groups be consulted on a regular basis about the nature of the required information.

Status:

a. The entire development of the regulatory framework, from the Regulations, to the requirements regarding Good Manufacturing Practices, to the development of appropriate Standards of Evidence has been elaborated through open and regular consultations with all interested Canadians.
b. The NHPD will continue to work in this transparent and inclusive manner.
c. NHPD will be developing an outreach and communication strategy to inform stakeholders, including consumers, about the nature of future issues related to NHPs, appropriate warnings if needed and the corrective measures, when applicable.

45. The federal government research bodies, including Health Canada, begin immediately to encourage research on NHPs. This could include studies focussing on the interactions of herbal products with conventional medications as well as studies that explore different uses by various groups in Canada.

Status:

a. The NHPD invited stakeholders from across the country to a session in Halifax in November 1999 to establish research priorities.
b. A second consultation session was organized in February 2002 by the NHPD to establish research priorities, particularly drug/NHP interactions.
c. In Vancouver, in February 2002, the NHPD conducted a consultation about the type of research that is needed to allow identification of different components in herbals products, such as active ingredients, markers, and others.
d. The NHPD has formed a partnership with Canadian Institutes of Health Research (CIHR) to support new training programs for researchers interested in the field of NHPs.
e. In November and December 2002, the NHPD funded an environmental scan of all researchers involved in NHPs in Canada.
f. In March 2003, the NHPD conducted an initial meeting of key researchers in NHPs in Canada.
g. In the fall of 2003, the NHPD intends to conduct a major national conference on NHP research.

46. Health Canada undertake, through its various established avenues, the dissemination of the resulting information to health care professionals and consumers.

Status:

a. Health Canada regularly communicates with various health care practitioners and other stakeholders via different publications, such as:
    1) the Health Canada website where the following documents can be located: advisories for health care professionals and consumers and Canadian adverse reaction newsletters;
    2) Health Canada issues letters directed to health care practitioners.
b. Representatives of the NHPD regularly make presentations to different stakeholders groups, including health care practitioner groups.
c. The NHPD has developed an electronic newsletter which is sent periodically to individuals or groups who are interested in being informed of any development in the field of NHPs. This tool is very useful and efficient in providing information in a timely manner.

Recommendations re: NHP PRACTITIONERS

47. Health Canada inform its provincial and territorial counterparts of the regulatory changes with regard to NHPs and of the concerns raised by practitioners.

Status:

a. Consultation documents have been disseminated to all provincial and territorial Deputy Ministers of Health.

Recommendations re: ENFORCEMENT

48. The new regulatory framework for NHPs be enforced in a regular and consistent manner and done in conjunction with education.

Status:

a. The Regulations and their requirements will be enforced in a consistent manner.
b. Once the GMP guidance document is finalized, joint training sessions for industry and inspection personnel will be held.
c. NHPD will develop a public education campaign to assist consumers and stakeholders in understanding the new Regulations.

49. Sufficient resources be provided for enforcement activities.

Status:

a. Health Canada will seek to ensure that enforcement resources support an acceptable program of compliance with the Regulations.

Recommendations re: ABORIGINAL HEALERS

50. If a product that is extemporaneously compounded for a particular person is not exempted from the regulatory framework, that such a product be exempted.

Status:

a. The definition of manufacturer in the NHP Regulations as published in Part II of the *Canada Gazette* defines this term as "*a person who fabricates or processes a NHP for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a NHP for the purpose of sale to that patient*."
b. Health care practitioners (for example, pharmacists, Traditional Chinese Medicine (TCM) practitioners, herbalists, naturopathic doctors, etc.) who compound products at the request of a patient are not included within the manufacturer definition. The NHP Regulations are not aimed at regulating the practice of complementary and alternative health care practitioners or the practice of traditional Aboriginal medicine.
c. A guidance document that will clarify the distinction between "manufacture and sale of NHPs" and "compounding and distribution of compounded products by complementary and alternative medicine practitioners and Aboriginal healers" is being developed by the NHPD. It will be available on the NHPD website before January 1, 2004, when the NHP Regulations come into force.

Recommendations re: PLANT CONSERVATION

51. Health Canada work with Foreign Affairs and International Trade to ensure that existing International Agreements that currently protect biological diversity are not violated and that additional strategies are developed if needed to prevent depletion of these valuable health resources.

Status:

a. In the next year, the NHPD intends to liaise with its partners, such as Department of Foreign Affairs and International Trade, Agriculture and Agri-Food Canada, Environment Canada, and Fisheries and Oceans, to ensure that the regulatory framework for NHPs in Canada is in harmony with other aspects impacting on NHPs, such as sustaining biological diversity through appropriate growing/cultivating/harvesting practices.

Recommendations re: TRANSITION

52. The interim enforcement policy regarding NHPs continue to be applied until the new framework is in place.

Status:

a. The Interim Drug Identification Number (DIN) Enforcement Directive of January 1, 1998, will remain in place until the coming into force of the new Regulations on January 1, 2004. The NHPD, in consultation with other Health Canada program areas, is developing an interim NHP phase-in-policy.

53. The Minister appoint, immediately, a transition team responsible for ensuring that the new framework is established quickly.

Status:

a. The Office of Natural Health Products (ONHP) Transition Team was composed of 17 members, 14 of whom were external stakeholders, with the mandate of facilitating the establishment of the new ONHP (now the Natural Health Products Directorate) and the NHP regulatory framework. They first met in June 1999, and presented their final report to the Minister of Health on March 31, 2000.
b. Four members of the Transition Team continued their activities as members of the Transition Advisory Team, which was then expanded to include more members and became the Interim Industry Liaison Committee (ILC), who regularly meets with the NHPD.
c. The NHPD is presently developing Terms of Reference and a nomination process for a permanent advisory committee that will include a broader representation of stakeholders.

Appendix A

Expert Advisory Committee

(see Recommendation 9)

Terms of Reference

The Expert Advisory Committee (EAC) has been selected from professional and scientific communities, to provide expert advice and opinion to the Natural Health Products Directorate (NHPD). Issues of interest related to the safety, quality and efficacy of Natural Health Products (NHPs), and matters regarding the development and implementation of regulations for NHPs, may be referred to the EAC. The collective expertise from the EAC will assist the management team in making decisions. However, final responsibility and authority remains within the NHPD.

Mandate

The mandate of the EAC is to provide the Natural Health Products Directorate with timely expert advice for questions on the safety, claims, use, and regulation of Natural Health Products. Questions referred to the EAC from the NHPD may be from a broad range of issues, but will focus on areas where detailed or difficult evaluation is required. Such issues referred for advice and recommendation may include, but not be limited to, the following:

a. providing advice, as required, to implement the new regulatory environment;
b. developing procedures to create new Canadian monographs based on nationally and internationally collected information;
c. establishing specific requirements for product labelling;
d. evaluating data sources used to establish safety, efficacy, quality and health claims;
e. establishing criteria for submissions regarding safety, efficacy, quality and health claims;
f. providing advice on specific issues related to reported adverse reactions, incidents and effects;
g. evaluating critical situations concerning the safety of a product or ingredient;
h. advising on research needed to support regulatory decisions;
I. establishing appropriate guidelines for Good Manufacturing Practices for various NHP classes;
j. establishing mechanisms for developing collaborations with the provinces with respect to those who practice various forms of medicines (Standing Committee recommendation #47).

Membership

The inaugural EAC has been proposed by a screening committee selected by the Assistant Deputy Minister, Health Protection Branch (HPB) in consultation with members of the Transition Team. The EAC will be chaired by a member external to

the Public Service of Canada, and chosen by the ADM, HPB. Subsequent members and Chairpersons will be chosen by the Director General, NHPD, taking into consideration recommendations made by current EAC members.

Members have been, and will be, identified through broad consultation with stakeholder groups, including health professional and scientific societies, academia, industry associations, consumer associations, and government agencies. The membership of the committee will endeavour to reflect an appropriate blend of gender, regional, ethnic and language representation for Canada.

Members have been and will be selected for their knowledge and expertise in NHPs, relevant medical sciences, and the practice of healthcare. Members have been and will be appointed as individuals on the basis of their individual expertise, and will not represent their firms, organizations or associations directly. They will serve in the best interests of all Canadians, recognizing the roles and responsibilities of consumers and health professionals in achieving optimal access to, and safe use of, NHPs.

The EAC may form sub-committees or seek out ad hoc members, where necessary, to ensure adequate expertise on matters referred to the committee. Sub-committee and ad hoc members will be selected by the EAC with concurrence of the Director General.

Health Canada staff will provide Secretariat support and may actively participate in discussions, as observers, at the call of the Chair.

Tenure

The EAC Chairperson and committee members will be appointed for a two or three year term at the choice of the Director General, NHPD. There may be consideration for re-appointment to office, to a maximum period of six years. Appointments shall be scheduled to ensure continuity and systematic rotation of membership for the EAC.

Sub-committee and ad hoc members may be appointed for specific meetings or for specific subjects in which they have expertise, for a term up to three years. They may be re-appointed for a further term, for a maximum of six years.

Committee members who are absent from three consecutive meetings of the committee may forfeit their membership.

An individual may withdraw from service on the EAC at any time, upon written notification to the Director General. Membership may be terminated at any time, upon written notification from the Director General.

Security and Conflict of Interest

All Committee members will be required to undergo a governmental security clearance to the level of "enhanced reliability".

Documents provided by the Natural Health Products Directorate to members must be securely stored at all times. All information must be returned to the NHPD, including electronic and word processing records.

All members are expected to keep confidential any trade secrets or privileged information they obtain through their work on the EAC. Information obtained from the work of the EAC must not be discussed with persons not on the committee, nor released, until such time as this information has been officially released for public distribution.

EAC members must refrain from any conflict of interest. In situations where a real or potential conflict of interest arises in the course of the work of the committee, the individual involved must declare this conflict, and disqualify himself/herself from participation in any discussions on that subject matter.

Management and Administration

The specific questions and issues for discussion at the meetings of the EAC will be determined by the Director General in conjunction with the Chair, with input from Health Canada staff, Committee members and stakeholders. The agenda will be developed by the Director General in collaboration with the Chair.

Meetings will be held in the National Capital Region, or by teleconference. They will be scheduled as needed according to the requirements of the NHPD, while being sensitive to the schedules and other commitments of the EAC members. There will be a standing schedule of at least two meetings per year. Invitations to attend meetings will be issued in writing.

All members of the Committee shall have equal status during discussion. Decisions of the Committee are reached by consensus. In situations where consensus is not achieved, then the number of members in disagreement, and their issues, will also be recorded. In such cases, the EAC may also make a recommendation of further study of the issue. Decisions of the Committee are recommendations to the Director General.

The Committee will develop recommendations based on consensus and seventy percent (70%) out of the Fourteen (14) members rounded up to the next person ten (10), duly assembled, constitute a quorum for the transaction of business.

Compensation

Members will be compensated for travel expenses according to Federal Government policy. Honorariums will be provided to those EAC members requesting one.

Terms of Reference approved by Wah Jun Tze, Phil Waddington, and EAC committee members.

Expert Advisory Committee minutes

Natural Health Products Directorate
July 18th and 19th, 2002
Ottawa Marriott Residence Inn Hotel

Present:

Committee Members
Laurie Chan, Frank Chandler, Patrick Choy, Albert Fok
(via teleconference)
Mark Goldberg, Ron Harris, Paul Saunders, Mary Wu, Valerie Assinewe

Health Canada - NHPD
Peter Chan - Product Review & Assessment
Joe-Anne Blanchette - Product Review Assessment
Wendy Simmons - Product Review & Assessment
Melissa Johnson - Product Review & Assessment
Chrissie Lees - Director General's Office

Regrets:

Chanchal Cabrera
Michelle Depot
Norman Farnsworth
William LaValley

1. Update

Peter Chan updated the group on the Directorate, and the recent reorganization activities within the Directorate. One of the major activities completed to date is the GMP consultation process. The Directorate consulted cross country on the proposed GMP regulations, and the responses to date have been positive. The GMP documents are posted on our website and we will be accepting comments until Aug. 15, 2002. The next step will be to post the Standards of Evidence document on the web for consultation. Following the approval of the Branch, the Directorate is planning on the best means to further consult on this document.

The Directorate is planning on going to Canada Gazette 2 about the end of the calendar year.

2. Listable Herbs

It was decided that NHPD would use the term "factor" rather than criteria to describe the points being developed that would determine if the herbs are NHP only.

The second half of the discussion focused on the proposed list of factors provided to the EAC by the NHPD. The group went through each factor and agreed on all of them with some minor edits to number two and the addition of another factor. Once factor was changed from "there is a significant potential for undesirable or severe side effects at normal therapeutic dosage levels" to now read "there is a risk of potential for undesirable or severe side effects at normal therapeutic dosage levels". The new one reads, "the action of the herb has significant physiological effects on specific organs or systems." It was also decided to delete the first factor as it did not apply.

An EAC subcommittee was formed and they will pick a number of herbs and apply the proposed factors to see how well they apply. They will report back to the NHPD with their comments and justification for their decisions by August 1, 2002.

3. Children's Herbs

The focus of this discussion was to develop a list of factors that would be used to determine which herbs may be suitable for use by children. The group revised the list of factors for listable herbs and modified some of them to suit children's herbs.

The list that was developed is as follows:

1. They possess a high level of safety;

2. Not for use in a critical condition where health care provider intervention is required;

3. Traditionally used for the benefit of childrens' health;

4. There is minimal potential for undesirable or severe side effects at normal therapeutic dosage levels;

5. There is low risk for interactions with drugs, particularly drugs with a narrow dosage range;

6. Not suspected or known to mask serious diseases or their development;

7. Possess no known potential for addiction, abuse, severe dependence or other harmful effects;

maximum of 7 days, unless otherwise directed by a health care provider."

The last topic discussed under children's herbs was the decision to go with age as a opposed to weight in setting an appropriate dose for children's herbs. There were some members who felt age was more user-friendly, others felt that weight was more accurate. It was agreed however that they would go by age because the Food and Drugs Act already incorporates a table with acceptable doses for children based on age. It was noted for future reference that weight would be a more accurate measure.

There was also a brief discussion of the reasons for setting the cut-off limit for the use of botanicals in children at 5 yrs old. This had been a recommendation of Dr. Tze, and was agreed upon for three reasons: 1) because the child can communicate better with parents and their health care provider at that age; 2) age was consistent with TPD and the act as it now exists; 3) parents are more familiar with the child's age rather than weight.

An EAC subcommittee was formed to apply the proposed factors to a number of herbs under the children's herbs category and determine if they apply. They are to report back to the NHPD with their decisions and justification by August 1, 2002.

4. List of References

The EAC was tasked with determining how to distinguish appropriate references. The group began a brainstorming session to come up with a list of factors that would assist the NHPD select the appropriate references to use.

The 7 factors that the group came up with is as follows:

1. Must be widely recognized and used documentation
2. Should have citations
3. Traditional references
4. Pharmacopias and dispensatories (USD)
5. Current/most recent scientific literature
6. Monographs
7. Primary literature

The next step is to see how the factors apply. An EAC subcommittee was formed to do this. The group will look at the definition and take the categories listed there, and then list references for them. They will then comment on the factors and how they apply as well as determine if any more should be added. In addition, they will also look at the current reference list and decide which ones should be removed.

5. Source Material

The discussion on source material began with reviewing the option analysis that had been discussed at the previous meeting. Some minor changes were made to points a) through l). They now read:

a. a plant of plant material, the part of the plant used (ie: bark, wood, root, rhizomes, leaf, stem, fruit, seed, bud, flower, seed, etc...)

b. an algae, the part of the algae used (ie: whole, thallus, holdfast, stipe, blades/fronds, reproductive structures, etc...)

c. a fungus, the part used (i.e. macroscopic, hyphae/mycelium, fruiting bodies)

d. a non human species material, the part used (i.e. antler, testes, etc...)

e. an extract or isolate of a plant or plant material, an alga, fungus, or a non-human species material, the same as described in a) to d).

f. a vitamin, the salt or derivative (e.g. sodium ascorbate as the source of vitamin C) source (a) to d) or I))

g. an amino acid or its salt, the part of the plant used or animal tissue from which the protein was hydrolysed (including collagen, or muscle)

h. an essential acid, the part of the plant or species part from which the oil is extracted

I. synthetic duplicate of a substance described in e) to h), the salt or derivative and specify the fact that it is "synthetic"

j. a mineral, the salt or derivative, species and part of the plant, animal or more from which the mineral is extracted.

k. A probiotic, the strain (e.g. lactobacillus casei YIT 9018 as the source of Lactobacillus casei)

l. A homeopathic medicine, the part of the botanical or zoological, the mineral, chemical or energetic sources from which they were derived (including species and part where appropriate)

The main changes being the addition of the phrase "species and part" to the definitions, and the addition of the term "ore" where appropriate.

It should also be noted that with respect to the source material for homeopathic remedies there were some objections made to this section, however, the group will be looking at homeopathic as a separate topic as a future agenda item.

6. Traditional Claims

The discussion began with determining what period of time would be the minimum to allow for "traditional use". It was agreed that 50 years would be appropriate. This was long enough to cover one and a half generations and also long enough to determine effects of products on offspring.

The next topic was oral tradition. There were some concerns around this topic because of the misinterpretation that could take place when dealing with oral tradition, especially as to the origins of the tradition. While it was agreed that most herbs have documentation, the concerns could continue to be explored.

The group then discussed how Australia handles oral tradition and it was agreed that their version could be applicable to Canada. Australia allows "recorded oral history, as evidence of traditional use. The oral history must be written down by the appropriate practitioner or indigenous group(s) who maintain the history. The therapy for which the NHP is used should be properly identified as well as the holistic principles that are apart of this therapy because the theories, concepts and cultural context of the therapy must be considered." Therefore the EAC recommended that the NHPD review the oral history material in this context. The NHPD will therefore look further into the Australian process and report back to the EAC.

7. Equivalency Ratio

The main issue to be discussed was what is acceptable as equivalency and ratio. The group reviewed various options and decided that Option 4 would be appropriate. The EAC looked at the different ratios for traditional, and determined that the three dosage ranges found in acceptable references would be acceptable. However, for non-traditional, the dosage ranges given did not apply because they referred to "new" dosage forms and were not directly supported by documentation. Therefore the group agreed that for non-traditional, the dosage form should equate back to the dried herb. This topic will be discussed further at the next meeting.

8. Country of Origin

At the last meeting it was agreed that due to safety reasons, it may be necessary to list the country of origin on certain herbs. An EAC subcommittee was formed to determine which herbs should have a country designation on them. The committee will report back to the NHPD by August 1, 2002.

9. Monographs

The main issue under monographs was duration of use. After some discussion, the EAC developed three general duration of use statements to be used on the monographs. For some products: "Must be taken for a minimum of (time period) for beneficial effects to be demonstrated. If symptoms persist, consult a health care provider."

For vitamins: "Consult a health care provider for prolonged use". The general statement for monographs: "May be used up to (time period), if symptoms persist

consult a health care provider." The rest of discussion focused on going through the monographs. Most of the monographs were approved subject to some minor edits. These will be reviewed at the next meeting. It was also agreed that for vitamins and minerals the liquid form should be added.

10. Definition of Specifications

The main issue for this topic was to determine the depth and definition of an acceptable specification for all NHP's to be submitted in an application for a product licence. The group agreed to go with the option which suggested: "NHPD describe the type of testing which is required, the manufacturer may develop their own methods, limits are set by the NHPD." The new wording suggested was "NHPD specifies the method for heavy metals, pesticides and microbes; for all other assays the manufacturer may adopt a method of mutual recognition (including in house assays). Limits are set by NHPD for all assays." The group also suggested that metals, pesticides and composition assays are to be on the finished product, and the maximum allowable for all contaminants is to be based on body weight.

11. Forward Agenda Items

Equivalency Ratio

Composition of EAC

Definition of synthetic

List of TCM herbs

Appendix B

(see Recommendation 37)

Importation of Human Use Drugs for Personal Use Enforcement Directive

Table of Contents:

1. Purpose
2. Background
3. Scope
4. Definitions
5. Policy
6. Responsibilities
7. Procedures
8. Effective date

Appendix A

1. PURPOSE

The purpose of this document is to ensure that the policy and enforcement measures related to the importation of human-use drugs for personal use are uniform throughout the Health Products and Food Branch Inspectorate.

This directive supersedes any Regional guidance or procedures.

2. BACKGROUND

This directive provides guidance to help officials of Health Canada to confirm that the importation is for personal use and provides a uniform framework for enforcement.

The Food and Drugs Act and Regulations (the Regulations) do not regulate the importation of drugs for personal use unless the drugs sought to be imported are listed in Schedule F to the Regulations (prescription drugs). The Controlled Drugs and Substances Act regulates the importation of substances or drugs classified as controlled, narcotic or restricted. It has been the policy of the Health Products and Food Branch Inspectorate (HPFBI) to permit individuals to import a three-month supply of a drug for their own personal use unless prohibited by law. This policy is comparable to policies in other countries.

Respecting the importation of drugs for personal use, Health Canada is primarily concerned that these importations will not be diverted for commercial purposes. Recent attention has been drawn to commercial importations of drug products that have circumvented regulatory requirements by claiming that these importations

were for "personal use." Foreign suppliers, which have commercial sales organizations in Canada, are claiming that individually packaged shipments, which are mailed directly to purchasers, qualify as an importation under the personal use import policy. The personal use exemption unfortunately provides an opportunity for these suppliers to conduct commercial activities, and to evade the submission review process for individual products, and/or the Establishment

individuals to import a three-month supply of a given drug for their own personal use, once during each quarter of the year. The exceptions to this policy are stipulated by legislation or the Regulations, and include the following:

Prescription Drugs

a) Section C.01.045 of the Regulations restricts the importation of a prescription drug; listed in Schedule F, Part I, or Schedule F Part II which is not for veterinary use; to a practitioner, a drug manufacturer, a wholesale druggist, a registered pharmacist or a resident of a foreign country while a visitor in Canada. However, persons (regardless of residence) coming from abroad will usually be permitted to import enough drug for a single course of treatment or a three-month supply, whichever is the lesser, of a Schedule F drug, if the drug is packaged in pharmacy or hospital dispensed packaging.

Controlled Drugs and Substances Act

b) Subsection 6.(1) of the Controlled Drugs and Substances Act restricts the importation of narcotic, controlled and restricted drugs to licensed dealers who have obtained an importation permit.

Any Drugs FOR SALE

c) Section A.01.040 of the Regulations prohibits the importation for sale of a drug if its sale in Canada constitutes a violation of the Food and Drugs Act and Regulations. Drugs destined for commercial establishments are considered to be imported for sale and therefore personal use exemptions cannot be applied.

Special Access Program

Individuals other than those listed in C.01.045 seeking to import prescription drugs listed in Schedule F to the Regulations for their personal uses are required to contact their physician to obtain a prescription for the medication. Drugs available in Canada should be obtained from a Canadian source. Drugs not available in Canada, (including prescription, controlled drugs, non-prescription drugs, or new drugs which have not yet been classified in any schedules), can be obtained through the emergency drug release provisions of section C.08.010. The Special Access Program (SAP), formerly the Emergency Drug Release Program (EDRP), provides for the release of drugs which are otherwise unavailable for sale in Canada to physicians, dentists and veterinarians. Through SAP, the HPFBI provides legal access to these drugs; however, it does not endorse their safety or efficacy. Practitioners who use the Program must agree to report on the outcome of the therapy with the drug, including any suspected adverse drug reactions. For drugs regulated by the Controlled Drugs and Substances Act, special permit procedures need to be followed involving the Bureau of Drug Surveillance.

6. RESPONSIBILITIES

The implementation of this directive is the responsibility of staff of the HPFBI.

7. PROCEDURES

Drugs Accompanying Travellers

When persons (regardless of residence) are coming from abroad, they will usually be permitted to import enough drug for a single course of treatment or a three-month supply, whichever is the lesser, of a prescription drug listed in Schedule F or any other drug which has been prescribed by a physician if it is packaged in pharmacy or hospital dispensed packaging, or of any non-prescription drug. Some discretion may be required in unusual circumstances, e.g., long term visitors to isolated locations, long-term visitors where language or other barriers may impede establishing good communications with a Canadian physician, persons returning from countries which dispense in trade packages.

No person may bring any substance that is regulated by the Controlled Drugs and Substances Act into Canada unless they have obtained an authorization from the Bureau of Drug Surveillance.

Drug Shipments

Where a shipment of a drug is encountered at Canada Customs, a Health Canada official determines:

1. Whether the importer is a legal recipient of the imported drug.

Prescription Drugs

a) Where the shipment contains a drug for human use listed in Schedule F to the Regulations that is not destined to a recipient as listed in C.01.045, it is normally refused entry. In order to not delay or interrupt a course of treatment or other situations in which refusal of entry could create a health risk, inspectors may allow entry of an initial 3-month supply of a drug, if the drug is packaged in hospital or pharmacy dispensed packaging. However, the recipient will be informed that all future shipments will be detained and that either a Canadian source should be used or that their physician should obtain a foreign supply through the Special Access Programme for drugs not available in Canada. Please see Appendix A for a copy of a suggested form letter which can be used for this purpose.

Controlled Drugs and Substances

b) Where the shipment contains any narcotic, controlled or restricted drug that is not destined to a licensed dealer who has obtained an importation permit, it is refused entry and further legal action is possible.

All Other Drugs (Usually in Trade Packaging)

2. Whether the importer is importing the drug for commercial purposes.

a) Where the shipment is destined for a retailer, distributor, or other commercial establishment, it will not be considered a personal shipment and A.01.040 will apply.

b) Where the shipment is part of a pattern of repeat personal importations of the same drug to the same individual or address within a three-month period, it is considered to be a commercial shipment and A.01.040 will apply.

c) Where the shipment is part of a larger shipment from a single foreign supplier, which consists of individually addressed parcels, and the importer of record as indicated on a separate customs invoice for each parcel, is not unique for each parcel, the shipment will be considered to be a commercial shipment and A.01.040 will apply. However, if each parcel is uniquely addressed, and if there is a separate invoice for each parcel, then entry is permitted.

d) Where the shipment is accompanied or associated with advertising or promotional material, except for patient information such as directions for use, the importer is considered to be a distributor. The shipment will therefore not be considered to be a personal shipment and A.01.040 will apply.

3. Whether the quantity of the drug which is sought to be imported represents a supply greater than three months of the drug for one individual's use, based on its directions for use or reasonable intake.

a) Where more than a three-month supply of a drug for use by one person is being imported, it is considered to be for sale and it is refused entry.

Available Measures of Enforcement

Refusal of entry or conditional entry at Customs to drug products which are not permitted entry due to conditions as stated in 1. a), b); 2. a), b) c), d); or 3. a) above.

Request voluntary detention, re-export, or voluntary disposal of drug products.

8. EFFECTIVE DATE

The first version of this Importation of Human-Use Drugs for Personal Use Enforcement Directive came into effect on January 1, 1998.

Appendix A

(HPB Office Address)

Date:

TO:

Dear Sir/Madam:

Re: Examination of Customs Parcel
Importation of Prescription Drugs

Your shipment has been examined under the provisions of the Food and Drugs Act and found to contain prescription medication. The importation of Schedule F (prescription) drugs is prohibited, except by certain designated persons (e.g., doctors or pharmacists). It is recommended that you contact your doctor to obtain a prescription for this medication which must be filled in Canada. Medications which are not available in Canada can often be obtained through Health Canada's Special Access Programme.

Your physician may contact the Special Access Program [Phone: (613) 941-2108 or Fax: (613) 941-3194] for authorization to obtain these for you.

Future importation of these or other prescription drugs could result in the return of those products to their origin.