Update on Vitamins and Minerals & the RD Scope of Practice

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It is well within the dietetic scope of practice to complete a nutritional assessment and develop a nutrition care plan for a client which includes a recommendation for a vitamin or mineral product. However, by law, there are some limitations. This article explains how the laws relative to vitamins and minerals apply to RDs in various practice settings.

ARE VITAMINS AND MINERALS DRUGS?

The Drug and Pharmacies Regulation Act, 1990, has quite a complex definition of a "drug", but what is most relevant to dietetic practice is understanding the classification of a drug as defined in the National Association of Pharmacy Regulatory Authorities (NAPRA) drug schedules database, specifically Schedules I, II and III:[1]

Schedule I drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner.

Schedule II drugs require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, the drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection (behind the counter).

Schedule III drugs are available without a prescription and are to be sold from the self-selection area of the pharmacy which is operated under the direct supervision of the pharmacist (over the counter).

Unscheduled drugs can be sold without professional supervision, because adequate information is available for the client to make a safe and effective choice.

Many vitamin and mineral products are not classified as drugs. Some vitamins and minerals are only considered scheduled drugs above a certain dose. For example, iron is considered a Schedule II drug in per pill doses over 30 mg, vitamin D is a Schedule I drug in per pill doses over 1,000 IU (see "Vitamin D & Dietetic Practice", p.7).

WHAT IS NOT A DRUG

Since the definition of a drug is quite broad, it may be helpful for you to know what is not a drug. The following are not drugs:

1. Food or drinks.
2. Natural health products (with a few exceptions, e.g., pseudoephedrine or ephedrine).
3. Schedule U substances (e.g., most low doses of vitamins and minerals).
4. Exceptions listed in the provincial regulations of the *Drug and Pharmacies Regulation Act, 1990* (e.g., castor oil).

CONSULT THE NAPRA WEBSITE

To determine whether a particular product is listed under one of the NAPRA drug schedules, consult the NAPRA database at: http://napra.ca/national-drug-schedules

In most cases, when a brand name product (e.g., Materna) is not listed in the NAPRA database, it means that the drug is unscheduled or that it is not considered a drug. However, NAPRA does not list private label products (e.g., Exact, Compliments, Life Brand, etc.), so it

may be unclear whether a private label brand is a scheduled drug. To determine if a particular private label product is a scheduled drug, you may need to compare bottles of brand name products with the private label equivalents. Alternatively, you can contact a pharmacist with your specific inquiry.

Note that the NAPRA drug schedule database is updated regularly. For the most current information regarding any product, it is best to consult the NAPRA website rather than relying on print articles or resources which may be out of date.

PRESCRIBING VS. RECOMMENDING VITAMINS AND MINERALS

The *Regulated Health Professions Act, 1991* (RHPA), Section 27, states that no person may perform a controlled act while providing health care services unless they are authorized by a health profession Act or have a delegation to do so. The states that the following is a controlled act (paragraph 8), "Prescribing, dispensing, selling or compounding a drug as defined in the *Drug and Pharmacies Regulation Act*, or supervising the part of a pharmacy where such drugs are kept."[2]

Prescribing, in the context of Controlled Act 8, refers to orders (oral or written) which authorize the dispensing of a drug that requires a prescription. An RD who recommends a particular vitamin or mineral supplement, along with a recommended dose, is not prescribing as long as the product is not listed under Schedule I (requiring a prescription). It is within the dietetic scope of practice to complete a nutritional assessment and develop a nutrition care plan for a client which includes a vitamin or mineral product. Depending on the practice setting, there are some limitations on how RDs may implement such recommendations. Refer to the "Recommending Vitamins in Various Practice Settings" (next page).

DISPENSING & SELLING VITAMINS AND MINERALS

If the product appears on any of the NAPRA Drug Schedules (I, II, or III), then providing a sample or selling a product to a client would be considered dispensing under the RHPA. An RD may only distribute Schedule I, II or III product samples or sell products to clients under the authority of a delegation of the controlled act of dispensing a drug. If the product is Unscheduled, not listed in the NAPRA database and/or falls under the "What is Not a Drug" section of this article (e.g., a food, drink or Natural Health Product), then RDs can legally provide samples to clients without any additional authority mechanism, subject to workplace specific policies. This applies to products with Drug Identification Numbers (DINs) such as Lactaid®, Beano®, Enteral Nutrition products as well as products with Natural Product Numbers (NPNs).

RDs may only give clients product samples when it is in the interest of the client to do so. Client safety and clinical appropriateness are the predominant considerations.

Whenever RDs provide samples or sell products to clients they may face a real or perceived conflict of interest. For more information on conflict of interest and dietetic practice, refer to the College's e-learning module.

Clear documentation in the client health record is essential for any recommendations of vitamin and mineral products.

SAFETY & SECURITY

Clients are placing their trust that product recommendations and samples provided by RDs are determined by client need, evidence-based, and most importantly, that they are safe. RDs have a professional responsibility to ensure the safety and integrity of any sample they provide to clients. You may wish to consult a pharmacist to ensure that you are following the appropriate protocols. Also, consider the following:

a. All products must be stored securely;

b. Check 'best before' or expiry date before providing samples;

c. Keep clear records of the origin and distribution trail of the product; and

d. Document in the client health record when a product sample was provided. Clear documentation in the client health record would be essential for any recommendations of vitamin and mineral products.

RECOMMENDING VITAMINS AND MINERALS IN VARIOUS PRACTICE SETTINGS

1. In a public hospital, RDs need an order or medical directive to recommend vitamins and minerals.

The *Hospital Management Regulation* under the *Public Hospitals Act, 1990,* states that only a physician, nurse practitioner, dentist, or midwife may order treatment or diagnostic procedures in a public hospital. In an inpatient environment, RDs may not order vitamins and minerals without the appropriate authority mechanisms. Even though this act does not fall within the controlled act of prescribing (except for Schedule I products), RDs would require a medical directive or order from one of the authorized providers listed above for a patient to receive vitamins or minerals from the hospital pharmacy.

2. In an outpatient hospital program, RDs may need an order or medical directive to recommend vitamins and minerals.

Depending on how a facility's outpatient programs operate, the inpatient restriction described above in #1 may or may not apply. For example, an outpatient department may be structured in a way that orders are required for every intervention, including vitamin and mineral product recommendations. In this case, RDs would need a medical directive to recommend vitamins and minerals to their clients.

However, most outpatient programs are structured less formally and orders are not required for every intervention or recommendation. When patients are being discharged or in outpatient hospital programs, RDs may recommend vitamins, minerals and other nutritional supplements. They may even write down the recommended dose and timing. Provided the products are not NAPRA Schedule I drugs (requiring a prescription), clients would then purchase these products on their own. As a safeguard, appropriate protocols and policies should be established within facilities.

3. In long-term care homes, there are no legal restrictions, but RDs should consult organizational policy for facility restrictions.

The *Long-Term Care Homes Act, 2016* and the *General Regulation* under this Act, do not restrict orders for treatment or diagnostic procedures. Therefore, there are no legal restrictions for RDs to write diet orders for vitamin and mineral products in a long-term care (LTC) home. However, organizational policies may set limitations. For example, some LTC homes have policies which state that RDs need a physician's co-signature to order diets and/or vitamin and mineral products. RDs should follow organizational policies accordingly and, where applicable, advocate for policies that enable more effective and efficient resident care.

4. In community practice, there are no additional legal restrictions to recommending vitamins and minerals.

Provided the product is not a Schedule I drug under NAPRA, there are no legal restrictions for RDs to recommend vitamins and minerals in family health teams, community health centres, public health programs, home care or private practice. In doing so, RDs must still act within the dietetic scope of practice and within their own knowledge, skill and judgement. RDs can also write down product recommendations, dosage and timing to assist clients with adhering to any recommendations.

1. National Association of Pharmacy Regulatory Authorities. (2016). Search National Drug Schedule. http://napra.ca/national-drug-schedules

2. *Regulated Health Professions Act, 1991.* https://www.ontario.ca/laws/statute/91r18#BK24

Quiz: Test Your Knowledge

about vitamins and minerals and the RD practice

Click here or go to
http://www.collegeofdietitiansofontariosurveys.com/surveys/CDO/vitamin-mineral-article-quiz-1/

Vitamin D and the RD Scope of Practice

The College has received several questions from RDs regarding vitamin D. According to the NAPRA Drug Schedule database, Vitamin D is considered a Schedule I drug under the following conditions and would require a prescription:

> "Vitamin D in oral dosage form containing **more than** 1,000 International Units of Vitamin D per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by the person of more than 1,000 International Units of Vitamin D." (see National Association of Pharmacy Regulatory Authorities. (2016). Search *National Drug Schedule.* http://napra.ca/pages/Schedules/Search.aspx)

Vitamin D products that are readily found on the shelves in health food stores and the retail aisles of pharmacies are not scheduled drugs under NAPRA. These products typically contain vitamin D in amounts of 200, 400 or 800 IU per pill. The label of such products would specify the recommended daily dose of one to two pills/day. This is acceptable as long as the label is not recommending greater than 1,000 IU/day. Typically, there is also a statement on the bottle that says: "or as directed by your health provider." Note that even if the product has 1,000 IU per pill this is still considered Unscheduled. It's only when the product contains an amount greater than 1,000 IU per pill or when the daily dosage on the label exceeds 1,000 IU that it is deemed a Schedule I prescription drug.

The College is aware that some RDs recommend clients take vitamin D supplements in dosages far greater than 1,000 IU to maintain normal blood levels or to correct low blood levels. Presumably, this would be based on medical protocols for particular patient populations (e.g., post-surgery bariatric patients) and/or evidence-based nutrition clinical practice guidelines for a particular client population.

Need to Know

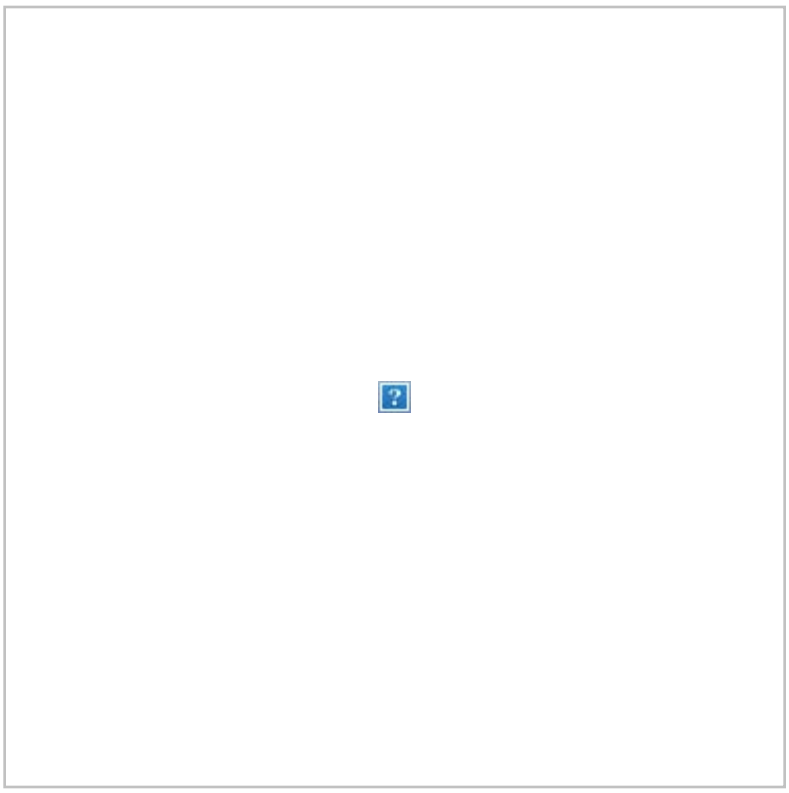
RDs can make recommendations for their clients to take vitamin D above 1,000 IU. The clients then purchase the products and take the number of pills/dosage as recommended by the RD.

When doing so, the RD's recommendation for vitamin D must be based on client need and evidence. It must be done in a manner that facilitates interprofessional collaboration, risk management protocols and appropriate documentation.

When recommending that clients take a high daily dose of vitamin D, for example 2,400 IU, RDs can suggest product(s) to look for (e.g., a per pill dose of 400 or 800 IU). This daily dose can be made up by either 3 x 800 IU pills or 6 x 400 IU pills. RDs may write down the recommended vitamin D regimen for clients and instruct them to purchase the product and take it accordingly.

Collaboration and effective communication with the health care team are important considerations for RDs when making high-dose vitamin D recommendations. Also, consider risk management and monitoring procedures when making a recommendation over the upper tolerable limits for vitamin D as it is a fat soluble vitamin that may pose some risk in high doses.

1. National Association of Pharmacy Regulatory Authorities. (2016). Search National Drug Schedule. http://napra.ca/pages/Schedules/Search.aspx
2. *Regulated Health Professions Act, 1991.* https://www.ontario.ca/laws/statute/91r18#BK24



National Drug Schedules

Drug Scheduling in Canada

NDS Process and Scheduling Factors

NDS Policies

Application for Drug Scheduling

National Drug Scheduling Advisory Committee

NDS Notice Board

Drug Scheduling External Liaison Group (DSELG)

NOTE - Effective December 19, 2013, Schedule F to the Food and Drug Regulationswas repealed and replaced by a list of prescription drugs, called the Prescription Drug List. Therefore, all entries in the National Drug Schedules (NDS) whose footnote indicates that they appear in Schedule F (F1/F2) should now be considered part of the Prescription Drug List (PDL).

Home » *National Drug Schedules*

Search: National Drug Schedules

Begin your search by using the generic name of the product:

Drug Name

Schedule

-- All --

Search by Glossary

A B C D E F G H I J K L M N O

P Q R S T U V W X Y Z

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Drug Name	Comment	Schedule	Date
Abacavir or its salts[PDL]		I	DEC / 13
Abatacept[PDL]		I	DEC / 13
Abciximab[PDL]		I	DEC / 13
Abiraterone or its derivatives[PDL]	including but not limited to abiraterone acetate	I	DEC / 13

Entries whose footnote indicates that they are "Schedule F Recommended" (FR) should now be considered recommended for addition to the PDL. Some of the "Schedule F Recommended" entries may have been added or will shortly be added to the PDL by Health Canada, but either way these entries will continue to be listed in Schedule I of the NDS.

For more information on the Prescription Drug List, please consult the Health Canada website .

Drug Product Database
Licensed Natural Health Products Database

Acamprosate or its salts[PDL]		I	DEC / 13
Acarbose or its derivatives[PDL]		I	DEC / 13
Acebutolol or its salts[PDL]		I	DEC / 13
Acepromazine or its salts[PDL]	for human use	I	DEC / 13
Acetaminophen[PDL]	when recommended for administration by intravenous injection	I	DEC / 13
Acetaminophen in sustained release formulations	up to and including 650 mg per unit, in package sizes containing no more than 50 units	U	JAN / 03
Acetaminophen in sustained release formulations.	in strengths of greater than 650 mg per unit or in package sizes of more than 50 units	III	JAN / 03
Acetaminophen.	in immediate release tablets, capsules, suppositories or liquid	U	SEP / 99
Acetanilide[PDL]	for human use	I	DEC / 13
Acetarsol		II	SEP / 98
Acetazolamide[PDL]		I	DEC / 13
Acetohexamide[PDL]		I	DEC / 13
Acetorphine[N]		I	JUN / 02

Acetyl-a-methylfentanyl[N]		I	JUN / 02
Acetylcarbromal[PDL]		I	DEC / 13
Acetylcholine Chloride[PDL]		I	DEC / 13
Acetylcysteine		II	SEP / 98
Acetyldihydrocodeine[N]		I	JUN / 02
Acetylmethadol[N]		I	JUN / 02
Acetylsalicylic acid and its salts	oral preparations containing 80 mg or less per dosage unit and intended for pediatric use or rectal preparations containing 150 mg or less per dosage unit, in package sizes containing no more than 1.92 g of acetylsalicylic acid.	II	FEB / 02
Acetylsalicylic acid and its salts.	in products for oral use in strengths of 325mg and 500mg per dosage unit	U	OCT / 00
Acetylsalicylic acid and its salts..	in products intended for oral adult use in strengths of 81 mg per dosage unit and 650 mg or greater per dosage unit, and in rectal preparations containing more than 150 mg per dosage unit	III	OCT / 00
Acitretin or its salts or derivatives[PDL]		I	DEC / 13

Aclidinium or its salts[PDL]		I	DEC / 13
Aconiazide or its salts[PDL]		I	DEC / 13
Acyclovir or its salts[PDL]		I	DEC / 13
Adalimumab[PDL]		I	DEC / 13
Adapalene or its salts or derivatives[PDL]		I	DEC / 13
Adefovir or its salts or derivatives[PDL]	including but not limited to adefovir dipivoxil	I	DEC / 13
Adenosine or its salts[PDL]	when sold or recommended for administration by intravenous injection	I	DEC / 13
Adiphene and its salts	for parenteral use	II	SEP / 98
Adrenocortical hormones or their salts or derivatives[PDL]	for human use including but not limited to: Betamethasone valerate, betamethasone sodium, betamethasone phosphate, betamethasone dipropionate, budesonide, ciclesonide, clobetasone, cortisone, dexamethasone sodium, dexamethasone phosphate, dexamethasone acetate, difluprednate, fludrocortisone acetate, flunisolide, fluticasone propionate, fluticasone	I	AUG / 16

furoate, hydrocortisone acetate, hydrocortisone aceponate, hydrocortisone sodium, methylprednisolone acetate, methylprednisolone, methylprednisolone succinate, methylprednisolone sodium, mometasone furoate, prednisolone acetate, prednisolone sodium, prednisolone phosphate, prednisone, triamcinolone acetonide, triamcinolone hexacetonide **except: (a)** hydrocortisone or hydrocortisone acetate, when sold as a single medicinal ingredient in a concentration that provides 1.0% or less hydrocortisone in preparations for topical use on the skin; or **(b)** hydrocortisone or hydrocortisone acetate, when sold in combination with any other nonprescription medicinal ingredient that provides 1.0% or less hydrocortisone in preparations for topical use on the skin; or **(c)** clobetasone butyrate when sold in a concentration of 0.05% in cream preparations for topical use on the skin; or **(d)** triamcinolone acetonide in a nasal

	spray that delivers 55 microgram (mcg)/spray for those 12 years of age and older; or, **(e)** mometasone furoate for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 12 years of age and older; or **(f)** fluticasone propionate for the treatment of allergic rhinitis in a nasal spray that delivers 50 microgram/spray for those 18 years of age and older.	
Afatinib or its salts[PDL]	I	DEC / 13
Aflibercept[PDL]	I	DEC / 13
Afoxolaner[PDL]	I	AUG / 14
Agalsidase Alfa[PDL]	I	APR / 07
Agalsidase Beta[PDL]	I	DEC / 14
Albiglutide[PDL]	I	AUG / 15
Aldesleukin[PDL]	I	DEC / 13
Alectinib or its salts[PDL]	I	NOV / 16
Alefacept[PDL]	I	DEC / 13

Alemtuzumab[PDL]	I	DEC / 13
Alendronic acid or its salts[PDL]	I	DEC / 13
Alfacalcidol[PDL]	I	DEC / 13
Alfentanil[N]	I	JUN / 02
Alfuzosin or its salts[PDL]	I	DEC / 13
Alglucosidase alfa[PDL]	I	DEC / 13
Alirocumab[PDL]	I	AUG / 16
Aliskiren or its salts[PDL]	I	DEC / 13
Alitretinoin or its salts or derivatives[PDL]	I	DEC / 13
Alkyl nitrites[PDL]	I	DEC / 13
Allergy serums and extracts	I	SEP / 99
Allethrins	II	SEP / 98
Allobarbital[C2]	I	JUN / 02
Allopurinol[PDL]	I	DEC / 13
Allylisopropylacetylurea[PDL]	I	DEC / 13
N		

Allylprodine		I	JUN / 02
Almotriptan or its salts[PDL]		I	DEC / 13
Aloe vera latex, its extracts and derivatives[except aloin]	dosage forms for systemic use containing more than 300 mg per dosage unit	III	SEP / 98
Alogliptin or its salts or its derivatives[PDL]		I	DEC / 13
Aloin		U	
Alpha-chloralose[PDL]		I	DEC / 13
Alpha-hydroxy acids[PDL]	including but not limited to citric acid, glycolic acid, lactic acid, malic acid, mandelic acid, ammonium glycolate, glycolic acid + ammonium glycolate, alpha-hydroxyethanoic acid + ammonium alpha-hydroxyethanoate, alpha-hydroxyoctanoic acid, alpha-hydroxycaprylic acid, hydroxycaprylic acid, mixed fruit acid, triple fruit acid, tri-alpha hydroxy fruit acids, alpha hydroxy and botanical complex, l-alpha hydroxy acid, glycomer in cross-linked fatty acids alpha nutrium, **when sold in** topical formulations containing alpha hydroxy acids alone or in combination	I	DEC / 14

	at concentrations of greater than 30% and/or with a pH lower than 3.0, except when sold to be applied to warts, corns or calluses		
Alphacetylmethadol[N]		I	JUN / 02
Alphadolone or its salts[PDL]		I	DEC / 13
Alphameprodine[N]		I	JUN / 02
Alphamethadol[N]		I	JUN / 02
Alphaprodine[N]		I	JUN / 02
Alphaxalone[PDL]	including but not limited to alfaxalone, alphaxolone	I	DEC / 13
Alphenal[C2]		I	JUN / 02
Alprazolam[TS]		I	SEP / 98
Alteplase or its salts or derivatives[PDL]	including but not limited to tenecteplase	I	DEC / 13
Altrenogest[PDL]		I	DEC / 13
Altretamine[PDL]		I	DEC / 13
Aluminum oxide		III	SEP / 98
Alverine and its salts	for parenteral use	I	SEP

			/ 98
Amantadine or its salts[PDL]		I	DEC / 13
Ambenonium Chloride[PDL]		I	DEC / 13
Ambrisentan[PDL]		I	DEC / 13
Amifostine or its salts[PDL]		I	DEC / 13
Amikacin or its salts or derivatives[PDL]	PDL, including but not limited to amikacin sulfate	I	DEC / 13
Amiloride or its salts[PDL]		I	DEC / 13
Amino Acid solutions	for parenteral use	I	SEP / 99
4- Amino-pteroyl aspartic acid or its salts[PDL]		I	DEC / 13
Aminocaproic acid[PDL]		I	DEC / 13
Aminoglutethimide[PDL]		I	DEC / 13
Aminolevulinic acid or its salts or derivatives[PDL]		I	DEC / 13
Aminophylline[PDL]		I	DEC / 13
Aminopromazine [proquamezine] and its salts		I	SEP / 98
Aminopterin or its salts or derivatives[PDL]		I	DEC / 13

Aminopyrine or its derivatives[PDL]	for human use	I	DEC / 13
Aminorex[C1]	(5-phenyl-4, 5-dihydro-1, 3-oxazol-2-amine), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, including 4-Methylaminorex (4-methyl-5-phenyl-4, 5-dihydro-1, 3-oxazol-2-amine) and 4,4'-Dimethylaminorex (4-methyl-5-(4-methylphenyl)-4, 5-dihydro-1, 3-oxazol-2-amine)	I	DEC / 17
4- Aminosalicylic Acid or its salts[PDL]		I	DEC / 13
5- Aminosalicylic acid[PDL]	including but not limited to mesalazine	I	DEC / 13
Amiodarone or its salts or derivatives[PDL]	including but not limited to dronedarone	I	DEC / 13
Amitraz[PDL]		I	DEC / 13

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Footnotes
C1: Drug is in the Controlled Drugs and Substances Act and Part I of the Schedule to Part G of the Food and Drug Regulations}

C2: Drug is in the Controlled Drugs and Substances Act and Part II of the Schedule to Part G of the Food and Drug Regulations
C3: Drug is in the Controlled Drugs and Substances Act and Part III of the Schedule to Part G of the Food and Drug Regulations
C4: drug is in the Controlled Drugs and Substances Act
C5: drug is in the Regulations Under CDSA
CR: drug has been recommended for addition to the Controlled Drugs and Substances Act
CR-C: drug has been recommended for addition to the Controlled Drugs and Substances Act, Part G of the Food and Drug Regulations
CR-N: drug has been recommend for addition to the Controlled Drugs and Substances Act, Narcotic Control Regulations
CR-TS: drug has been recommended for addition to the Controlled Drugs and Substances Act, Benzodiazepines and Other Targeted Substances Regulations
F1: drug appears in Part I of Schedule F to the Food and Drugs Act and Regulations
F2: drug appears in Part II of Schedule F to the Food and Drugs Act and Regulations
FR: drug has been recommended for addition to Schedule F to the Food and Drugs Act and Regulations ("Schedule F Recommended")
N: drug is in the Narcotic Control Regulations under the Controlled Drugs and Substances Act
NR: drug has not been reviewed by NDSAC
PDL: drug is in the Prescription Drug List (effective Dec. 19, 2013)
R: drug is in Part J of the Food and Drus Act and listed in the Controlled Drugs and Substances Act
TS: drug is in the Benzodiazepines and Other Targeted Substances Regulations under the Controlled Drugs and Substances Act
U: drug has been reviewed by NDSAC and is unscheduled

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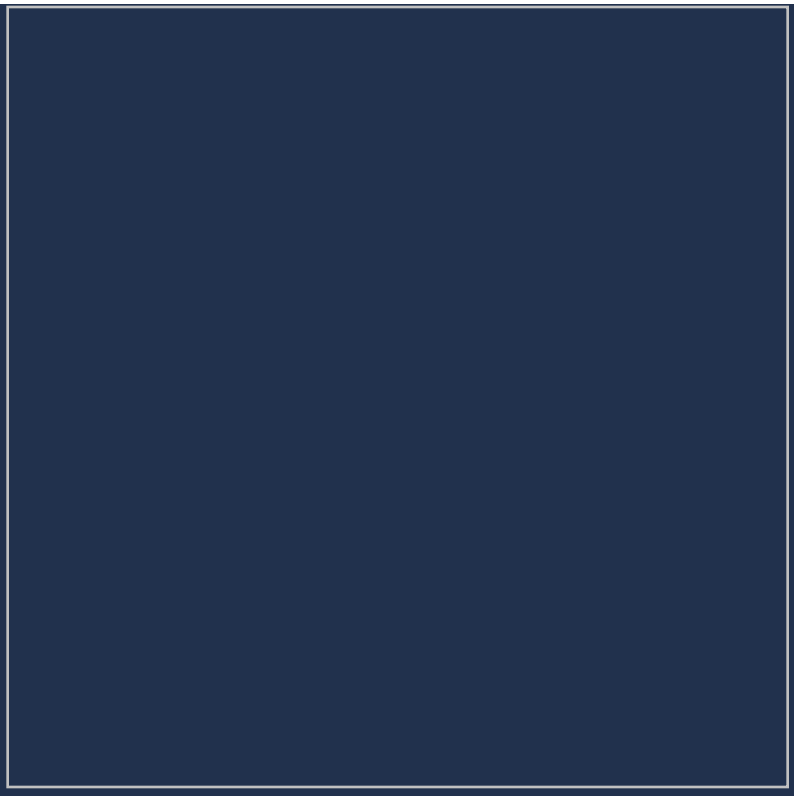

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