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Drugs Directorate  
Tunney's Pasture  
Postal Locator # 0702A  
OTTAWA, Ontario  
K1A 0L2

September 22, 1995

Sent to Various Associations

Dear :

Please find attached the *Drugs Directorate Policy on Herbals used as Non-medicinal Ingredients in Nonprescription Drugs in Human Use*.

This policy provides written clarification of the currently applied policy for non-medicinal ingredients of botanical origin and provides expanded direction and detail. The increased understanding of and compliance with this policy by industry is expected to result in efficiencies that, in turn, will assist the Directorate in achieving its performance standards.

Please note that this policy is effective immediately. All Drug Identification Number (DIN) submissions which contain herbals as non-medicinal ingredients (NMIs) received in the Drugs Directorate after publication of the policy, and those that have been received but not yet accepted for review, will be screened for compliance with this policy in accordance with the *Drugs Directorate Policy on Management of Drug Submissions*.

For those DIN submissions that have already been screened and accepted for review prior to publication of this revised policy, but for which the review has not yet started, sponsors are encouraged to voluntarily update their submissions to comply with this policy only, without penalty to the status of those submissions. The update should consist of a completed Appendix III form and a covering letter/fax which identifies the name of the drug and the Submission Control Number, and should be sent to the Bureau of Nonprescription Drugs, Fax (613)954-6511.

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For those DIN submissions that have not been updated before being picked up for review, sponsors will be sent a Clarifax, and incomplete or late responses will be treated as stated in the *Drugs Directorate Policy on Management of Drug Submissions*.

If, upon subsequent review of the response to the Clarifax, noncompliance with provisions of the policy is noted, a Notice of Noncompliance will be issued. If compliance with this policy is verified upon review but other submission deficiencies are noted, a separate Clarifax relating to these deficiencies will be issued.

Note that the following Category IV monographs have been revised to be consistent with this policy on herbals used as nonmedicinal ingredients:

- Acne Therapy
- Antidandruff Products
- Antiperspirants
- Antiseptic Skin Cleansers
- Athlete's Foot Treatments
- Medicated Skin Care Products
- Sunburn Protectants

In addition, the Category IV Submission Certification Form has been revised to provide for attestation of compliance with this policy and other guidance documents. Copies of the revised monographs and Category IV Certification Form are posted on the Electronic Bulletin Board.

(originally signed by:)

Dann M. Michols  
Executive Director

Attachment

**Bureau of Nonprescription Drugs:**

**Herbs used as Non-medicinal Ingredients in Nonprescription  
Drugs for Human Use**

**Purpose:**

This policy is intended to describe the conditions under which non-medicinal ingredients of botanical origin (herbs, ), having therapeutic properties, may be accepted in nonprescription drug products for human use and to define the information that must be submitted by drug manufacturers to confirm compliance with those conditions.

**Scope:**

This policy will be applied to oral and topical nonprescription drug products for human use identified below that are not homeopathics and are not otherwise restricted with respect to content of non-medicinal ingredients of botanical origin (eg., as a Category IV monograph requirement).

**Policy:**

**PART A**

**For topical nonprescription products to be applied to  
unbroken skin:**

1. Ingredients of botanical origin may be included as non-medicinals provided:
  - i) they are listed in the Cosmetics, Toiletry and Fragrance Dictionary<sup>1</sup> and,
  - ii) they are not listed in Schedule F or C.01.038 of the Regulations to the Food and Drugs Act (Appendix 1) and,
  - iii) they are within the limits described in Appendix 1 and,
  - iv) they do not have the same pharmacological action(s) as the medicinal ingredient(s).
2. Information contained in the Drug Identification Number (DIN) application and Submission Certification forms will be considered sufficient to confirm compliance with Part A of this policy.

## PART B

### For nonprescription drug products intended for oral use:

1. Only those ingredients of botanical origin that present negligible risk may be considered acceptable as non-medicinal ingredients in nonprescription drug products for oral use. Some herbs that are considered unacceptable in this regard are identified in Appendix II. Note that this list is intended as a guide only and is not necessarily all inclusive.
2. The amount of a non-medicinal ingredient of botanical origin contained in the daily dose must not exceed 10% of the lowest therapeutic daily dose documented in traditional herbal literature.
3. In the case of two or more like-acting herbs, the pharmacological effects are considered to be additive and their combined activity must not exceed 10% for the same pharmacological action, based on the lowest documented therapeutic daily dose for each ingredient concerned.
4. A drug submission for a product intended for oral use and containing herbal non-medicinal ingredient(s) may be accepted for review if compliance with the policy, and with other requirements, is confirmed. Information in the submission must support compliance as follows:
  - a) herbal non-medicinal ingredients, that are identified as being unacceptable, are not included (Appendix II):
  - b) a herbal evaluation form, completed according to the instructions given in Appendix III, is appended to the submission:
  - c) photocopies of two herbal references (Appendix IV) are included with the title page (title, year, authorship, place of publication) and monograph indicating:
    - i) the reputed pharmacological action(s)/therapeutic uses for the part of the plant used, as identified in the submission, (eg., leaf, root), and
    - ii) the minimum dosage for:
      - . the part of the plant in the product,

as identified in the submission,  
(eg., leaf, root, stem...) and

. the form used, as identified in the  
submission, (eg., powdered extract,  
liquid extract, powdered leaf,  
tincture...)

d) where a herb is present in a concentrated form  
(extract, tincture), the specifications must be  
provided in the following manner:

i) where the specifications are exactly the same  
as given in the references provided, in terms  
of the concentration (eg., 1:5) and content  
of alcohol (if applicable), they should be  
declared accordingly in the submission or,

ii) where different from those stated in the  
references provided, the specifications and  
the crude dried herb equivalent must be  
declared as follows:

Rosemary (leaf) ..... X mg  
(Rosemarinus Officinalis)  
liquid extract 1:5  
in 25% alcohol)

Passiflora (aerial parts) ..... Y mg  
(Passiflora incarnata)  
(solid extract 1:5)

This means that contained in each unit of finished  
product (eg., dosage unit, millilitre etc.) is the  
equivalent of X mg or Y mg of the crude dried  
herb, respectively, provided by the liquid or  
solid extracts (as the source).

Regarding the composition of the extract  
itself:-

**Solid extract:** 1:5 means that 1g of extract  
was derived from 5g crude  
dried material

**Liquid extract:** 1:5 means that 1g crude dried  
material was used to prepare  
5ml liquid extract

For liquid extracts, the concentration of  
alcohol in the extract should also be

declared as in the example above.

- e) the non-medicinal herb is present in an amount that is no more than 10% of the minimum reference dose, calculated as shown in Appendix III
- f) the combined activity of two or more like-acting non-medicinal herbs results in the product being medicated to a level that is no more than 10% for the same pharmacologic action:
- g) non-medicinal herbs must not have the same pharmacological action as medicinal ingredients.

## **PART C**

### **For nonprescription drug products not included in Parts A or B**

This group includes, but may not be limited to, drugs administered via the rectal, vaginal, nasal otic, ocular and sublingual routes or topically to abraded skin. The acceptability of nonmedicinal herbs in these products will be assessed on a case by case basis since the Drugs Directorate must be satisfied that there is no additional risk imposed by their presence.

#### **Implementation**

Following publication of the policy, submissions received in the Drugs Directorate for all products that are subject to the policy will be screened for compliance with the policy upon receipt. This is consistent with the provisions of the Drugs Directorate Policy on Management of Drug Submissions.

For Category IV products, an attestation of compliance with published policies is included in the DIN Certification form.

September 11, 1995

APPENDIX I

Herbal Ingredients to be Excluded from or Limited in  
Products Intended for Topical Use that are Subject to Part A

The following ingredients are listed in the CTTA Dictionary but are subject to the following limitations as nonmedicinal ingredients in topical products to be applied to unbroken skin:

Rauwolfia extract	(Schedule F)	0 level
Centenella asiatica extract (Hydrocotyl extract)	(Schedule F)	0 level
Wintergreen oil	up to 1% methyl salicylate	

**NOTE:** this list is intended as a guide and is not necessarily all inclusive



APPENDIX II  
**LIST OF HERBS UNACCEPTABLE AS NONMEDICINAL  
 INGREDIENTS IN ORAL USE PRODUCTS SUBJECT TO PART B**

Note: Botanical names in bold type

(F) French Synonyms

**This list is intended as a guide only and is not  
 necessarily all inclusive**

NAME	SYNONYMS
Aconite	.Aconit Napel (F) .Monkshood, .Wolfsbane, <b>.Aconitum napellus</b>
Adonis	.Adonis du printemps (F) .Red chamomile, .False hellebore, .Yellow pheasant's eye, <b>.Adonis Vermalis</b> <b>.A. Autumnalis</b>
Angelica root	.Angélique archangélique (F) .European Angelica, <b>.A. officinalis</b> <b>.A. archangelica</b>
Arnica	.Arnica .Wolf's bane, .Leopard's bane, .European arnica, <b>.Arnica montana</b>
Arrowroot, Spanish	.Arrow-root d'espagne (F) .Marante (F) .Bermuda Arrowroot, <b>.Maranta arundinaceae</b> <b>.M. malaccensis</b>
Autumn Crocus	refer to Colchicum
Balloon Flower	.Platycodon à grandes feuilles(F) .Chinese Bellflower, <b>.Platycodon grandiflorum</b>
Baneberry, white	.Actée à gros pedicelles (F) <b>.Actea Pachypoda</b>

Barberry, common	.Épine-vinette (F) .Berberry, .Pipperidge bush, .European barberry <b>.Berberis vulgaris</b> <b>.B. dumetorum</b> <b>.Berberidis cortex</b>
Barberry, nepal	.Épine-vinette aristée (F) .Ophtalmic barberry, .Darlahad, <b>.Berberis Arista</b>
Bayberry	.Écorce de cirier (F) .Wax myrtle, .Wax berry, .Candleberry, <b>.Myrica cerifera</b>
Bearberry	.Arbousier Uva-ursi (F) .Uva-ursi, <b>.Arctostaphylos uva-ursi</b>
Betel Nut	.Noix d'arec (F) <b>.Areca Nut,</b> <b>.Areca Catechu</b>
Bittersweet	.Morelle Douce-Amère (F) .Woody Nightshade, .B. Nightshade .Fellonwood, .Fellonwort, <b>.Solanum Dulcamara</b>
Black Cohosh	.Actée à grappes (F) .Black snake root, .Black Snakeroot, .Bugbane, .Rattleweed, .Rattlewood, <b>.Macrotys actaeae,</b> <b>.Actaeae racemosae radix,</b> <b>.Cimifuga racemosa</b>
Blood Root	.Sanguinaire (F) .Red indian paint, <b>.Sanguinaria canadensis</b>
Blue Cohosh	.Caulophylle Faux-Pigamon (F) .Squaw root, .Papoose root, <b>.Caulophyllum Thalictroides</b>
Bryony, White	.Bryone Blanche (F) .Wild vine <b>.Bryona alba or B.dioica</b>

Calabar Bean	.Février de calabar (F) .Ordeal Bean, .Chopnut, <b>.Physostigma Venenosum</b>
Calamus	.Acore odorant (F) .Sweet flag, .Sweet sedge, <b>.Calamus Aromaticus,</b> <b>.Acorus Calamus</b>
Calotropis	.Calotropis Procera (F) .Mudar Bark, .Mudar Yercum, <b>.Asclepias procera,</b> <b>.Calotropis procera</b>
Camphor Oil (oral use)	.Huile de camphre (usage oral) (F) <b>.Cinnamomum camphora</b>
Castor Oil Plant	.Ricin (F) .Wonder tree, .Castor bean, .Palma christi, <b>.Ricinus communis</b>
Celandine, Common	.Chelidoine (F) .Greater celandine <b>.Chelidonium majus</b>
Chaparral	.Chaparral (F) .Creosote bush, .Greasewood, <b>.Larrea divarticulat,</b> <b>.L. tridentara</b>
Colchicum	.Colchique (F) .Crocus, Autumn .Meadow saffron, .Naked ladies, <b>.Colchicum autumnale</b>
Coltsfoot	.Tussilage (F) .Coughwort, .Horsehoof, .Foal's foot, .Bull's foot, <b>.Tussilago Farfara</b>
Comfrey (common, prickly, russian)	.Grande consoude (F) .Blackwort, .Nipbone, Knitbone, .Consolida, .Tuberous comfrey <b>.Symphytum officinale</b> <b>.S. uplandicum</b>

Convallaria	.Muguet (F) .Lilly of the valley leaves, .May Lily, .Muguet, <b>.Convallaria majalis</b>
Coonties Seeds	.Graines de zamier (F) .Florida arrowroot seeds, <b>.Zamia integrifolia</b>
Cramp Bark (Berries)	.Boule de neige (F) .Cranberry tree, .Guelder rose, .Snowball tree, <b>.Virbunum opulus</b>
Crocus, Autumn	.refer to Colchicum
Croton seeds	.Graines de Croton Tiglium (F) .Tiglium, .Badou, <b>.Tiglium officinale,</b> <b>.Croton tiglium</b>
Daffodil	.Narcisse des prés (F) .Chinese Sacred Lily, .Porillon, .Lent Lily, <b>.Narcissus pseudo-narcissus, .</b> <b>.N. tazetta</b>
Daphne, Mezereum	.Dwarf Bay, .Daphne, .Mezereon, .Spurge olive, .Spurge Laurel, <b>.Daphne mezereum (F), D.</b> <b>gnidium,</b> <b>.D.laureola,</b> <b>.Daphne spp.</b>
Deadly Nightshade	.Belladone (F) .Devil's cherries, .Naughty man's cherries, .Divale, .Black cherry, .Devil's herb, .Great morel, .Dwayberry, .Dwale, .Belladonna, <b>.Atropa belladona</b>
Devil pepper	<b>.Rauwolfia (F) spp.</b>
Digitalis	see Foxglove

Dogbane (Spreading)	.Apocyn (F) <b>.Apocynum androsaemifolium</b>
Dong Quai	.Don Quai (F) .Tang-Kuei, <b>.Angelica sinensis,</b> <b>.A. polymorpha</b>
Ephedra	.Éphèdre (F) .Ma Huang, <b>.E. Sinica,</b> <b>.E. equinestina,</b> <b>.E. gerardiana</b>
Euphorbia	.Euphorbe (F) .Pill-bearing spurge, <b>.E. spurge</b> <b>.E. pilulifera,</b> <b>.E. hirta,</b> <b>.E. resinifera</b>
Foxglove	.Digitale pourprée (F) .Purple foxglove, .wholly foxglove, <b>.Digitalis lanata,</b> <b>.D. purpurea</b>
Fritillaria	.Fritillaire (F) .Pei mu .Zhe bei mu, <b>.Fritillaria verticillata,</b> <b>.F. thubergii,</b> <b>.Fritillia vericillia,</b> <b>.F. meleagris</b>
Gelsemium	.Gelsemium (F) .Yellow Jasmine or Jessamine, .Wild jasmine or jessamine, .Wild woodbine <b>.Bignonia sempervirens,</b> <b>.G. Sempervirens,</b> <b>.G. nitidum</b>
Germander	.Germandrée (F) .Wall germander, <b>.Teucrium Chameadrys</b>
Ginkgo Biloba (fruits & seeds)	.Ginkgo biloba (F) .Gingko .Maidenhair tree, .Kew tree
Golden Ragwort <b>(Senecio)</b>	.Seneçon doré (F) .Squaw weed, .Life root, .Golden senecio, <b>.Senecio Aureus</b>

Goldenseal ( <b>Hydrastis</b> )	.Hydraste du Canada (F) .Orange or Yellow root, <b>.Hydrastis canadensis</b>
Gotu Kola (Extracts)	.Gotu kola (F) .Hydrocotyle asiatica, .Indian Pennywort, .Hydrocotyle, .Marsh Penny, .White Rot, .Fo Ti Tieng, <b>.Centella asiatica</b>
Hellebore, American	.Ellebore Vert (F) <b>.Veratrum viride</b>
Hellebore, European	.Verâtre blanc (F) <b>.Veratrum album</b>
Hemlock	.Grande cigüe (F) .Poison hemlock, .Mother die, <b>.Conium maculatum</b>
Henbane	.Jusquiame noire (F) .Common Henbane, .Hog's Bean, .Jupiter's Bean, <b>.Hyoscyamus niger</b>
Horse chestnut	.Marron d'Inde (F) <b>.Aesculus hippocastanum,</b> <b>.Hippocastanum vulgare</b>
Hydrastis	refer to goldenseal
Jessamine, yellow	refer to gelsemium
Jimson weed	.Stramoine (F) .Thornapple, .Jamestown weed, .Stramonium, <b>.Datura stramonium</b>
Juniper Berries	.Baie de genièvre (F) .Common Juniper, .Ginepro, .Genevrier, <b>.Juniperus communis</b>
Kava	.Kava (F) .Kava-Kava, .Kew, .Tonga .Kawa, <b>.Piper methysticum</b>
Lantana	.Lantana (F) <b>.Lantana camara</b>

Liferoot	refer to Golden ragwort
Lily of the valley	refer to Convallaria
Lobelia	.Lobélie gonflée (F) .Indian Tobacco, .Pukeweed, <b>.Lobelia inflata</b>
Magnolia Officinalis	.Magnolier (F)
Male Fern	.Fougère mâle (F) .Marginal fern, .Aspidium, .American aspidium, <b>.Aspidium filix-mas,</b> <b>.Dryopteris filix-mas,</b> <b>.D. Abbreviata</b>
Mandrake, american	.Podophylle pelté (F) .May or hog Apple, .Apples of the Fool, .Devil's apple, .Wild Mandrake, .Wild Lemon, .Racoonberry, .Duck"s foot, <b>.Podophyllum peltatum</b>
Mandrake, european	.Mandragore (F) .Satan's apple, <b>.Mangragona officinarum,</b> <b>.Atropa mandragora</b>
Mezereon	refer to Daphne .Mezereon (F)
Micranthum oil	.Essence de micranthum (F) <b>.Cynnamomum micranthum</b>
Mistletoe, american	.Gui de chêne (F) .False mistletoe, .Birdlime, .Golden Bough, <b>.Phorandendron flavescens, P.</b> <b>tomentosum, P. serotinum</b>
Mistletoe, european	.Gui (F) .Birdlime Mistletoe, .Herbe de la Croix, <b>.Viscum album</b>
Mountain grape root	.Mahonia à feuilles de houx (F) .Oregon grape root, <b>.Mahonia aquifolium,</b> <b>.M. nervosa</b>

Mountain laurel	.Laurier de montagne (F) .Calico Bush, .Sheepkill, .Lambkill, .Spoonwood, .Broad-leaved Laurel, <b>.Kalmia latifolia,</b> <b>.Kalmia angustifolia</b>
Oregon Grape	refer to Mountain grape
Parsley oil	.Essence de persil (F) .Persely, .Persele, <b>.Apium petroselinum,</b> <b>.Petroselinum lativum,</b> <b>.Petroselinum sativum</b>
Pennyroyal, American & European  OIL	.Hédéome essence (F) .Pulegium, .Run by the ground, .Lurk in the ditch, .Puddling grass, .Piliolerial, <b>.Menth pulegium (european),</b> <b>.Hedeoma pulegiodes(american)</b>
Peony	.Pivoine Officinale (F) .Paeony, <b>.Paeonia officinalis</b>
Platycodon	refer to Balloon flower
Pleurisy root	.Asclépiade (F) .Butterfly weed, .Milkweed, .Canada root, .Flux root, .Orange swallow-wort, .Tuber root, .White root, .Wind root, <b>.Asclepias tuberosa</b>
Poke root	.Raisin d'amérique (F) .Pokeweed or red P. .Pokeberry, .Pigeonberry, .Pocan, .Red plant, <b>.Phytolacca decandra,</b> <b>.P. americana</b>
Ragwort	refer to Golden ragwort (Senecio)
Red Baneberry	.Actée rouge (F) <b>.Actea rubra</b>



Red Pokeweed	refer to Pokeroot
Rue	.Rue (F) .Garden or german rue, .Ruta, .Galena, .Herb of grace, .Herby grass, <b>.Ruta graveolens</b>
Rye Ergot	.Ergot de seigle (F) .Cockspur rye, .Hornseed, . .Mother of Rye, .Smut Rye, .Spurred Rye <b>.Claviceps purpurea</b>
Sabadilla	.Sabadilla (F) .Cevadilla, <b>.Schoenocaulon officinale,</b> <b>.Veratrum sabadilla</b>
Sage (Oil)	.Sauge (essence)(F) .Garden, spanish or red sage, <b>.Salvia officinalis</b>
Sassafras (Oil & root/bark)	.Sassafras (Essence & racine/ écorce) (F) .Sassafrax, .Cinnamon Wood, .Ague Tree, .Saloop, <b>.Sassafras albidum, S.</b> <b>officinale, S. varifolium,</b> <b>.Laurus Sassafras</b>
Savin Oil	.Essence de sabine (F) .Savin tops, <b>.Juniperus sabina</b>
Scoparius	.Genêt à balai (F) .Broom, .Broom-Tops, .Irish Broom .Spartium, .Scotch Broom, <b>.Sarthothamnus scoparius</b> <b>.S. vulgaris</b> <b>.Planta Genista</b> <b>.Cytisus scoparium L.</b>
Senecio Jacobae	refer to Golden ragwort
Sowbread	.Cyclamen d'Europe (F) .Cyclamen, .Groundbread, .Swinebread, <b>.Cyclamen europaeum</b>

Squill	.Scille (F) .Indian Squill, .Scilla, .Red and White Squill, .Sea Onion, .Maritime Squill, <b>.Urginea maritima, .Drimia maritima</b>
Stephania Rotunda	.Stephania Rotunda
Stephania Tetranda	.Stephania Tetranda
Strophanthus	.Strophanthus (F) <b>.Strophanthus kombe, .S. gratus</b>
Tansy (Oil)	.Tenaisie (essence) (F) .Buttons, .Tanacetum, <b>.Chrysanthemum vulgare, .Tanacetum vulgare</b>
Thuja	.Thuya (F) .Tree of Life, .Yellow Cedar, .American Cedar Leaves, .White Cedar, <b>.Thuja occidentalis, Arbor vitae</b>
Tonka Bean	.Fève Tonka (F) .Tonquin Bean, <b>.Dipteryx odorata, .D. oppositifolia, .Coumarouna odorata</b>
Unicorn root, false	.Chamaelire doré (F) .Helonias root, .Blazing star root, <b>.Chamaelirium luteum</b>
Unicorn Root, True	.Licorne vraie (F) .Argue Root, .Colic Root, .Stargrass, .Starwort, .Star-root, .Blazing star, .Black-root, .Aloe-root, .Bitter grass or bettie grass, .Crow corn, .Devil's bit <b>.Alettris farinosa</b>
Uva-ursi	refer to Bearberry

Virginia Snakeroot	.Serpentaire de Virginie (F) .Birtwort, .Serpentary Rhizome, .Sangree, <b>.Aristolochia serpentaria, Serpentaria</b>
White Bryony, european	.Bryone blanche (F) <b>.Bryona dioica</b>
Wild cherry	.Cerisier de Virginie (F) .Black Cherry, .Virginian Prune, .Prunier de Virginie, .Prunus, <b>.Prunus serotina, .Prunus virginiana</b>
Wintergreen (acceptable only as a flavor)	.Gaulthérie (F) .Teaberry, .Boxberry, .Aromatic Wintergreen, .Mountain Tea, .Deerberry, .The du Canada, <b>.Gaultheria procumbens</b>
Wormseed	.Anserine (F) .Wormseed, American, <b>.Chenopodium ambrosoides</b>
Yohimbe	.Yohimbe (F) .Yohimbine (F) .Corynanthe yohimbe, .Yohimbehe, <b>.Pausinstalia yohimbe</b>

APPENDIX III

<b>Product Name:</b>				
<b>Indication(s):</b>				
<b>Single Dosage:</b>		<b>Daily Dosage:</b>		

Nonmedicinal herb & Minimum Daily Reference Dosage  <b>X mg*</b>	Weight*/ dosage unit mg*	Weight*/ maximum daily dosage  <b>Y mg*</b>	% Medicated	Pharmacological Effect(s)

**Total % Medication:**

**References used:**

**Note:** Instructions over leaf.

\* May be expressed in grams or as volume (eg., ml) provided all values are in the same units for a particular herb and the reference dose is specified as such

....APPENDIX III continued:

**Ex. 1:** Compliance with the 10% limit for a product with herbal nonmedicinal ingredient(s) in non-concentrated form is ascertained as follows:

Calculate the % medication for each ingredient using the following formula:

minimum reference daily dose .... **X mg**  
 content in minimum daily dose.... **Y mg**

$$\% \text{ medication} = \frac{100 \ Y}{X} \% \quad (\text{see table below for example})$$

Identify and attach the two references used and note that all pharmacological actions given should be identified; dosages must be for the part of the plant and form used.

<b>Product Name:</b> Accord Tablets				
<b>Indication(s):</b> Vitamin Supplement				
<b>Single Dosage:</b> 1 tablet		<b>Daily Dosage:</b> 2 tablets		

Nonmedicinal herb & Minimum Daily Reference Dosage  <b>X mg</b>	Weight/ dosage unit mg	Weight/ maximum daily dosage  <b>Y mg</b>	% Medicated	Pharmacological Effect(s)
valerian root (dried) 900 mg <sup>1</sup>	25 mg	50 mg	5.5	sedative carminative anodyne.....
peppermint herb 6000 mg <sup>1</sup>	50 mg	100 mg	1.6	carminative spasmolytic diaphoretic....
passion flower 750 mg <sup>1</sup>	15 mg	30 mg	4.0	sedative antispasmodic anodyne....

**Total % Medication:**

**References used:**

<sup>1</sup> British Herbal Pharmacopoeia 1983

as a sedative = 9.5% (acceptable)  
 as a carminative = 7.1% (acceptable)  
 as antispasmodic = 5.6%  
 (acceptable) as a  
 nonmedicinal

...APPENDIX III continued:

**Example 2:**

Compliance with the 10% limit for a herb in concentrated form (extract\*, tincture) is ascertained by calculating 10% of the daily dose as follows:

- i) where the specifications of the dosage form is exactly the same as those in the references provided.

eg. **product contains:**

echinacea (E. augustifolia) tincture 1:5 (in 45% alcohol) as a nonmedicinal ingredient and

**reference dose:**

1 - 2 ml of echinacea tincture 1:5 (in 45% alcohol)

maximum amount of this extract that can be provided by the daily dose of the product is:

$$10\% \text{ of the minimum dose} = \frac{10 \times 1}{100} = 0.1 \text{ ml}$$

- ii) where the specifications of the dosage form are different from those in the references provided:

eg. **product contains:**

Capsicum (C. minimum) (dried fruit extract 1:3)

**reference dosages:**

three times daily:

dried fruit 30 - 120 mg or

tincture 1:20 in 60% alcohol, 0.3-1ml or

strong tincture 1:3 in 60% alcohol, 0.06-0.2 ml

maximum amount:

since specifications of the reference doses are not the same as that of the nonmedicinal concentrated capsicum in the product, the equivalent weight of dried herb (expressed as in 4 (d), Part B of the policy) must be used as the basis for calculating the 10% limit

$$\begin{aligned} \text{ie. } & \frac{10}{100} \times \text{minimum daily crude dried herb dose} \\ & = \frac{10 \times (30 \times 3)}{100} = 9 \text{ mg dried capsicum} \end{aligned}$$

\* liquid extract, solid extract, powdered extract etc.

**APPENDIX IV**

The following list of reference texts is intended as a guide only and is not all inclusive. It is comprised of some references texts available to the Drugs Directorate. Although certain references are more frequently used than others, the Drugs Directorate does not specifically endorse any of those listed and it is recognized that references outside of this collection may also provide valuable information.

Note that more recent evidence of toxicity will take precedence over information contained in the following references on traditional use.

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