



Notice

Our file number: 12-118879-948

Listing of Drugs Currently Regulated as New Drugs (The New Drugs List)

The Therapeutic Products Directorate (TPD) has completed an assessment to determine whether *the Listing of Drugs Currently Regulated as New Drugs* (also known as the *New Drugs List*) should be updated or removed entirely from the Health Canada website. This is to notify sponsors that the list will not be updated to include any new substances or formulations. The 1999 version, with changes, will remain on the website since those substances and formulations have already been determined to be new drugs. The changes include: the deletion of one substance that was removed from the Canadian market due to safety reasons, the deletion of footnotes that are no longer applicable and the addition of footnotes identifying substances that were previously considered to be in new drug status but are now acceptable when used as a non-medicinal ingredient (NMI) in topical cosmetic-like drug products. The addition of footnotes will assist in decreasing the regulatory burden for stakeholders as well as to improve consistency in approaches between the TPD, the Natural Health Products Directorate (NHPD) and the Cosmetics Program.

Background:

The *New Drugs List* is an administrative list posted on the Health Canada website that represents substances or formulations in prescription and nonprescription drug products pursuant to an application to market. The list is used by TPD and external stakeholders as a guide in determining the type of submission to be filed pursuant to Division 1 only or Division 8 and the appropriate section of Division 1 in Part C of the *Food and Drug Regulations* for a subsequent market entry drug product.

The *New Drugs List* posted on the Health Canada website has not been updated since 1999. With the increasing workload and limited resources in TPD, updating and the annual maintenance of a list which is not all encompassing or up-to-date at any given time were not considered an efficient use of resources.

Sponsors currently have access to other sources on the Health Canada website to assist them in making drug status assessments for subsequent market entry drug products. For information on any new drugs approved since 1999, the [Notice of Compliance \(NOC\) Listings](#) and the [Notice of Compliance \(NOC\) database](#) can be used to determine whether the Canadian Reference product

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was granted market authorization through the issuance of an NOC. The approved Product Monograph in the [Drug Product Database](#) (DPD) can be consulted to determine the approved indication(s) for the reference product. If the information from these sources is not sufficient to make such an assessment, sponsors can submit a drug status request to the Regulatory Project Management Division servicing the applicable bureau to inquire what type of submission should be filed.

Questions regarding this notice should be directed to:

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LISTING OF DRUGS CURRENTLY REGULATED AS NEW DRUGS

This list represents substances and formulations which have been assessed by the Therapeutic Products Directorate on the basis of an application to market or further to promotion of products for medicinal purposes where safety and efficacy for such purposes have not been established. Certain substances have been considered to be new drugs regardless of their use as a medicinal or non-medicinal ingredient in drug products.

This listing is not all-encompassing due in part to the complexity of Division 8 of the *Food and Drug Regulations*. It should be used as a guide only in determining the status of subsequent market entry drug products.

“drug” includes any substance or mixture of substances manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

(Section 2 of the *Food and Drugs Act*)

“new drug” means

- (a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;
- (b) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or
- (c) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

(Division 8 of the *Food and Drugs Regulations*)

Please note: Unless otherwise indicated, all dosage forms and routes are included.

Substances which may otherwise be a Natural Health Product remain on the list as they would be considered a new drug if a submission is filed with Therapeutic Drugs Directorate (TPD) or if they are included in “Schedule 2-Excluded Natural Health Substances” of the *Natural Health Products Regulations*.

REVISED

September 2012

Drug	Form/Route
Acarbose	
Acebutolol and its salts	
Acetaminophen	rectal suppository
Acetaminophen/Belladonna	
Acetaminophen/Butalbital	
Acetaminophen/Butalbital/Caffeine	
Acetaminophen /Butalbital/ Caffeine / Codeine	
Acetaminophen/Butalbital/Codeine	
Acetaminophen/Diphenhydramine (as asleep aid)	
Acetaminophen/Pseudoephedrine (for the treatment of earache)	
Acetylcysteine (mucolytic, antidote for acetaminophen poisoning)	
Acetylene/Carbon Monoxide/Methane/ Nitrogen/Oxygen	
Acetylsalicylic Acid (Anti-platelet)	
Acetylsalicylic Acid/ Diphenhydramine (as a sleep aid)	
Acitretin	
Acyclovir and its salts	
Adenosine and its salts ²	
Adapalene	
Alatrofloxacin and its salts	

Alclometasone and its salts	
Alfentanil and its salts	
Alkyl Salicylates	Spray or Aerosol - as per I.L. 659
Allopurinol	
Alprazolam	
Alteplase	
Altretamine	
Amantadine and its salts	
Amcinonide	
Amikacin and its salts	
Amiloride and its salts	
Amino Acids [Tryptophan, Arginine, Ornithine, Phenylalanine, Tyrosine, Lysine, Carnitine, Methionine (other than Lipotropic Factor)] ¹	
Amino Acids (Total Parenteral Nutrition Products)	injection
Aminocaproic Acid	
Aminoglutethemide	
Aminophylline	suppository, oral modified release preparation
Aminosalicylic Acid (5-)	
Amiodarone and its salts	
Amitriptyline/Perphenazine	
Amlodipine and its salts and esters	
Ammonium Chloride (single active ingredient) ²	
Ammonium Molybdate	
Amodiaquine	
Amoxicillin and its salts	

Amphotericin B	
Amrinone and its salts	
Anagrelide and its salts	
Anastrozole	
Apomorphine and its salts	
Apraclonidine and its salts	
Aprotonin	
Articaine and its salts	
Articaine HCl/Epinephrine	
Asparaginase ⁷	
Aspartates ²	
Astemizole	
Atenolol and its salts	
Atorvastatin and its salts	
Atovaquone	
Atracurium and its salts and esters	
Atropine and its salts	oral tablet
Auranofin	
Azathioprine and its salts	
Azelaic Acid ⁴	
Azithromycin and its salts	
Aztreonam and its salts	
Baclofen and its salts	
Bambuterol and its salts	
Beclomethasone and its salts	
Benazepril and its salts	
Benzalkonium Chloride ⁷ /Boric Acid ⁷	

Benzoyl Peroxide/Erythromycin	
Benzoyl Peroxide/Titanium Dioxide ⁷	
Benzydamine and its salts	
Betahistine and its salts	
Betaine Anhydrous (for the treatment of homocystinuria)	
Betamethasone and its salts	rectal enema, injection
Betamethasone Dipropionate/Clotrimazole	
Betamethasone/Gentamicin	ophthalmic/otic
Betaxolol and its salts	
Bezafibrate	
Bicalutamide	
Biperiden and its salts	
Bismuth subcitrate (when used in combination to eradicate H. Pylori)	
Bisoprolol and its salts	
Bleomycin and its salts	
Boron ⁷	oral
Bretylium Tosylate	
Brimonidine and its salts	
Brinzolamide	
Bromazepam and its salts	
Bromocriptine and its salts	
Budesonide	
Bumetanide and its salts	
Bupivacaine and its salts	
Buprenorphine and its salts	
Bupropion and its salts	

Buserelin and its salts	
Buspirone and its salts	
Butenafine and its salts	
Butorphanol and its salts	
Caffeine ⁷ /Ephedrine ⁷	
Calcipotriol	
Calcitonin Salmon Synthetic	
Calcitriol	
Calcium Acetate ⁷ (for the control of hyperphosphatemia)	
Calcium Carbaspirin	
Calcium Glycerophosphate ⁷	injection
Calcium Polystyrene Sulphonate	
Candesartan Cilexetil	
Capecitabine	
Caprylic Acid ²	
Captopril and its salts	
Carbamazapine	
Carbetocin	
Carbidopa and its salts	
Carbocysteine	
Carbon Monoxide/Methane/Nitrogen/Oxygen	
Carboplatin	
Carboprost and its salts	
Carvedilol	
Cefaclor	
Cefadroxil	
Cefazolin and its salts	

Cefdinir	
Cefepime and its salts	
Cefixime and its salts	
Cefonicid and its salts	
Cefotaxime and its salts	
Cefotetan and its salts	
Cefoxitin and its salts	
Cefpodoxime and its salts	
Cefprozil	
Ceftazidime	
Ceftibuten Dihydrate	
Ceftizoxime and its salts	
Cefuroxime	
Centella ²	
Cephalexin (Monohydrate)	
Cephalothin and its salts	
Cerivastatin	
Cetirizine and its salts	
Chitosan ²	
Chloramphenicol	tablet
Chloramphenicol/Hydrocortisone/Butoxyethylnicotinate	topical
Chlordiazepoxide/Clidinium and its salts	
Chlorhexidine and its salts ⁷	oral rinse and dental solution
Chlormezanone	
Cholestyramine Resin	
Choline Theophyllinate	
Chondroitin and its salts ²	

Chromic Chloride	injection
Chromium Chloride Hexahydrate	injection
Chymopapain ⁷	
Ciclopirox and its salts	
Cilazapril and its salts	
Cimetidine and its salts	
Ciprofloxacin and its salts	
Cisapride	
Cisatracurium and its salts	
Cisplatin	
Citalopram and its salts	
Cladribine	
Clarithromycin	
Clindamycin and its salts	
Clobazam and its salts	
Clobetasol and its salts	
Clodronic Acid and its salts	
Clofibrate	
Clomiphene and its salts	
Clomipramine and its salts	
Clonazepam and its salts	
Clonidine and its salts	
Clopidogrel and its salts	
Clorazepic Acid and its salts	
Clotrimazole	
Clozapine and its salts	
Co-enzyme Q-10 (other than as source of Co-enzyme Q-10 or Ubiquinone) ²	

Co-Trimoxazole	
Codeine Polistirex/Chlorpheniramine Polistirex	
Codeine Sulphate	oral modified release
Colestipol and its salts	
Colfosceril Palmitate	
Coryceptin (Jing Ahi Dongchongxiacao)	
Cromolyn and its salts	
Cupric Sulfate ⁷	injection
Cyclobenzaprine and its salts	
Cyclosporine	
Cyproterone and its salts	
Cytarabine and its salts	
Dacarbazine	
Dalteparin and its salts	
Danaparoid and its salts	
Danazol and its salts	
Dantrolene and its salts	
Dapiprazole and its salts	
Daunorubicin and its salts	
Deferoxamine and its salts	
Delavirdine and its salts	
Deprenyl and its salts	
Desflurane	
Desipramine and its salts	
Desmopressin and its salts	
Desonide and its salts	
Desoximetasone	

Devil's Claw ⁷ (as anti-inflammatory/analgesic)	
Dexamethasone (in combination)	ophthalmic / otic preparation
Dexfenfluramine and its salts	
Dexrazoxane	
Dextran ⁷	liquid intravenous (IV)
Dextrothyroxine and its salts	
Diatrizoic Acid and its salts	
Diazepam	
Dibenzozide	
Diclofenac and its salts	
Didanosine and its salts and derivatives	
Diethylpropion and its salts	
Diflucortolone and its salts	
Diflunisal and its salts	
Dihydroepiandrosterone (DHEA) (Prasterone) ³	
Dihydroergotamine and its salts	nasal
Diltiazem and its salts	
Dimenhydrinate	chewing gum
Dimethylglycine (DMG) ⁷	
Dimethyl Sulfoxide	
Dinoprostone	
Diphenidol and its salts	
Diphenoxylate and its salts	
Dipivefrin and its salts	
Dipyridamole	
Dirithromycin	
Disopyramide and its salts	

Divalproex and its salts	
Dobutamine and its salts	
Docetaxel	
Docosahexanoic Acid (DHA)	
Dolasetron and its salts	
Domperidone and its salts	
Dong Quai ⁷	
Dopamine and its salts	
Doxacurium and its salts	
Doxapram and its salts	
Doxazosin and its salts	
Doxepin and its salts	
Doxorubicin and its salts	
Doxycycline and its salts	
Doxylamine Succinate (night time sleep aid)	
Droperidol and its salts	
Echothiophate Iodide	
Econazole and its salts	
Edetic Acid and its salts ⁷	injection
Edoxudine	
Edrophonium and its salts	
Eicosapentaenoic Acid (EPA) ^{3,7}	
Electrolytes (Total Parenteral Nutrition Products)	
Emedastine and its salts	
Enalapril and its salts	
Enalaprilat and its salts	
Enflurane	

Enoxacin and its salts	
Enoxaparin and its salts	
Epirubicin and its salts	
Epoprostenol and its salts	
Erythromycin	topical
Erythromycin (prophylaxis of neonatal chlamydial conjunctivitis)	ophthalmic
Erythromycin Ethylsuccinate/Sulfisoxazole	
Esmolol and its salts	
Estazolam	
Estradiol and its salts	
Estramustine and its salts	
Estrogens / Progestogens	
Ethambutol and its salts	
Ethinyl Estradiol	
Etidronic Acid and its salts	
Etidronate Disodium/Calcium Carbonate ⁷	
Etodolac	
Etoposide and its salts	
Evening Primrose Oil	
Famciclovir	
Famotidine and its salts	
Fat Emulsion (Total Parenteral Nutrition Products)	
Felodipine and its salts	
Fenfluramine and its salts	
Fenofibrate	
Fenoterol and its salts	

Fentanyl and its salts	
Fenticonazole	
Ferulic Acid ²	
Fexofenadine and its salts	
Finasteride	
Flecainide and its salts	
Fleroxacin	
Floctafenine	
Fluconazole	
Flucytosine	
Fludarabine and its salts	
Fludrocortisone and its salts	
Flumazenil	
Flumethasone/Iodochlorohydroxyquin	
Flunarizine and its salts	
Flunisolide and its salts	
Fluocinolone and its salts	
Fluoride and its salts ⁷	
Fluorometholone and its salts	
Fluorouracil	
Fluoxetine and its salts	
Flupenthixol and its salts	
Fluphenazine enanthate	
Fluphenazine decanoate	
Flurazepam and its salts	
Flurbiprofen and its salts	
Flutamide	

Fluticasone and its salts	
Fluvastatin and its salts	
Fluvoxamine and its salts	
Formestane	
Formoterol and its salts	
Foscarnet and its salts	
Fosinopril and its salts	
Fosphenytoin and its salts	
Furosemide	
Fusidic acid	
Gabapentine	
Gadodiamide	
Gadolinium	
Gadopentetate Dimeglumine	
Gadoteridol	
Galactose	
Galactose/Palmitic Acid	
Gallamine and its salts	
Gallium Nitrate and its salts	
Gamma Amino Butyric Acid (GABA) ^{4,6}	
Gamma Hydroxybutyric Acid (GHB) ⁵	
Gamma Oryzanol ²	
Ganciclovir and its salts	
Gemcitabine and its salts	
Gemfibrozil	
Gentamicin Sulphate	injection
Germanium	

Gestonorone Caproate	
Ginseng ⁷	
Ginseng ⁷ /Guarana ⁷ /Bee pollen ⁷	
Glatiramer and its salts	
Gliclazide	
Glucomannan ²	
Glucosamine ²	
Glyburide	
Glycopyrrolate	
Gonadorelin and its salts	
Goserelin and its salts	
Gotu-Kola (see Centella) ²	
Granisetron and its salts	
Grepafoxacin and its salts	
Griseofulvin	ultramicrosize tablet preparation
Halcinonide	
Halobetasol and its salts	
Halofantrine and its salts	
Haloperidol and its salts	
Haloprogin	
Halothane	
Heparin ⁷	topical
Hyaluronidase ⁷	
Hydralazine and its salts	injection
Hydrochlorothiazide (in combination)	
Hydrocodone	oral modified release preparation
Hydrocortisone	rectal foam

Hydrocortisone - 17 - Valerate	topical
Hydrocortisone/Allantoin	topical
Hydrocortisone/Pramoxine	rectal foam
Hydrocortisone/Urea	topical
Hydromorphone and its salts	modified release preparations, injection, immediate release spheroids
Hydroquinone/Retinoic Acid	topical
Hydroxychloroquine Sulfate	
Hydroxycitric Acid ⁷	
Hydroxyurea	
Hyoscine Butylbromide	
Ibandronate	
Ibuprofen	
Idarubicin and its salts	
Imipramine and its salts	injection
Imiquimod	
Indapamide Hemihydrate	
Indinavir and its salts	
Indomethacin	
Iodixanol	
Iodoquinol	
Iohexol	
Iopamidol	
Iopentol	
Iopromide	
Iothalamate Meglumine	
Iotrolan	
Ioversol	

Ipratropium and its salts	
Irbesartan	
Irinotecal and its salts	
Iron Dextran	
Isoflurane	
Isoproterenol and its salts	oral inhalation
Isosorbide Dinitrate	
Isosorbide-5 Mononitrate	
Isotretinoin	
Isradipine	
Itraconazole	
Kava	
Ketamine and its salts	
Ketazolam	
Ketoconazole	
Ketoprofen and its salts	
Ketorolac and its salts	
Ketotifen and its salts	
Khat (Kat, Chat - Catha Edulis, Cathenone)	
Kojic Acid ⁷	
Kola Nitida	
Labetalol and its salts	
Lamotrigine	
Lansoprazole	
Latanoprost	
Letrozole and its salts	
Leucovorin and its salts	

Leuprolide and its salts	
Levamisole and its salts	
Levobunolol and its salts	
Levocabastine and its salts	
Levocarnitine ^{1,2}	
Levodopa and its salts	
Levofloxacin	
Levonorgestrel	
Levorphanol	
Lidocaine and its salts (antiarrhythmic agent)	
Lidocaine/Prilocaine	
Lidocaine hydrochloride (HCl) / Dextrose 5% (antiarrhythmic agent)	
Lidocaine HCl/ Norepinephrine Bitartrate	
Lincomycin and its salts	
Liothyronine and its salts	
Lisinopril and its salts	
Lithium and its salts	
Lodoxamide Tromethamine	
Lomefloxacin and its salts	
Loperamide and its salts	
Loracarbef	
Loratadine	
Loratadine/Pseudoephedrine	
Lorazepam	
Losartan and its salts	
Lovastatin	
Loxapine and its salts	

Mafenide and its salts	
Magnesium Pyrrolidone	
Malathion	
Maprotiline and its salts	
Mebendazole	
Meclofenamic Acid and its salts	
Medroxyprogesterone Acetate	
Mefenamic Acid and its salts	
Mefloquine and its salts	
Megestrol and its salts	
Melatonin ²	
Melatonin ² /Vitamin E ²	
Melphalan and its salts	
Mercaptopurine	
Meropenem	
Mesalamine	
Mesna	
Metaproterenol and its salts	
Metformin and its salts	
Methadone	
Methazolamide	
Methenamine ²	
Methenamine ² /Benzoic Acid ² /Sodium Salicylate ⁷	
Methimazole	
Methotrexate and its salts	
Methoxsalen	
Methyl Salicylate ²	spray

Methyldopate Hydrochloride	injection
Methylprednisolone and its salts	tablet, topical, injection
Metoclopramide and its salts	
Metolazone	
Metoprolol and its salts	
Metrizamide	
Metronidazole and its salts	enema, vaginal gel, injection, topical
Mexiletine and its salts	
Miconazole and its salts	
Midazolam and its salts	
Midodrine and its salts	
Miglitol	
Milrinone and its salts	
Minocycline and its salts	
Minoxidil	
Misoprostol	
Mitomycin and its salts	
Mitoxantrone and its salts	
Mivacurium and its salts	
Moclobemide	
Mometasone Furoate	
Montelukast and its salts	
Morphine Sulphate	modified release preparations, epidural
Mupirocin	
Mycophenolate Mofetil	
Nabumetone	
Nadroparin and its salts	

Nadolol and its salts	
Nafarelin and its salts	
Nafcillin and its salts	
Naftifine and its salts	
Nalbuphine and its salts	
Nalidixic Acid	
Nalmefene and its salts	
Naloxone and its salts	
Naltrexone and its salts	
Nandrolone and its salts	
Naproxen and its salts	
Naratriptan and its salts	
Nedocromil and its salts	
Nelfinavir and its salts	
Neomycin/Polymyxin B	sterile irrigation
Nevirapine	
Nicardipine and its salts	
Niclosamide	
Nicotinamide	
Nicotine	patch, gum
Nifedipine	
Nilutamide	
Nimodipine	
Nitrazepam	
Nitrofurantoin macrocrystals	
Nitroglycerin	oral modified release, patch, ointment, injection, spray
Nizatidine	

Nonoxynol-9 [human immunodeficiency virus (HIV) claim] ⁷	
Norfloxacin	
Nortriptyline and its salts	
Nylidrin and its salts	
Nystatin/Zinc Oxide ²	
Octacosanol	
Octreotide	
Octyl Methoxycinnamate/Oxybenzone/ Hydrocortisone	
Ofloxacin	
Olanzapine	
Olopatadine and its salts	
Olsalazine and its salts	
Omega-3 Fatty Acids, EPA and DHA ³	
Omeprazole	
Ondansetron and its salts	
Oral Contraceptives	
Orciprenaline and its salts	
Oxacillin and its salts	
Oxaprozin	
Oxazepam	
Oxiconazole and its salts	
Oxybutynin and its salts	
Oxycodone and its salts (as a single active ingredient)	
Oxymetholone	
Paclitaxel	

Pamidronic Acid and its salts	
Pancuronium and its salts	
Pangamic Acid and its salts	
Pantoprazole and its salts	
Papain ²	
Papaverine and its salts	
Paroxetine and its salts	
Pau D'Arco (Taheebo Tea)	
Penciclovir	
Penicillamine	
Pentamidine and its salts	
Pentastarch	
Pentazocine and its salts	
Pentosan Polysulfate Sodium	
Pentostatin and its salts	
Pentoxifylline and its salts	
Peppermint Oil ²	enteric coated capsules
Pergolide and its salts	
Pericyazine	
Perindopril and its salts	
Permethrin	
Phentermine and its salts	
Phenylbutazone	injection
Phenylephrine and its salts /Oxymetazoline and its salts	
Phenytoin and its salts	oral
Picolinates	
Pilocarpine and its salts	tablets

Pimozide	
Pinaverium and its salts	
Pindolol and its salts	
Piperacillin and its salts	
Pipotiazine and its salts	
Pirbuterol and its salts	
Piroxicam and its salts	
Plant Sterols ²	
Podofilox	
Podophyllotoxin	
Polynicotinates	
Porfimer and its salts	
Potassium Citrate ²	
Potassium Fluoride ²	
Pramipexole	
Pravastatin and its salts	
Praziquantel	
Prazosin and its salts	
Prednicarbate	
Prednisolone and its salts	oral syrup, injection
Prednisolone/Gentamicin	ophthalmic
Prednisone	oral solution
Prilocaine and its salts	
Probucol	
Procainamide and its salts	
Procarbazine and its salts	
Procaterol and its salts	

Prochlorperizine Edisylate	
Progesterone	topical, capsules
Propafenone and its salts	
Propofol	
Propolis (for Herpes)	
Propoxyphene and its salts	
Propranolol and its salts	
Pyrazinamide	
Pyridostigmine Bromide	tablet 30 milligram or any strength with nerve gas antidote claim, oral modified release tablet, injection
Pyrimethamine	
Quetiapine and its salts	
Quinacrine and its salts	
Quinapril and its salts	
Quinidine Bisulfate	
Quinidine Gluconate	oral modified release preparation, injection
Raloxifene and its salts	
Raltitrexed and its salts	
Ramipril and its salts	
Ranitidine and its salts	
Remifentanil and its salts	
Retinoic Acid	
Reviparin and its salts	
Ribavirin	
Rifabutin	
Rifampin	
Rifampin/Isoniazid/Pyrazinamide	

Risperidone	
Ritonavir and its salts	
Rocuronium and its salts	
Ropinirole and its salts	
Ropivacaine and its salts	
Salbutamol and its salts	
Salcatonin	
Salicylic Acid ² /Corticosteroids	
Salsalate	
Sanguinarine (as antiplaque agent)	
Scopolamine HCl/Dihydroergotamine / Barbital/Phenobarbital/Butalbital Sodium	
Selegiline and its salts	
Selenious Acid	
Selenomethionine	
Sermorelin and its salts	
Sertraline and its salts	
Sevoflurane	
Silicon ²	
Silver Nitrate ⁷	topical ointment
Silver Sulfadiazine	
Simvastatin and its salts	
Sodium Nitroprusside	
Sotalol and its salts	
Spectinomycin	
Spironolactone	
Squalene ²	
Stannous Fluoride ⁷ (for gingivitis/plaque)	

Stanozolol	
Streptokinase	
Sucralfate	
Sufentanil and its salts	
Sulbactam/Ampicillin	
Sulfadoxine	
Sulfamethoxazole/Trimethoprim	
Sulfasalazine	
Sulfinpyrazone	
Sulindac	
Sumatriptan and its salts	
Superoxide Dismutase (SOD) ⁷	
Tamoxifen and its salts	
Tamsulosin and its salts	
Tazarotene and its salts	
Temazepam	
Tenoxicam	
Terazosine and its salts	
Terbinafine and its salts	
Terconazole	
Terfenadine	
Terlipressin and its salts	
Testosterone and its salts	transdermal, oral
Tetracycline and its salts	dental floss
Tetrahydrocannabinols	
Thenoic Acid	
Theophylline	oral modified release preparation

Thiabendazole	
Tiaprofenic Acid and its salts	
Ticarcillin and its salts	
Ticlopidine and its salts	
Tiludronate and its salts	
Timolol and its salts	
Tinzaparin and its salts	
Tioconazole	
Tixocortol Pivalate	
Tizanidine and its salts	
Tobramycin and its salts	
Tolbutamide	
Tolcapone	
Tolmetin and its salts	
Tolonium and its salts	
Tolterodine l-tartrate	
Topiramate	
Topotecan and its salts	
Toremiphen and its salts	
Torseamide	
Trace Elements (Total Parenteral Nutrition Products)	
Trandolapril and its salts	
Tranexamic Acid	
Tranlycypromine Sulfate	
Trazodone and its salts	
Tretinoin	
Triamterene	

Triazolam	
Trichloroacetic Acid	
Trichosanthin ⁷	
Triclosan ⁷	medicinal use in oral cavity
Trifluoperazine/Isopropamide	
Trifluridine	
Triglycerides-Medium chain ⁷	injectable
Trimebutine and its salts	
Trimeprazine and its salts	
Trimethoprim	
Trimetrexate Glucuronate	
Trimipramine and its salts	
Troglitazone and its salts	
Trovafloxacin and its salts	
Tryptophan (L-) ^{1,2}	
Ursodiol	
Valproic Acid and its salts	
Valsartan	
Vancomycin and its salts	
Vecuronium and its salts	
Venlafaxine and its salts	
Verapamil and its salts	
Vinblastine and its salts	
Vincristine and its salts	
Vinorelbine and its salts	
Vitamins-Multi (with claim for Total Parenteral Nutrition)	injection

Warfarin and its salts (prophylaxis of systemic embolism after myocardial infarction)	
Yohimbine (aphrodisiac)	
Zafirlukast	
Zalcitabine and its salts	
Zidovudine	
Zinc Sulfate Heptahydrate	injection
Zolmitriptan	
Zolpidem and its salts	
Zopiclone	
Zuclopenthixol and its salts	

1. Amino acids are present in a protein configuration are not considered to be drugs; only when isolated and present as a single ingredient or in a configuration other than a completed protein is the drug/new drug status applicable.
2. This substance is not considered to be a new drug when used as a non-medicinal ingredient in topical cosmetic-like products if either of the two guiding principles are met or the data requirements are submitted and approved by Health Canada (see Appendix 1).
3. This substance, an omega-3 fatty acid, is present in fish oil and other food substances. It is to be regarded as a new drug only when intended as a therapeutic agent, when isolated/concentrated and sold as a single ingredient or added to other ingredients.
4. This substance is not considered to be a new drug when used in topical cosmetic-like products in a concentration up to 3% in “leave on” preparations and up to 10% “rinse off” formulations.
5. This substance is not considered to be a new drug when used as a non-medicinal ingredient in topical cosmetic-like products in a concentration up to 5%.
6. There is no known safe use of this substance. It is not acceptable as a non-medicinal ingredient at any level and is a new drug when associated with therapeutic claim(s).
7. This substance is considered to be a new drug (on the New Drugs List) because of the particular combination, form, route or indication. Each substance may not be considered to be a new drug when used as a non-medicinal ingredient in topical cosmetic-like products if either of the two guiding principles are met or the data requirements are submitted and approved by Health Canada (see Appendix 1).

Appendix 1

Guiding principles for substances on the New Drugs List which are not considered to be new drugs when used as non-medicinal ingredients in topical cosmetic-like drug products

Certain substances have been considered to be new drugs regardless of their use as a medicinal or non-medicinal ingredient and as a result, TPD has evaluated a number of substances on the *1999 New Drugs List*. Substances used as non-medicinal ingredients in topical cosmetic-like drug products are not considered to be new drugs if they meet either of the following two guiding principles:

1. If the substance is an active ingredient in a topical preparation (prescription or non-prescription), this substance will not be accepted as a non-medicinal ingredient (NMI) unless there is an authoritative review, such as that conducted by the Cosmetic Ingredient Review (CIR) expert panel that may have established threshold levels at, and below, which the substance can be safely used as an NMI.
2. If the substance is listed as an acceptable and identical NMI in the Natural Health Product Ingredient Database (NHPID), and the acknowledged functions are consistent with that of non-medicinal ingredient functions in cosmetics, such as a skin conditioning, film former, antioxidant, light/formulation stabilizer, etc.

Note:

- restrictions for any ingredient listed on the Cosmetic Ingredient Hotlist are applicable.
- unless otherwise specified, the concentration of all substances as well as Standard of Manufacture must be in compliance with the Good Manufacturing Practices (GMP) as outlined in Division 2 of the Food and Drug Regulations.

Requirements for substances used as non-medicinal ingredients in cosmetic-like products that are considered to be New Drugs (on the New Drugs List) if either of the two guiding principles are not met or the substance has not been previously assessed by Health Canada.

The following requirements to be submitted to Health Canada as a Drug Identification Application (DINA) are:

1. A cover letter identifying the substance and a rationale using the two guiding principles or alternatively, a justification of why it should not be considered a new drug when used as a non-medicinal ingredient in a topical cosmetic-like drug product;
2. The justification may include the following information for each substance, if applicable, but not limited to:

- a) Confirmation of its role as a pharmaceutical excipient [for example (e.g.), in The Handbook of Pharmaceutical Excipients, The Cosmetic Ingredient Identification Database, The European Cosmetic Ingredients Database, The Personal Care Products Council, Cosmetic Ingredient Identification Database, the CosIng (European Cosmetic Ingredients Database) or review by the International Pharmaceutical Excipients Council)];
 - b) Evidence in support of the concentration at which the NMI would not have any therapeutic effect but would have well-documented cosmetic attributes, such as a moisturizer;
 - c) Evidence in support of the concentration at which the NMI safety profile has been established for the target population and the topical route of administration. This evidence should demonstrate that percutaneous absorption is such that there is no risk of systemic toxicity even under conditions of potential misuse as well as local tolerance studies [e.g., irritation and sensitization in the presence and absence of ultraviolet (UV) light];
 - d) Limitation, if any, provided for the ingredient on the Cosmetic Hotlist;
 - e) Approval of its inclusion as an excipient or non-medicinal ingredient by other regulatory agencies [e.g., Therapeutic Goods Administration (TGA), United States Food and Drug Administration (FDA), European Medicines Agency (EMA)] that is based upon internationally accepted scientific standards; and
3. Any additional information or material respecting the proposed use of the substance as an NMI that is considered to be pertinent.

To obtain more information on the data requirements, it is strongly recommended that the sponsor request a pre-submission meeting with the appropriate review Bureau to discuss any questions or issues they may have. Alternatively, a sponsor can file a Drug Identification Number Application (DINA) to Office of Submissions and Intellectual Property of TPD.