
**AMENDMENTS TO
TGA APPROVED TERMINOLOGY FOR MEDICINES – July 1999**

THE AMENDED TABLE OF CONTENTS FOR THE JULY 1999 EDITION OF THIS PUBLICATION IS SHOWN IN THIS DOCUMENT.

NOTE: THOSE SECTIONS OF THE PUBLICATION THAT HAVE BEEN AMENDED SINCE JULY 1999 ARE **SHOWN IN RED AND MARKED WITH AN ASTERISK BELOW. SECTIONS AND FORMS THAT HAVE BEEN ADDED TO THE DOCUMENT SINCE ITS LAST PUBLICATION ARE INDICATED AS **NEW SECTION**. Numbering is in accordance with the July 1999 edition of the publication**

ALL APPLICATION FORMS (APPENDICES 1-8) ARE INCLUDED IN THIS DOCUMENT.

Sponsors and other users of the list should note the following:

- 1 Inclusion of a name in the list of Australian Approved Names for Substances Included in Therapeutic Goods does NOT imply any recommendation for the use of the substance in therapeutic goods.**
- 2 The citation of an authority or reference for a name in the list does NOT imply that the standard specified by that authority is applicable to the substance used in a particular therapeutic good. (See Citations and Authorities below.)**
- 3 The list is NOT a list of ingredients found in products currently entered on the Australian Register of Therapeutic Goods.**

TGA APPROVED TERMINOLOGY FOR DRUGS

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CHAPTER 1 – AUSTRALIAN APPROVED NAMES FOR THERAPEUTIC SUBSTANCES

1. CHEMICAL SUBSTANCES

1.4 AUSTRALIAN APPROVED NAMES – CHEMICAL LISTS

1.4.1 Chemical Substance Names List

APPROVED NAME	REFERENCE	COMMENT
Abacavir sulfate	USAN	
Acetyllevocarnitine hydrochloride	CAS 5080-50-2	
N-Acetyltryptophan	BPAP	
Acidopholus/grape ferment	ICID	PRV
Acrylamide	CAS 79-06-1	
Adenine sulfate dihydrate	USP	
(S)-S-Adenosylmethionine	CAS 78548-84-2	
DL-Alanine	CAS 3020-72-7	
Aluminium zirconium trichlorohydrate complex	ICID*	
Amisulpride	INN	
DL-Aspartic acid	CAS 617-45-8	
Atosiban	INN	
Atosiban acetate	INN*	
Balsalazide	BAN	
Balsalazide sodium	BAN	
Bicisate dihydrochloride	CAS 14344-58-2	
Bupivacaine hydrochloride anhydrous	BP*	
Bupropion	INN*	
Bupropion hydrochloride	INN*	
Buserelin	INN	
C6-14 Olefin polymers - hydrogenated	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
C12-16 Alcohols	ICID	PRV
Calcium ascorbate threonate complex	TGA 2000	
Calcium diglutamate	FAO	
Calcium hydroxycitrate	TGA99	
Calcium pyruvate anhydrous	CAS 17070-07-4	
Calteridol calcium	BAN	
Carboprost	INN	
Carboprost trometamol	BAN	
Ceramide 2	ICID	PRV
Ceteareth-15	ICID	PRV
Cetrorelix	INN	
Cetrorelix acetate	BAN	
Cetyl myristate	ICID	PRV
Cholesteryl/behenyl/octyldodecyl lauroyl glutamate	ICID	
Chromium citrate	TGA2001	
Chromium nitrate nonahydrate	MI	
Conjugated linoleic acid 75%	CG	
Cystine dihydrochloride	CAS 300925-07-6	
Desoxyribose	MI*	
Dexamethasone sodium metasulfobenzoate	CAS 16978-57-7	
Dexmedetomidine	INN	
Dexmedetomidine hydrochloride	INN*	
Dicaprylyl carbonate	ICID	PRV
Dienogest	INN	
Diethylhexyl-2,6-naphthalate	CAS 127474-91-3	
Diisopropyl adipate	ICID	PRV
Dimethiconol stearate	ICID	PRV
Dimethylsiloxane/methylvinylsiloxane cross linked elastomer	TGA 2000	
Dioxane	CAS 123-91-1	
Dipropylene glycol dibenzoate	ICID	PRV
Disodium dimethicone copolyol sulfosuccinate	ICID	PRV
DNA (from Saccharomyces cerevisiae) ICID 2000 - hydrolysed	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
Eletriptan	USAN	
Epoprostenol	INN	
Epoprostenol sodium	BAN	
Ertapenem	USAN*	
Ertapenem sodium	USAN	
Esomeprazole	INN	
Esomeprazole magnesium trihydrate	INN*	
Ethyl butylacetylaminopropionate	ICID	PRV
Ethylene dioleamide	ICID	
Exemestane	INN	
Ferric nitrate	BPAP	
Ferucarbotran	BAN	
Fludeoxyglucose[18F]	BP*	Formerly 2-Deoxy-2-[18F]-fluoro-d-glucose. Change of name in BP reference.
Fomivirsen	INN	
Fomivirsen sodium	INN	
Fosphenytoin sodium	USAN	
Frusemide sodium	BP*	
Gadoteridol	INN	
Galantamine	INN	
Galantamine hydrobromide	USAN	
Ganirelix	INN	
Ganirelix acetate	INN*	
Gatifloxacin	INN	
Gatifloxacin sesquihydrate	BAN	
Gemifloxacin	INN	
Gemifloxacin mesilate sesquihydrate	USAN	
Glucosamine	INN	
Glucosamine sulfate-potassium chloride complex	TGA99	
Glucosamine sulfate-sodium chloride complex	TGA99	
DL-Glutamic acid	CAS 617-65-2	
Glycereth-26	ICID	PRV
Glycol montanate	ICID	

APPROVED NAME	REFERENCE	COMMENT
Glycylglutamine monohydrate	CAS 13115-71-4	
Glycyltyrosine dihydrate	CAS 658-79-7	
Guanine hydrochloride monohydrate	USP	
Hydroxocobalamin acetate	BP	
Hydroxocobalamin chloride	BP	
Hydroxocobalamin sulfate	BP	
Hydroxycitric acid	CAS 6205-14-7	
Hypromellose acetate succinate	TGA 2000	
Ibandronic acid	INN	
Ibuprofen lysine	CAS	
Ibutilide	INN	
Icodextrin	INN	
Ipriflavone	INN	
DL-Isoleucine	CAS 443-79-8	
Lactic-glycolic copolymer	CAS 343436-01-5	
Lanreotide	INN	
Lanreotide acetate	USAN	
Lecithin liquid - soy phosphatidylserine-enriched soy	CG 2000	
Lecithin powder - soy phosphatidylserine-enriched soy	CG 2000	
Lercanidipine	INN	
Lercanidipine hydrochloride	BAN	
DL-Leucine	MI	
Levetiracetam	INN	
Levocarnitine	INN	
Levocarnitine fumarate	CAS 90471-79-7	
Levocarnitine hydrochloride	CAS 6645-46-1	
Levocarnitine magnesium citrate	CAS 134620-06-7	
Linezolid	INN	
R-alpha Lipoic acid	CAS 62-46-4	
R,S-alpha Lipoic acid	CAS 1077-28-7	
Lopinavir	INN	
Lovastatin	INN	
Lycopene	CG	

APPROVED NAME	REFERENCE	COMMENT
Magnesium diglutamate	FAO	
Magnesium silicate dihydrate	TGA99	
Magnesium sulfate heptahydrate	BP*	
Magnesium sulfate dihydrate	BP*	
Maize syrup - high fructose	TGA 2001	
Menthoxypropanediol	ICID	
Modafinil	INN	
Monoammonium glutamate	FCC*	
Myreth-4	ICID	
Nonoxinol 100	BAN*	
Nordihydroguaiaretic acid	ICID	PRV
Octafluoropropane	CAS 76-19-7	
Oseltamivir	INN	
Oseltamivir phosphate	CAS 204255-11-8	
Oxaliplatin	INN	
Oxcarbazepine	INN	
Oxitriptan	INN	
Paroxetine mesilate	INN*	
PEG-4 Oliviate	ICID	PRV
PEG-20 glyceryl stearate	ICID	
PEG-150 Pentaerythrityl tetrastearate	ICID	PRV
Pigment green 18 CI77288	CI	PRV
Pioglitazone	INN	
Pioglitazone hydrochloride	USAN	
Polifeprosan	INN	
Polycarbophil	INN	
Polyglyceryl-2 triisostearate	ICID	PRV
Potassium ascorbate dihydrate	CAS	
Potassium carbomer	ICID	PRV
Potassium cocoyl hydrolysed soy protein	ICID	PRV
Potassium hydroxycitrate	TGA99	
PPG-10 cetyl ether	ICID	PRV
PPG-15 stearyl ether benzoate	ICID	PRV
PPG-51/SMDI copolymer	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
Propionyllevocarnitine	CAS 119793-66-7	
Propionyllevocarnitine hydrochloride	CAS 119793-66-7	
Propylene glycol caprylate	ICID	PRV
D-Pulegone	CAS 89-82-7	
Rabeprazole	INN	
Rabeprazole sodium	BAN	
Rapacuronium bromide	INN	
Ribose	BPAP	
Risedronate sodium	USAN	
Risedronic acid	INN	
RNA (from <i>Saccharomyces cerevisiae</i>) ICID 2000 - hydrolysed	ICID	PRV
Saccharide isomerate	ICID	PRV
Saccharomyces/calcium ferment	ICID	PRV
Saccharomyces/manganese ferment	ICID	PRV
Safrole	CAS 94-59-7	
DL-Serine	MI	
Sodium hydroxycitrate	TGA99	
Sodium hypoxanthine	TGA 2000	
Sodium ibandronate	BAN	
Sodium myreth sulfate	ICID	PRV
Sodium selenite pentahydrate	MI12	
Sodium xanthine	CAS 1196-43-6	
Sorbitan	CAS 27299-12-3	
Sorbitan olivate	ICID	PRV
Sorbitan palmitate	ICID	PRV
Stearoyl macroglycerides	BP	
Sugar cane wax alcohols	CG 2000	
Sulpiride	INN	
Tazarotene	INN	
Technetium[99mTc] biccisate	BAN	
Tegafur	INN	
Tegaserod	INN	
Tegaserod maleate	INN*	
Tetrahydrodiferuloylmethane	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
Thujone	MI	
Thymine	BPAP	
DL-alpha Tocopherol phosphate disodium	CAS 60934-46-5	
D-alpha Tocopheryl polyethylene glycol 1000 succinate	USP*	
Tocotrienols complex - palm	CG	
Travoprost	INN	
Tributyl citrate	USP	
Triisocetyl citrate	ICID	
DL-Tryptophan	FCC	
Tyrosine disodium	CAS 69847-45-6	
Unoprostone	INN	
Unoprostone isopropyl	INN*	
Uracil	USAN	
Urea[13C]	TGA99	
DL-Valine	MI	
Vanadyl sulfate	MI12	
Vanadyl sulfate dihydrate	MI12*	
Verteporfin	INN	
Wheat amino acids	ICID	PRV
Yeast - hydrolysed	ICID	PRV
Zinc picolinate monohydrate	CAS17949-65-4*	
Zoledronic acid	INN	

1.4.2 Label-AANs – Chemical List

LABEL- AAN	APPROVED NAME(S)	TYPE OF LABEL-AAN
Alcohol	Ethanol Ethanol - absolute	Excipient Group for Schedule 1 Medicines Labelling Order
Benzoates	Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate	Excipient Group for Schedule 1 Medicines Labelling Order

LABEL- AAN	APPROVED NAME(S)	TYPE OF LABEL-AAN
Hydroxybenzoates	Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate	Excipient Group for Schedule 1 Medicines Labelling Order
Sodium salts	Sodium chloride Sodium bicarbonate	Excipient Group for Schedule 1 Medicines Labelling Order
Sorbates	Sorbic acid Potassium sorbate	Excipient Group for Schedule 1 Medicines Labelling Order
Sugars	Glucose Honey Honey - purified Invert sugar Lactose Maltose Sucrose	Excipient Group for Schedule 1 Medicines Labelling Order
Sulfites	Sulfur dioxide Potassium metabisulfite Sodium metabisulfite Sodium sulfite	Excipient Group for Schedule 1 Medicines Labelling Order

1.5 AMENDMENTS AND SYNONYMS

1.5.1 Monograph Changes

APPROVED NAME	OLD REFERENCE	NEW REFERENCE
Calcium saccharate	USP	INN
Ipratropium bromide	BAN	BP
Oestrone sulfate – sodium	MAR	USAN
Camphor	BP	BP88

1.5.2 Synonyms for Chemical Substance Names

Applicants should note that synonyms ARE NOT approved names and should NOT BE USED in applications or on labels where approved terminology is required.

The following synonyms are provided for the assistance of applicants.

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Acetaldehyde-diethylacetal (CAS 105-57-7)	Acetal
Acetate PA	Allyl phenoxyacetate

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Acetic acid, ethyl ester	Ethyl acetate
Acid Yellow 17 CI18965	Yellow 2G CI18965
Alcohol C-6	Hexan-1-ol
Alcohol C-7	1-Heptanol
Alcohol C-9	n-Nonyl alcohol
Alcohol C-10	Decan-1-ol
Alcohol C-12	1-Dodecanol
Aldehyde C-6	Caproic aldehyde
Aldehyde C-7	Heptanal
Aldehyde C-8	Caprylic aldehyde
Aldehyde C-9	Nonanal
Aldehyde C-10	Decanal
Aldehyde C-11 undecyclic	Undecanal
Aldehyde C-11 undecylenic	10-Decanal
Aldehyde C-12 lauric	Lauryl aldehyde
Aldehyde C-12 MNA	2-Methylundecanal
Aldehyde C-14 (true)	Myristic aldehyde
Aldehyde C-14 So-called	gamma-Undecalactone
Aldehyde C-16 So-called	Ethyl methylphenylglycidate
Aldehyde C-18 So-called	gamma-Nonalactone
Aldehyde C-18 true	Octadecanal
Amfebutamone	Bupropion
Amfebutamone hydrochloride	Bupropion hydrochloride
Basic violet 10 CI45170	Rhodamine B CI45170
Benzodioxole-5-carbohyaldehyde	Piperonal
Benzoic acid, sodium salt	Sodium Benzoate
BHT	Butylated hydroxytoluene
Carbomer ETD 2050	Carbomer 2050
Carbomer Ultrez 10	Carbomer U-10
4-Chloro-3-methyl phenol	Chlorocresol
2-Deoxy-2-[18F]-fluroro-d-glucose	Fludeoxyglucose[18F]
Dimethyl siloxane reaction products with Silica	Simethicone
Dimethylcyclosiloxane	Cyclomethicone
Disodium adenosine triphosphate	Adenosine disodium phosphate

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
3-Ethoxy-4-hydroxy-benzaldehyde	Ethyl vanillin
Formic acid, ethyl ester	Ethyl formate
D-Glucosamine sulfate-potassium chloride complex	Glucosamine sulfate-potassium chloride complex
D-Glucosamine sulfate-sodium chloride complex	Glucosamine sulfate-sodium chloride complex
Glucose syrup dried	Glucose - liquid
Glucose syrup solids	Glucose - liquid
cis-3-Hexenol	cis-3-Hexen-1-ol
4-Hydroxy-3-methoxy-benzaldehyde	Vanillin
3-Hydroxy-2-methyl-4H-pyran-4-one	Maltol
3-Hydroxy-1,2,3-Propanetricarboxylic acid	See Citric acid
5-Hydroxytryptophan	Oxitriptan
l-5-Hydroxytryptophan	Oxitriptan
Isopentanal	Isovaleraldehyde
Lauryl alcohol	1-Dodecanol
Lutein	Xanthophyll
3-Methylbutyl acetate	Isoamyl acetate
Montanglycol	Glycol montanate
Ornithine hydrochloride	Ornithine monohydrochloride
Parachlorometacresol	Chlorocresol
Polyvinylpyrrolidone	Povidone
Ponceau 4R	Brilliant scarlet 4R CI16255
PVP	Povidone
Sodium carboxymethylcellulose	Carmellose sodium
Tocophersolan	Tocofersolan
D-alpha-Tocopheryl polyethylene glycol 1000 succinate	Tocofersolan
Tribasic calcium phosphate	Calcium phosphate
Trimethyl hexadecyl ammonium chloride	Cetrimonium chloride
Tromethamine	Trometamol

1.5.3 Other Changes to Entries

The following entries have had additions, deletions or changes made to the statements shown in the Comments field since the publication of the July 1999 edition. Current entries are shown.

APPROVED NAME	REFERENCE	COMMENT
Butyl ester of PVM/MA copolymer	ICID	PRV
Camphor	BP88	Includes natural (D) and synthetic (DL) forms.
Farnesol	MI	PRV
Lanosterol	ICID	PRV
Palmitoyl hydroxypropyltrimonium amylopectin/glycerin crosspolymer	ICID	PRV
Polyglyceryl-2 dipolyhydroxystearate	ICID	

1.6 DEVICE INGREDIENT CHEMICAL NAMES

1.6.2 Approved Device Ingredient Substance Names List

APPROVED NAME	REFERENCE	CAS NUMBER
Acid green 28	CI	
Acid red 1 CI18050	CI	
Acid violet 48	CI	CAS 12220-51-8
Alcohols, C6-C10 ethoxylated propoxylated	CAS 1569-01-3	CAS 1569-01-3
4-Benzyl-2-chlorophenol	CAS 31089-49-3	CAS 31089-49-3
2-Benzyl-4,6-dichlorophenol	CAS 19578-81-5	CAS 19578-81-5
4-Benzyl-2,6-dichlorophenol	CAS 38932-58-0	CAS 38932-58-
2-Benzyl phenol	CAS 28994-41-4	CAS 28994-41-4
4-Benzyl phenol	CAS 101-53-1	CAS 101-53-1
Butoxyethyl acetate	ICID	CAS 112-07-2
C6-12 Pareth-6	CAS 68439-45-2	CAS 68439-45-2
C11-15 Pareth-9	ICID	CAS 68131-40-8 (generic)
C12-15 Pareth-7	ICID	CAS 68131-39-5 (generic)

APPROVED NAME	REFERENCE	CAS NUMBER
C12-15 Pareth-12	ICID	CAS 68131-39-5 (generic)
C12-16 Pareth-7	CAS 68551-12-2	CAS 68551-12-2 (generic)
C12-16 Pareth-9	CAS 68551-12-2	CAS 68551-12-2 (generic)
Cupric nitrate trihydrate	MI	
Decamethylcyclopentasiloxane	MI	CAS 541-02-6
Decyldimethylisononylammonium chloride	CAS 138698-36-9	CAS 138698-36-9
Dimethyldioctylammonium chloride	CAS 5538-94-3	CAS 5538-94-3
Disodium cocoamphodipropionate	ICID	CAS 68604-71-7
Dodecamethylcyclohexasiloxane	MI	CAS 540-97-6
Ethylenediamine - ethoxylated propoxylated	CAS 26316-40-5	CAS 262316-40-5
Octamethylcyclotetrasiloxane	MI	CAS 556-67-2
PEG-9 Stearate	ICID	
para-tert-Pentylphenol	MI	CAS 80-46-6
ortho-Phthalaldehyde	CAS 643-79-8	CAS 643-79-8
Pigment violet 23 CI51319	CI	CAS 6358-30-1
PPG-4 C9-11 pareth-7	ICID*	
PPG-6 C12-18 Pareth-11	ICID	CAS 69227-21-0
Propylene glycol monopropyl ether	CAS 1569-01-3	CAS 1569-01-3
Quaternium-24	ICID	CAS 32426-11-2

1.6.3 Synonyms for Device Ingredient Chemical Names List

Applicants should note that synonyms ARE NOT approved names and should NOT BE USED in applications or on labels where approved terminology is required.

The following synonyms are provided for the assistance of applicants.

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Basic violet 10 CI45170	Rhodamine B CI45170
Basic violet 10 acetate	Rhodamine B acetate
C6-C12 Ethoxylated alcohol	C6-12 Pareth-6
4-Chloro-3-methyl phenol	Chlorocresol
2-Chloro-4-(phenylmethyl)-phenol	4-Benzyl-2-chlorophenol

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Dioctyl dimethyl ammonium chloride	Dimethyldioctylammonium chloride
Ethylene glycol monobutyl ether acetate	Butoxyethyl acetate
3-[(Ethylphenylamino)methyl]benzenesulfonic acid	alpha-N-Ethylanilintoluene-3-sulphonic acid
Myristyldimethylamine oxide	Myristamine oxide
Nonylphenol polyethylene glycol ether	Nonoxinol (Chain length to be specified)
Octyl decyl dimethyl ammonium chloride	Quaternium-24
Parachlorometacresol	Chlorocresol
Pareth-25-9	C12-15 Pareth-9
Sodium cocoamphodipropionate	Disodium cocoamphodipropionate
Trimethyl hexadexyl ammonium chloride	Cetrimonium chloride

2. BIOLOGICAL SUBSTANCES

2.4 AUSTRALIAN APPROVED NAMES – BIOLOGICAL LISTS

2.4.1 Biological Substance Names List

APPROVED NAME	REFERENCE	ANIMAL ORIGIN	OTHER INFORMATION REQUIRED OR COMMENT
Agalsidase beta	INN	BIOTECH	Biotechnology descriptor required.
Anti-inhibitor coagulant complex	MAR		
Basiliximab	USAN	BIOTECH	Biotechnology descriptor required.
Becaplermin	BAN	BIOTECH	Biotechnology descriptor required.
Blood – deer	TGA99	DEER	<i>Cervus</i> spp.
Casein hydrolysate	MI*	BOVINE	
Chondroitin sulfate – bovine	CG 2000	BOVINE	
Chondroitin sulfate – bovine calcium	TGA 2000	BOVINE	
Chondroitin sulfate – bovine potassium	TGA 2000	BOVINE	
Chondroitin sulfate – bovine sodium	TGA 2000	BOVINE	
Chondroitin sulfate – shark	CG 2000	SHARK	
Chondroitin sulfate – shark calcium	TGA 2000	SHARK	
Chondroitin sulfate – shark potassium	TGA 2000	SHARK	
Chondroitin sulfate – shark sodium	TGA 2000	SHARK	
<i>Clostridium botulinum</i> type a toxin – haemagglutinin complex	TGA99	MICRO	
<i>Clostridium butyricum</i>	BMSB	MICRO	Preparation details required.
Daclizumab	BAN	HUMAN BIOTECH	Biotechnology descriptor required.
Darbepoetin alfa	USAN	BIOTECH	Biotechnology descriptor required.
Egg phosphatidylglycerol sodium	TGA99		

APPROVED NAME	REFERENCE	ANIMAL ORIGIN	OTHER INFORMATION REQUIRED OR COMMENT
Gelatin – succinylated	TGA98	BOVINE PORCINE	Animal origin required
Hepatitis B surface antigen recombinant	MAR	BIOTECH MICRO	Biotechnology descriptor required.
Immunoglobulin A - human	EP*	HUMAN	
Immunoglobulin G - human	EP*	HUMAN	
Infliximab	INN	BIOTECH	Biotechnology descriptor required.
Insulin detemir	INN	HUMAN	
Insulin glargine	INN	BIOTECH	Biotechnology descriptor required.
<i>Lactobacillus amylovorus</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus crispatus</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus gallinarum</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus gasseri</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus johnsonii</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus kefiranoferiens</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus kefirgranum</i>	IJFM	MICRO	Preparation details required.
<i>Lactobacillus parakefiri</i>	IJFM	MICRO	Preparation details required.
Lactoferrin – bovine	MI*	BOVINE	
Moroctocog alfa	INN	BIOTECH	Biotechnology descriptor required.
Mussel oil - green lipped	TGA99	MOLLUS	<i>Perna canaliculata</i>
Nonacog alfa	INN	BIOTECH	Biotechnology descriptor required.
Octocog alfa	INN	BIOTECH	Biotechnology descriptor required.
Osteogenic protein 1	TGA 2001	HAMSTER	Biotechnology descriptor required.
Peginterferon alfa-2b	TGA2001	BIOTECH	Biotechnology descriptor required.
Sodium caseinate	ICID	BOVINE	
Spider – red back	AIN	ARTHRO	<i>Latrodectus hasselti</i> . Part and/or preparation details required.
<i>Streptococcus thermophilus</i>	IJFM	MICRO	Preparation details required.
Tasonermin	INN	BIOTECH	Biological descriptor required.
Tenecteplase	INN	BIOTECH HAMSTR	Biotechnology descriptor required.
Thyrotropin alfa	INN	BIOTECH	Biotechnology descriptor required.
Trastuzumab	INN	BIOTECH	Biotechnology descriptor required.
Varicella vaccine – live	BP	MICRO	Preparation details required.

APPROVED NAME	REFERENCE	ANIMAL ORIGIN	OTHER INFORMATION REQUIRED OR COMMENT
Von Willebrand factor	BP	HUMAN	

2.4.2 Animal Codes List

ANIMAL/ ORGANISM ORIGIN CODE	ORGANISM	COMMENT
No new entries		

2.4.3 Animal Parts and Preparations Lists

2.4.3.1 Animal Parts List

ANIMAL PART	DESCRIPTION
No new entries	

2.4.3.2 Animal Preparations List

PREPARATION	DESCRIPTION
No new entries	

2.4.4 Description of Biotechnology Products List

CODE	DESCRIPTION	REFERENCE
No new entries		

2.5 AMENDMENTS AND SYNONYMS

2.5.1 Amendments to Monographs

APPROVED NAME	OLD REFERENCE	NEW REFERENCE
No new entries		

2.5.2 Synonyms for Biological Substance Names and Terms

Applicants should note that synonyms ARE NOT approved names and should NOT BE USED in applications or on labels where approved terminology is required.

The following synonyms are provided for the assistance of applicants.

2.5.2.1 Synonyms for Biological Substance Names

SYNONYM (NOT TO BE USED)	APPROVED NAME
No new entries	

2.5.2.2 Synonyms for Animal Part Names

SYNONYM (NOT TO BE USED)	APPROVED NAME
No new entries	

2.5.3 Other Changes to Entries

The following entries have had additions, deletions or changes made to the statements shown in the Comments field since the publication of the July 1999 edition. Current entries are shown.

APPROVED NAME	REFERENCE	ANIMAL ORIGIN	OTHER INFORMATION REQUIRED OR COMMENT
Aldesleukin	INN	HUMAN BIOTECH	Biotechnology descriptor required.
Desirudin	USAN	BIOTECH	Biotechnology descriptor required.
Erythropoietin	MAR*	BIOTECH	Biotechnology descriptor required.
Etanercept	TGA 99	HUMAN BIOTECH	Biotechnology descriptor required.
Gelatin	BP	BOVINE PORCINE	
Gelatin – hydrolysed	BPAP	BOVINE PORCINE	

APPROVED NAME	REFERENCE	ANIMAL ORIGIN	OTHER INFORMATION REQUIRED OR COMMENT
Glucagon	BP	BOVINE PORCIN BIOTECH	Biotechnology descriptor required.
Glucagon hydrochloride	BP*	BOVINE PORCIN BIOTECH	Biotechnology descriptor required.
Imiglucerase	INN	HUMAN BIOTECH	Biotechnology descriptor required.
Influenza virus proteins	TGA	MICRO BIOTECH	Biotechnology descriptor required.
Insulin aspart	INN	HUMAN BIOTECH	Biotechnology descriptor required.
Lactoferrin	MI	HUMAN	PRV
Lepirudin	INN	BIOTECH	Biotechnology descriptor required.
<i>Vibrio cholerae</i>	BMSB Vol. 1	MICRO BIOTECH	Preparation details required. Biotechnology descriptor required.

3. HERBAL SUBSTANCES

3.3 HERBAL SUBSTANCES AAN LIST

3.3.2 Herbal Substances AAN List

3.4 HERBAL SUBSTANCES INDEX OF COMMON NAMES

3.5 HERBAL SUBSTANCES PLANT PARTS AAN LIST

3.5.2 Herbal Substances Plant Parts AAN List

3.6 HERBAL SUBSTANCES PLANT PREPARATIONS AAN LIST

3.6.2 Herbal Substances Plant Preparations AAN List

3.7 HERBAL COMPONENTS AAN LIST

APPROVED HERBAL COMPONENT NAME	APPROVED LABEL HCN	HCN or AAN	NAME REFERENCE	CHEMISTRY REFERENCE
arecoline	-	HCN	MI	MI
bacosides calculated as bacoside A (of <i>Bacopa monnieri</i>)	-	HCN	TGA 99(O3)	TGA 99(O3)
caffeoylquinic acids calculated as cynarin (of <i>Cynara scolymus</i>)	-	HCN	TGA 2000(18)	TGA 2000(18)
L-canavanine (of <i>Medicago sativa</i>)	-	HCN	TGA 2000(15)	TGA 2000(15)
dibenzocyclooctadiene lignans calculated as gamma-schisandrins (of <i>Schisandra chinensis</i> fruit)	-	HCN	TGA 2000 (16)	TGA 2000 (16)
ginsenosides Rg1, Re, Rf, Rb1, Rc, Rb2 and Rd (of <i>Panax quinquefolium</i>)	-	HCN	TGA 2000 (18)	TGA 2000 (18)
gluten	-	HCN	TGA 2000 (17)	TGA 2000 (17)

oil (of <i>Syzygium aromaticum</i>)	-	HCN	TGA 2000 (17)	TGA 2000 (17)
oil (of <i>Tanacetum vulgare</i>)	-	HCN	TGA 2000 (17)	TGA 2000 (17)
picrotoxin	-	HCN	MI	MI
podophyllin	-	HCN	MI	MI
scutellarin (of <i>Scutellaria lateriflora</i>)	-	HCN	MI	MI
sparteine	-	HCN	MI	MI
triterpenes: asiaticoside, asiatic acid and madecassic acid (of <i>Centella asiatica</i>)	selected triterpenes	HCN	TGA 2000 (O5)	TGA 2000 (O5)
volatile oil components (of <i>Armoracia rusticana</i>)	-	HCN	TGA 2000 (17)	TGA 2000 (17)
volatile oil components (of <i>Chenopodium ambrosioides</i>)	-	HCN	TGA 2000 (17)	TGA 2000 (17)
volatile oil components (of <i>Mentha pulegium</i>)	-	HCN	TGA 2000 (17)	TGA 2000 (17)
volatile oil components (of <i>Peumus boldus</i>)	-	HCN	TGA 2000 (17)	TGA 2000 (17)

CHAPTER 2 – AUSTRALIAN APPROVED TERMS FOR USE IN THE COMPLETION OF APPLICATIONS FOR THE REGISTRATION OR LISTING OF THERAPEUTIC GOODS

4. CONTAINER TYPES

The following approved terms are to be used to specify container types when making applications for the registration/listing of drug products.

Only those container types designated “L” in the “Listable” column can be specified in an application to list medicines for supply in Australia.

Note

1. The definitions of container types are intended to be independent of the material used to fabricate the container and the size of the container, although the examples may refer to specific materials.
2. The definitions of container type are for guidance. Not all container types have formal definitions where the meaning of the term is well understood.

CONTAINER TYPE	DESCRIPTION	LISTABLE
No new entries		

5. DOSAGE FORMS

5.1 SYNONYMS FOR DOSAGE FORMS

Applicants should note that synonyms ARE NOT approved names and should NOT BE USED in applications or on labels where approved terminology is required.

The following synonyms are provided for the assistance of applicants.

SYNONYM (NOT TO BE USED)	APPROVED DOSAGE FORM NAME (TO BE USED)
No new entries	

5.2 APPROVED DOSAGE FORM NAMES

Where there is more than one subtype of a dosage form (eg. capsule), the general description is shown at the start of the relevant entries. The general term for the dosage form is in **BOLD CAPITALS** and its description is in **bold**. The definitions of the subtypes should be read in the context of this general description.

DOSAGE FORM	DESCRIPTION	LISTABLE
Spray, Nasal	A liquid preparation for application, after dispersion with a suitable device, other than an aerosol, to the mucous membrane of the nose.	L

6. ROUTES OF ADMINISTRATION

The following approved terms are to be used to specify route of administration when making applications for the registration/listing of drug products.

Only those dosage forms designated “L” in the “Listable” column can be specified in an application to list drugs for supply in Australia.

ROUTE OF ADMINISTRATION	DESCRIPTION	LISTABLE
Intracranial	Within the cranium	

7. UNITS AND EXPRESSION OF PROPORTION

The following approved terms are to be used for units and expressions of proportion when making applications for the registration/listing of drug products.

Only those dosage forms designated “L” in the “Listable” column can be specified in an application to list drugs for supply in Australia.

DESCRIPTION	UNIT/PROPORTION	LISTABLE
MASS		
picogram	picogram	L
picogram/gram	picogram/g	L
picogram/milligram	picogram/mg	L

DESCRIPTION	UNIT/PROPORTION	LISTABLE
picogram/millilitre	picogram/mL	L
VOLUME		
No new entries		
MOLECULAR EQUIVALENTS		
No new entries		
INTERNATIONAL UNITS		
International Unit/litre	IU/L	L
million International Units/gram	million IU/g	L
million International Units/milligram	million IU/mg	L
million International Units/millilitre	million IU/mL	L
RADIOACTIVITY		
No new entries		
MICROBIOLOGICAL CULTURE		
Billion organisms/milligram	billion organisms/mg	L
Million Colony Forming Units	million CFU	L
Million Colony Forming Units/gram	million CFU/g	L
Million Colony Forming Units/milligram	million CFU/mg	L
Million Colony Forming Units/millilitre	million CFU/mL	L
Million organisms/milligram	million organisms/mg	L
Thousand organisms/milligram	thousand organisms/mg	L
Tuberculin Unit/millilitre	tuberculin unit/mL	
BIOLOGICAL UNITS		
anti-Thrombin Unit	ATU	
anti-Thrombin Unit/gram	ATU/g	
anti-Thrombin Unit/milligram	ATU/mg	
anti-Thrombin Unit/millilitre	ATU/mL	
HOMOEOPATHIC UNITS		

DESCRIPTION	UNIT/PROPORTION	LISTABLE
No new entries		
IMPREGNATED DRESSINGS		
No new entries		

[This form may be photocopied]

**PROPOSED NAME FOR A CHEMICAL SUBSTANCE USED
IN THERAPEUTIC GOODS
APPLICATION FORM**

Proposed Name	
Synonym(s)
For inclusion as (tick as appropriate):	<input type="checkbox"/> Chemical Australian Approved Name (AAN) <input type="checkbox"/> Provisional Name (PRV) <input type="checkbox"/> Australian Approved Device Name (ADN)
Definition or structure (including waters of hydration)	

OFFICE USE ONLY

Committee Session		Approval Type	
Date Approved		Listable Active	
Date Entered		Listable Excipient	

REFERENCE(S)

Indicate references **searched**. If successful mark with a tick, if unsuccessful mark with a cross. ATTACH COPIES of relevant MONOGRAPHS or REFERENCES. Further guidance can be obtained from the explanatory notes in the Introduction and Explanatory Notes Chemical Substances AAN List #####.

✓ x	Ref. Code	Edition, Year, Vol. no	Page(s)	Reference
	BP			British Pharmacopoeia
	INN			International Nonproprietary Names
	BAN			British Approved Names
	USP			United States Pharmacopeia
	USAN			United States Adopted Name
	BPAP			British Pharmacopoeia - Appendix

✓ x	Ref. Code	Edition, Year, Vol. no	Page(s)	Reference
	EP			European Pharmacopoeia
	IP			International Pharmacopoeia
	BPC			The Pharmaceutical Codex (formerly British Pharmaceutical Codex)
	MAR			Martindale, The Extra Pharmacopoeia
	MI			Merck Index
	FCC			Food Chemicals Codex
	PFC			Perfumes and Flavour Chemicals
	ICID			International Cosmetic Ingredient Dictionary (formerly CTFA)
	CAS			Chemical Abstracts Service
	CI			Colour Index (Society of Dyers and Colourists)
	CFFM			Common Fragrance and Flavour Materials
	HPUS			The Homoeopathic Pharmacopoeia of the United States
				Other (specify)

DETAILS OF PROPOSER

Company Name		ENTID	
Proposer Name		Phone No	
Address	Fax No	
	The substance is an (tick one)	
	[] active ingredient	
	[] excipient ingredient	
Product Name	The ingredient is to be included in a product to be assessed by:	
	[] Aust. Listed Drug [] Export Drug	
	[] OTC Reg. [] DSEB Reg.	
	[] Complementary Medicines	
	[] ARTG (Proprietary Ingredients)	
		[] Devices	

✓ x	Ref. Code	Edition, Year, Vol. no	Page(s)	Reference
	VIR			Murphy, F.A. <i>et al. Virus Taxonomy</i> (6 th Report of the ICTV)
	IP			International Pharmacopoeia
	BPC			The Pharmaceutical Codex (formerly British Pharmaceutical Codex)
	MAR			Martindale, The Extra Pharmacopoeia
	MI			Merck Index
	FCC			Food Chemicals Codex
	PFC			Perfumes and Flavour Chemicals
	ICID			International Cosmetic Ingredient Dictionary (formerly CTFA)
	CAS			Chemical Abstracts Service
	AAT			Sutherland, S. <i>Australian Animal Toxins.</i>
	AFS			Australian Food Standard
	ACLH			ATCC Cell Lines and Hybridomas (8 th Edition, 1994)
	C			Bensky, D. and Gamble, A. <i>Chinese Herbal Medicine, Materia Medica</i>
	HPUS			The Homoeopathic Pharmacopoeia of the United States
	WMW			Nowak, R.M. and Paradiso, J.L. (Editors) <i>Walker's Mammals of the World</i> (4th Edition) Baltimore, John Hopkins 1983
	AIN			Naumann, I. <i>CSIRO Handbook of Australian Insect Names</i>
	MDF			Multilingual Dictionary of Fish
	CFFM			Bauer, K. <i>et al. Common Fragrance and Flavor Materials</i>
	HBW			del Hoyo <i>et al. Handbook of Birds of the World</i> Volumes 1-4
				Other (specify)

DETAILS OF PROPOSER

Company Name		ENTID	
Proposer Name		Phone No	
Address	Fax No	
	The substance is an (tick one) <input type="checkbox"/> active ingredient <input type="checkbox"/> excipient ingredient	
Product Name	The product is to be evaluated by:	
	<input type="checkbox"/> Aust. Listed Drug <input type="checkbox"/> Export Drug <input type="checkbox"/> OTC Reg. Drug <input type="checkbox"/> DSEB Reg. Drug <input type="checkbox"/> Complementary Medicines <input type="checkbox"/> Devices	

[This form may be photocopied]

PROPOSED BOTANICAL NAME FOR A HERB USED IN THERAPEUTIC GOODS APPLICATION FORM

Send to:
The Herb Names Co-ordinator
Chemicals & Non-Prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

This form may be photocopied. A double sided
copy is preferred.

These applications are assessed by the Therapeutic
Goods Administration Herb Names Co-ordinator

PROPOSED BOTANICAL SPECIES-AHN*

.....
genus species botanical authority

Other Names for this Herb

Common names:

.....

Other botanical names:

.....

Comments:

Is the proposed species-AHN in the Herbal Substances AAN List? Yes No

Is any other botanical name for this herb in the Herbal Substances AAN List? Yes No

Person Proposing Name

Sole trader/Employee/Agent:

Company: Enterprise ID:

Address:

Telephone: Facsimile:

Product Name

.....

If in ARTG: AUST L/R: File: 9 /

..

A COPY OF THE SUPPORTING MATERIAL MUST BE ATTACHED see over page

Supporting Material Attached by Person Proposing Name (author, title, year, page)

(1)

(2)

(3)

OFFICE USE ONLY

<p>Species-AHN</p> <hr/> <p>Classification & Distribution HSAL bot syn:</p> <p>HSAL common name:</p> <p>Family: <input type="checkbox"/> Angiosperm Distribution:</p>	<p>Comments</p> <hr/> <p>Product File: AUST L/R:</p> <p>List/Reg name:</p>
---	---

<p>Product</p> <p><input type="checkbox"/> under evaluation</p> <p><input type="checkbox"/> approved – new</p> <p><input type="checkbox"/> approved – Grand.</p>	<p><input type="checkbox"/> Listing</p> <p><input type="checkbox"/> Registration</p> <p><input type="checkbox"/> Export only</p> <p><input type="checkbox"/> Clinical trial</p>	<p>Herbal Ingredient</p> <p><input type="checkbox"/> active</p> <p><input type="checkbox"/> excipient</p> <p><input type="checkbox"/> excip. in prop. ingred.</p>
---	---	--

<p>References</p> <p><input type="checkbox"/> PI CSIRO LC date:</p> <p><input type="checkbox"/> MAB87 p</p> <p><input type="checkbox"/> HOR76 p</p> <p><input type="checkbox"/> PER80 p</p> <p><input type="checkbox"/> HPUS92 p</p> <p><input type="checkbox"/> UPH68 p</p> <p><input type="checkbox"/> POT88 p</p> <p><input type="checkbox"/> PEN82 p</p>	<p><input type="checkbox"/> BP 98, 93, 88 p</p> <p><input type="checkbox"/> USP 23, 22 p</p> <p><input type="checkbox"/> CCFM90 p</p> <p><input type="checkbox"/> COL90 p</p> <p><input type="checkbox"/> SAL90 p</p> <p><input type="checkbox"/> BHP83 p</p> <p><input type="checkbox"/> CHA89 p</p> <p><input type="checkbox"/> MAR 31, 30, 29 p</p> <p><input type="checkbox"/> MI11 p</p> <p><input type="checkbox"/> ABOR88 p</p> <p><input type="checkbox"/> BEN86 p</p>	<p><input type="checkbox"/> DUK85 p</p> <p><input type="checkbox"/> DAY85 p</p> <p><input type="checkbox"/> LAS84 p</p> <p><input type="checkbox"/> BHP83 p</p> <p><input type="checkbox"/> NAD82 p</p> <p><input type="checkbox"/> FCC381 p</p> <p><input type="checkbox"/> BPC79 p</p> <p><input type="checkbox"/> HPUS79 p</p> <p><input type="checkbox"/> BUR66 p</p> <p><input type="checkbox"/> GRI31 p</p>
--	---	---

Received	Date
PO2:	/ /
Review Outcome	Date
Reviewer:	
<input type="checkbox"/> not suitable:	/ /
<input type="checkbox"/> incomplete:	/ /
<input type="checkbox"/> accepted – prod Grand.	/ /
<input type="checkbox"/> accept when prod approv	/ /

Action	Date
<input type="checkbox"/> PO2 notified	/ /
<input type="checkbox"/> Sponsor notified	/ /
<input type="checkbox"/> Entered HSAL by	/ /
<input type="checkbox"/> Entered Sys Table by	/ /

[This form may be photocopied]

PROPOSED NAME FOR A HERBAL SUBSTANCE USED IN THERAPEUTIC GOODS APPLICATION FORM

Send to:
The Herb Names Co-ordinator
Chemical & Non-Prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

This form may be photocopied. A double sided copy is preferred.
These applications are assessed by the Therapeutic Goods Administration Herb Names Co-ordinator

PROPOSED HERBAL SUBSTANCE-AHS*

.....

substance-AHS pharmacopoeial reference

Other Names for this Substance

.....

.....

Herbal Substance Identity

Botanical name:

Plant part used:

Preparation:

Is the botanical name in the Herbal Substances AAN List as a species-AHN? [] yes [] no
 - if 'no', attach a completed Proposed Botanical Name form.

Is the proposed substance-AHS in the Herbal Substances AAN List? [] yes [] no

Is there another name for this substance in the Herbal Subst. AAN List? [] yes [] no
 - search under the species-AHN and the genus

Person Proposing Name

Sole trader/Employee/Agent:

Company: Enterprise ID:

Address:

Telephone: Facsimile:

Product Name

.....

If in ARTG: AUST L/R: File: 9 /

..

* A COPY OF THE SUPPORTING MATERIAL MUST BE ATTACHED see over page

Supporting Material Attached by Person Proposing Name (pharmacopoeia, year, page)

(1)

(2)

(3)

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Substance-AHS
Substance-AHS Description
Sp-AHN:
Part-AAN:
Prep-AAN:

Comments
Product File: AUST L/R:
List/Reg name:

Product	<input type="checkbox"/> Listing	Herbal Ingredient
<input type="checkbox"/> under evaluation	<input type="checkbox"/> Registration	<input type="checkbox"/> active
<input type="checkbox"/> approved – new	<input type="checkbox"/> Export only	<input type="checkbox"/> excipient
<input type="checkbox"/> approved - Grand.	<input type="checkbox"/> Clinical trial	<input type="checkbox"/> excip. in prop. ingred.

Approved Pharmacopoeias	
<input type="checkbox"/> BP98, BP93, BP88, BP80, BPAD	p
<input type="checkbox"/> BHP 90, 83, 76	p
<input type="checkbox"/> USP23/NF18, USP22, USP21	p
<input type="checkbox"/> FCC3 – Suppl 1, 2, 3	p
<input type="checkbox"/> BPC 79, 73, 68, 63, 59, 54, 49, 34	p

Related Monographs	
<input type="checkbox"/> HPUS92	p
<input type="checkbox"/> EP2-92	p
<input type="checkbox"/> CFFM90	p
<input type="checkbox"/> MAR 31, 29, 28	p
<input type="checkbox"/> MI11	p
<input type="checkbox"/> Other:	p

Received	Date
PO2:	/ /
Review Outcome	Date
Reviewer:	
<input type="checkbox"/> not suitable:	/ /
<input type="checkbox"/> incomplete:	/ /
<input type="checkbox"/> accepted – prod Grand.	/ /
<input type="checkbox"/> accept when prod approv	/ /

Action	Date
<input type="checkbox"/> PO2 notified	/ /
<input type="checkbox"/> Sponsor notified	/ /
<input type="checkbox"/> Entered HSAL by	/ /
<input type="checkbox"/> Entered Sys Table by	/ /

Supporting Material Attached by Person Proposing Name (pharmacopoeia, year, page)

HCN Chemical Structure Reference(s):

(1)

(2)

Other References:

(1)

(2)

OFFICE USE ONLY

ARTG - HCN

ELF Entry

Label - HCN

Name reference

Chemical Struct Ref.

HSAL Cross-references

Component present in:

Sp-AHN:

Part-AAN:

Prep-AAN:

Comments

Approved References

BP99, 98, 93, 88, 80, BPAD p

MI 12, 11 p

USP23/NF18, USP22, USP21 p

BHC 92 p

BHP 96, 90, 83, 76 p

FCC3 – Suppl 4, 3, 2, 1 p

BPC 79, 73, 68, 63, 59, 54, 49, 34 p

Other references

HPUS93 p

EP2-92 p

CFFM90 p

MAR 31, 30, 29, 28 p

Other: p

Received by	Date
Officer	/ /
Review	Date
Reviewer: HINC	/ /
Outcome	
<input type="checkbox"/> accepted	/ /
<input type="checkbox"/> accepted pending *	/ /
<input type="checkbox"/> not suitable*	/ /
<input type="checkbox"/> incomplete*	/ /
* reason :	

Action	Date
<input type="checkbox"/> Applicant notified	/ /
<input type="checkbox"/> ARTG PO's notified	/ /
<input type="checkbox"/> CNPD PO's notified	/ /
<input type="checkbox"/> Entered ELF	/ /
by	
<input type="checkbox"/> Entered HSAL	/ /
by	

[This form may be photocopied]

**PROPOSED NAME FOR A PLANT FOOD
USED IN THERAPEUTIC GOODS
APPLICATION FORM**

Send to:
The Herb Names Co-ordinator
Chemicals & Non-Prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

This form may be photocopied. A double sided copy is preferred.
These applications are assessed by the Therapeutic Goods Administration Herb Names Co-ordinator

PROPOSED FOOD-AFN*

.....

Other Names for this Food

.....

Food Substance Identity

Botanical name(s):

Plant part(s) used:

Preparation(s) fresh dry powder fixed oil
 juice fresh juice dry juice concentrate

Are all the botanical name(s) in the Herbal Substances AAN List as species-AHNs? yes no
- if 'no', attach a completed Proposed Botanical Name form(s).

Is the proposed food-AFN in the Herbal Substances AAN List? yes no

Is there another name for this food in the Herbal Substances AAN List? yes no

- search under the species-AHN and the genus

Person Proposing Name

Sole trader/Employee/Agent:

Company: Enterprise ID:

Address:

Telephone: Facsimile:

Product Name

.....

If in ARTG: AUST L/R: File: 9 /

* A COPY OF THE SUPPORTING MATERIAL MUST BE ATTACHED see over page

Supporting Material Attached by Person Proposing Name (author, title, year, page)

Attach evidence of the botanical name of each plant species and the part used.
Only if requested, also provide evidence of common food use in Australia.

(1)

(2)

(3)

OFFICE USE ONLY

Food-AFN
Comments

Plant Food Description
Sp-AHN(s):
Plant part-AAN(s):
Preparation-AAN(s):

Product	File:
	AUST L/R:
List/Reg name:	

Food Description & Use References	
<input type="checkbox"/> PI CSIRO LC	date:
<input type="checkbox"/> Hartley 79 CSIRO Econ Plants	p
<input type="checkbox"/> HOR76	p
<input type="checkbox"/> UPH68	p
<input type="checkbox"/> Food Plants 85	p

Product	<input type="checkbox"/> Listing	Herbal Ingredient
<input type="checkbox"/> under evaluation	<input type="checkbox"/> Registration	<input type="checkbox"/> active
<input type="checkbox"/> approved – new	<input type="checkbox"/> Export only	<input type="checkbox"/> excipient
<input type="checkbox"/> approved] Grand.	<input type="checkbox"/> Clinical trial	<input type="checkbox"/> excip. in prop. ingred.

Received	Date
PO2:	/ /
Review Outcome	Date
Reviewer:	
<input type="checkbox"/> not suitable:	/ /
<input type="checkbox"/> incomplete:	/ /
<input type="checkbox"/> accepted – prod Grand.	/ /
<input type="checkbox"/> accept when prod approv	/ /

Action	Date
<input type="checkbox"/> PO2 notified	/ /
<input type="checkbox"/> Sponsor notified	/ /
<input type="checkbox"/> Entered HSAL	/ /
by	
<input type="checkbox"/> Entered Sys Table	/ /
by	

[This form may be photocopied]

PROPOSED NAME TO BE USED TO NAME MEDICINAL INGREDIENTS ON LABELS OF THERAPEUTIC GOODS APPLICATION FORM

Proposed Label-AAN		
Approved Name(s) and Approval Types (AAN, ABN etc) to Which This Label-AAN Refers	Approved Name	Approval Type

For inclusion as a Label-AAN for (tick as appropriate):	<input type="checkbox"/> Excipient Group for Schedule 1 Medicines Labelling Order <input type="checkbox"/> New Complementary Substance <input type="checkbox"/> Lengthy Approved Name	

OFFICE USE ONLY

Committee Session		Approval Type	
Date Approved		Date Entered	

CONDITIONS ATTACHING TO APPROVAL (if any)

.....

.....

.....

.....

DETAILS OF PROPOSER

Company Name		ENTID	
Proposer Name		Phone No	
Address	Fax No

[This form may be photocopied]

PROPOSAL FOR APPROVED NAME(S) TO BE ADDED TO A LABEL-AAN GROUP APPLICATION FORM

Proposed Approved Name(s) and Approval Types (AAN, ABN etc) to be Added to the Group to Which the Label-AAN Refers	Approved Name	Approval Type

Label-AAN to Which the Name(s) Should be Added		
Reason for inclusion in the Label-AAN Group (tick as appropriate):	<input type="checkbox"/> Excipient Group for Schedule 1 Medicines Labelling Order <input type="checkbox"/> New Complementary Substance <input type="checkbox"/> Lengthy Approved Name	

OFFICE USE ONLY

Committee Session		Approval Type	
Date Approved		Date Entered	

DETAILS OF PROPOSER

Company Name		ENTID	
Proposer Name		Phone No	
Address	Fax No