Court File No.
T-651-23

FEDERAL COURT

W E E N:

ORGANIGRAM INC.

Applicant

- and -

MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Respondents

NOTICE OF APPLICATION

TO THE RESPONDENT:

A PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Applicant. The relief claimed by the Applicant appears below.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicant. The Applicant requests that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must file a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the Applicant's solicitor or, if the Applicant is self-represented, on the Applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date March 31, 2023 Issued by "Taina Wong"
(Registry Officer)

Address of local office: 180 Queen Street West
Suite 200
Toronto Ontario
M5V 3L6

TO: **ATTORNEY GENREAL OF CANADA**
c/o This Honourable Court pursuant to Rule 133(1) of the Federal Court Rules

AND TO: **MINISTER OF HEALTH**
Health Canada
c/o This Honourable Court pursuant to Rule 133(1) of the Federal Court Rules

Attn: Anika Chassé, Acting Director General
Compliance Directorate, Controlled Substances and Cannabis Branch

Address Locator 0300A
Ottawa, Ontario
K1A 0K9

APPLICATION

1. This is an Application for judicial review in respect of a decision by Health Canada, as represented by Anika Chassé, Acting Director General, Compliance Directorate – Controlled Substances and Cannabis Branch, in which Health Canada:

(a) Determined that the Applicant's Edison Jolts Freshly Minted Sativa, Electric Lemon and Arctic Cherry Lozenges (collectively, the "**Lozenges**"), which have been marketed and sold as a cannabis extract since as early as August 2021, meet the definition of edible cannabis under the *Cannabis Regulations* (the "***Regulations***");

(b) In consequence, determined that the Lozenges are not properly classified as a cannabis extract, and therefore, as currently packaged and sold, exceed the allowable quantity of tetrahydrocannabinol (THC) per immediate container for edible cannabis, in contravention of section 102.7 of the *Regulations*; and

(c) Accordingly, requested that (i) the Applicant cease the production of new lots of the Lozenges in their current format by March 7, 2023, and (ii) cease the sale and distribution of any remaining inventory of Lozenges by May 31, 2023,

all of which was communicated to the Applicant by email correspondence on March 1, 2023 (the "**Decision**").

2. The Applicant makes Application for:

(a) An order quashing or setting aside the Decision and requiring Health Canada to make a determination that the Lozenges are a

cannabis extract and do not constitute edible cannabis under the *Regulations*;

(b) In the alternative, an order quashing or setting aside the Decision and remitting the matter back to Health Canada for redetermination in accordance with such directions as this Honourable Court deems appropriate;

(c) The costs of the within Application; and

(d) Such further and other relief this Honourable Court may deem just.

3. The grounds for the Application are:

Background

(a) The Applicant, Organigram Inc., is a licensed producer of cannabis and cannabis-derived products for medical patients and adult-use recreational consumers in Canada;

(b) The Applicant was first licensed to produce cannabis over nine years ago and since that time, has established its reputation as a manufacturer of quality, compliant products. The Applicant has had nearly 50 Health Canada inspections (including compliance verifications) and is in good standing with the regulator. The Applicant's reputation in the market is as an established licensed producer of cannabis that meets the needs of consumers in both the medical and adult-use channels, with a focus on providing consumers with safe and compliant products;

(c) The Applicant's portfolio of cannabis brands includes the Edison Cannabis Co. brand, which is a premium brand offering cannabis in different product formats such as whole flower, pre-roll joints, infused pre-rolls, vape cartridges and lozenges;

(d) Under the Edison Cannabis Co. brand, the Applicant manufactures and distributes the Lozenges, which are contained in child-resistant packages consisting of ten lozenges per pack (the "**Jolts**"). Each Lozenge contains 10 milligrams of THC, for a total of 100 mg THC per container of Jolts. The Jolts are available in three flavours – mint, electric lemon and arctic cherry – all of which are the subject of the Decision;

(e) The first cannabis extract of its kind, the Jolts are a lozenge intended for sublingual and/or buccal absorption, which allows for faster absorption of active ingredients and differs from the consumption method of edible cannabis, which is chewed and/or swallowed, like food. The Lozenges also offer an alternative consumption format to other cannabis extracts such as oils, tinctures and inhalables;

(f) Similar to other lozenges, the Lozenges are hard, coloured and translucent, small spherical tablets. Consumers of the Lozenges are directed to "suck on lozenge for about 15 seconds, then hold under tongue or between cheek and gum until fully dissolved", and the product's labelling is also explicit that the Lozenges are to be consumed via sublingual (administration under the tongue) or buccal absorption (administered in the mouth by absorption through the skin of the cheek) through slow dissolution. This method of consumption is distinct from the manner in which food is consumed;

(g) All three flavours of the Lozenges contain a harsh menthol flavour that is designed to limit consumption. The Lozenges include oligofructose and other ingredients, including flavouring agents, which are all permitted ingredients for a cannabis extract per the *Regulations*. The Lozenges do not contain any sugars,

sweetening agents or sweeteners, which are prohibited by the *Regulations* for use as ingredients in a cannabis extract;

(h) Oligofructose is a non-digestible dietary fibre used as a carrier and bulking agent in producing the Lozenges. In particular, oligofructose assists in forming a solid and glassy lozenge and provides for even dispersion and dissolution. The Applicant has sought patent protection for this invention;

(i) Currently, the Jolts are widely distributed across Canada in nine provinces and one territory. Since launching the Jolts over one year and eight months ago, the Applicant has received no reports of serious adverse reactions despite widespread distribution;

Statutory Definitions

(j) The *Regulations* define a ***cannabis extract*** as follows:

> **(a)** a substance produced by
>
> > **(i)** subjecting anything referred to in item 1 of Schedule 1 to the Act to extraction processing, or
> >
> > **(ii)** synthesizing a substance that is identical to a phytocannabinoid produced by, or found in, a cannabis plant; or
>
> **(b)** a substance or mixture of substances that contains or has on it a substance produced in a manner referred to in paragraph (a).
>
> It does not include a cannabis topical or edible cannabis.

(k) The *Regulations* define ***edible cannabis*** as:

> a substance or mixture of substances that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended to be consumed in the same manner as food…

(l) Based on the definitions above, a cannabis product can only be edible cannabis if it is "intended to be consumed in the same manner as food";

Correspondence with Health Canada Leading up to the Decision

(m) The *Regulations* require that a license holder submit to Health Canada a Notice of New Cannabis Product ("**NNCP**") at least 60 calendar days before making any new cannabis product available for sale. The NNCP serves as a notification to Health Canada of proposed new product launches, and gives Health Canada an opportunity to object to any products that it determines to be non-compliant. The Applicant submitted NNCPs for each flavour of the Jolts on April 6, 2021 (Freshly Minted), November 17, 2021 (Electric Lemon) and December 1, 2021 (Arctic Cherry);

(n) The Applicant has been submitting NNCPs for cannabis extract lozenge products since as early as August 21, 2020, as set out below. As such, Health Canada has had notice of this product category for nearly 3 years;

(o) On August 21, 2020, the Applicant submitted six NNCPs for cannabis extracts similar to the Jolts (i.e., the predecessors to the ultimate Jolts product);

(p) On December 4, 2020, in response to the initial NNCPs, Health Canada raised a concern with the use of oligofructose in the cannabis extracts, erroneously linking oligofructose to the prohibition against using sugars, sweeteners and sweetening agents, as defined under the *Food and Drug Regulations* ("**FDR**"), in a cannabis extract. In its correspondence, Health Canada incorrectly referenced another chemical compound defined as a sweetener – sorbitol – to suggest that the proposed

extracts “could potentially contravene” the *Cannabis Act* or *Regulations*. Health Canada provided the Applicant a mere two business days to respond;

(q) On the same day, the Applicant responded by noting that its proposed extract products did not contain sorbitol, that oligofructose is entirely distinct from sorbitol – in nomenclature, classification and property – and that the oligofructose present in its proposed extract serves as a carrier for the cannabis, as permitted by section 101.3(1)(a) of the *Regulations*;

(r) On February 8, 2021 (over 2 months later), Health Canada responded to the Applicant’s submissions and stated, among other things:

(i) The reference to sorbitol was made in error and the December 4, 2020 correspondence should have referred to oligofructose;

(ii) That sugars, sweeteners and sweetening agents are prohibited under the *Regulations* to curb the appeal of cannabis products to young persons; and

(iii) Health Canada incorrectly defined sweeteners as being “a food additive that is used to impart a sweet taste to a food”, and on this basis, erroneously concluded that “oligofructose could impart a sweet taste and therefore may be in contravention of s. 101.3(2)(b)” of the *Regulations*;

(s) In response, the Applicant and Health Canada held a telephone meeting on February 16, 2021, during which the Applicant outlined the reasons why the use of oligofructose in the proposed cannabis extracts was not in contravention of the *Regulations*.

The Applicant summarized its position in a written response to Health Canada dated February 19, 2021. In this correspondence, the Applicant, among other things, noted that:

(i) The Jolts were designed for sublingual and buccal absorption (unlike cannabis edibles, which are consumed in the same manner as food) and to provide an alternative format for cannabis extract consumers (e.g. an alternative to vaping);

(ii) Oligofructose contains several functional properties that render it suitable for use in a lozenge product, including, among other things, that it has a neutral and non-intrusive taste;

(iii) The Lozenges' harsh menthol flavour mitigates against the risk of over-consumption, is not known to be appealing to youth, and is consistent with other traditional adult-oriented lozenges;

(iv) The correct definition of sweetener under the *Regulations* explicitly incorporates the specific additives included in the List of Permitted Sweeteners under the *FDR* and not "any food additive used to impart a sweet taste to a food", as erroneously advanced by Health Canada; and

(v) Cannabis extracts containing oligofructose are consistent with policy goals surrounding the regulation of cannabis, including reducing the appeal of cannabis products to youth and reducing the risk of overconsumption;

(t) On March 1, 2021, Health Canada acknowledged the Applicant's rationale for the use of oligofructose;

(u) With no further correspondence from Health Canada on this topic, the Applicant continued developing and refining the extracts, and submitted NNCPs for each of the Lozenges, as set out in paragraph (m) above;

(v) On January 14, 2022 (nearly 10 months after submission of the first NNCP for a Jolts product), Health Canada advised the Applicant of its position that the Jolts could potentially contravene the *Cannabis Act* and/or the *Regulations*. In particular, Health Canada reasoned:

(i) that the Jolts products are believed to be consumed in the same manner as food on the basis of the four criteria used to classify natural health products and foods (i.e., product format, product composition, product representation, and public perception and history of use) and as such, Health Canada concluded the Jolts fit the definition of edible cannabis on the basis that:

(1) Confectionary products are considered food;

(2) The Jolts are represented as flavoured lozenges;

(3) The Jolts contain ingredients that Health Canada considers to be food products, such as oligofructose and sulphites; and

(4) The Jolts' intended use is listed as "ingestion";

(ii) That as a result, the Jolts products may be non-compliant with the *Regulations*, including with the 10 milligram THC limit for edible cannabis per section 102.7. Health Canada requested that the Applicant respond within five business days;

(w) On January 21, 2022, the Applicant responded with detailed submissions. Among other things, the Applicant described that:

(i) The Lozenges do not meet the definition of "food" as defined under the *Food and Drugs Act* (the "**FDA**"). It noted that the Jolts are slow-dissolving sublingual lozenges intended for sublingual and/or buccal absorption; that the directions for use are inconsistent with consumption of food; and that the Lozenges are not intended to provide nourishment, satisfy hunger, thirst or a desire for taste, texture or flavour;

(ii) The factors listed in the *Guidance Document: Classification of products at the food-natural health product interface: products in food formats* (the "***Guide***") do not support a food classification for the following reasons:

(1) *Product Composition* – In contrast to confectionaries, the use of oligofructose in the Lozenges is solely for functional effect, and not to satisfy any food-related purposes, and the Lozenges do not contain any sugar or sweetening agent;

(2) *Product Representation and Format* – The use of the term "lozenge" and the directions for use provided in connection with the Lozenges are inconsistent with food consumption and are thus clear indicators that the Lozenges are not intended to be consumed in the same manner as food. The Applicant noted this argument finds support in the *Guide*, which states that i) the use of the term

"lozenge" would "not support classification as food", and ii) directions of use provided on the labelling "suggest that a product is being manufactured, sold or represented for use as [something other than a food product]". Similarly, the Applicant also pointed out that none of the traditional confectionary product terms are used in association with the Lozenges. The Lozenges are therefore not represented as a product to be consumed ad libitum (i.e., freely and at will), which is also inhibited by their harsh menthol flavour; and

(3) *Public Perception and History of Use* – Lozenges are not perceived by the public as food, including references in the *Guide* that provides that lozenges are not to be classified as "foods", but rather as "natural health products". In line with the *Guide*, the Applicant also noted that other lozenges are not regulated as foods;

(iii) Oligofructose serves a functional purpose in the Lozenges as a carrier and bulking agent, and any sulphite is present only as a biproduct of processing, and thus cannot be viewed as a food ingredient – especially as oligofructose has been approved for use as a bulking and carrier substance in natural health products (which are non-food items); and

(iv) Health Canada's assessment as outlined in its January 14, 2022 correspondence ignores several key facts, including that many non-food products (including lozenges classified as natural health products) are consumed by

> ingestion, are often flavoured and contain both oligofructose and sulphites;

(x) On March 17, 2022 Health Canada sent correspondence to the Applicant stating it had “no further questions at this time”. The Applicant received no further communication from Health Canada in response to its detailed submissions, and continued with the manufacturing, sale and distribution of the three Jolts products;

(y) On September 22, 2022, Health Canada sent an email to the Applicant seeking clarification regarding the constituents of the sulphites and the role of oligofructose in the Lozenges. The Applicant responded on September 29, 2022, providing the same information regarding the roles of sulphites and oligofructose as previously provided to Health Canada on January 21, 2022, i.e., that the sulphites are used as a processing aid in the manufacture of the bulking agent and carrier, oligofructose, and that oligofructose is a bulking agent and carrier per section 101.3(1)(a) of the *Regulations*;

(z) The Applicant did not receive any further correspondence from Health Canada until January 3, 2023 when Health Canada issued a notice of non-compliance alleging that the Jolts contravene section 102.7 of the *Regulations* on the basis that the Lozenges are edible cannabis, rather than a cannabis extract. This correspondence stated:

> Subject to subsection 97(2), edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain a quantity of THC that exceeds 10 mg per immediate container, taking into account the potential to convert THCA into THC.

(aa) In its January 3, 2023 notice of non-compliance, Health Canada requested that the Applicant voluntarily stop sale of the Jolts on the basis that the Lozenges are edible cannabis, and as such, in their current packaging format, exceed the allowable amount of THC per immediate container;

(bb) In coming to this conclusion, Health Canada relied on the definitions of edible cannabis and cannabis extract in the *Regulations* and the definition of food in the *FDA*, and noted (without regard to the specific product format or its directions for use) that it considers the Lozenges are consumed in the same manner as food (without any discussion as to how the Lozenges are *consumed in the same manner as food*) based on the following high-level factors:

(i) The Lozenges are similar to confectionary products given the directions on packages indicate they are “Cannabis extract (lozenge) for ingestion”;

(ii) The Lozenges are represented for their taste and flavour, which are generally associated with confectionary products; and

(iii) The Lozenges may be perceived by consumers as intended for consumption in the same manner as food because confectionary products “have a long history of being consumed as foods”, per the *Guide*;

(cc) On January 6, 2023, the Applicant notified Health Canada that it disagreed with the position taken, that it is factually incorrect and inconsistent with the *Cannabis Act*, *Regulations* and other applicable Health Canada guidance, and that as such, it would

not cease the sale of the Jolts, and requested the opportunity for further dialogue;

(dd) In particular, the Applicant raised the following considerations:

(i) The Jolts have been marketed since August 2021, with no known consumer confusion or perception that the products are foods. This accords with the Jolts' directions for use and product marketing, as well as their harsh menthol flavour;

(ii) The Lozenges lack food properties, as they are slow-dissolving sublingual lozenges with directions for use that are inconsistent with how food is consumed. The Lozenges are also neither palatable nor intended to provide nourishment or satisfy a desire for hunger, thirst or a desire for taste, texture or flavour;

(iii) The factors in the *Guide* do not support the classification of the Lozenges as food:

(1) Terms used in connection with the consumption of food products are not used in representing the Lozenges. Instead, the Lozenges contain explicit instructions that are inconsistent with the consumption of food products. Moreover, the *Guide* explicitly notes that lozenges are not food products; and

(2) Lozenge products have historically been used and classified as non-food product, and that the public perceive lozenges as something other than a food; and

(iv) Reliance on the fact that the Lozenges are consumed by way of ingestion is misplaced and unfounded as several other lozenges are consumed by ingestion yet are nonetheless classified by Health Canada as something other than foods;

(ee) On January 13, 2023, the parties participated in a telephone call. There were seven representatives from Health Canada on this call, including Anika Chassé, Acting Director General, Compliance Directorate – Controlled Substances and Cannabis Branch. During this call, the Applicant reiterated its request for further engagement with Health Canada on the legal and regulatory analysis required for the proper classification of the Lozenges. The Health Canada representatives refused to discuss the merits of the parties' arguments and continued to reiterate the position that the Lozenges are a cannabis edible, without engagement;

(ff) On January 16, 2023, the Applicant wrote to Health Canada in follow up and to reiterate its request to engage with legal counsel at Health Canada on the classification;

(gg) Health Canada advised on January 20, 2023 that it would revert back with further correspondence, and had prepared a guidance document, but never acknowledged or responded to the Applicant's request for reasonable dialogue. Health Canada further advised on February 3, 2023 that it was still preparing its response;

The Decision

(hh) In response to the written submissions and the oral representations made by the Applicant in January 2023, and

despite the continued requests for dialogue regarding product classification, on March 1, 2023, Health Canada issued the Decision in the form of a Non-Compliance Determination for the Jolts;

(ii) As set out above, the Decision requires the Applicant to phase-out the Jolts by i) ceasing the production of new lots by March 7, 2023; ii) ceasing the sale of the Jolts altogether by May 31, 2023; and iii) responding with a written confirmation that the Applicant is undertaking action to comply with the phase-out of the Jolts;

(jj) The Decision asserts that the Lozenges are edible cannabis and thus the Jolts contain a quantity of THC that exceeds the allowable limit of 10 milligrams per immediate container, in contravention of section 102.7 of the *Regulations*. Health Canada provided the following reasons in support of its conclusion, which are disputed by the Applicant:

(i) *Product format* – The Lozenges are consistent with hard candies, which are confectionary products and thus considered as food under the *Guide*. Health Canada also clarified that lozenges are classified as natural health products for their active ingredients and health claims, and not because they are not a food. It also noted that a lozenge with no active ingredients or health claims would be regulated as a hard candy. In support, Health Canada referred to the Codex Alimentarius General Standard for Food Additives and Labelling requirements for confectionery, chocolate and snack food products;

(ii) *History of use* – That Canadians perceive and consume confectionary products as foods, and that these have a long history of being consumed as foods;

(iii) *Product sensory and physical characteristics* – The Lozenges resemble hard candies and are sweet-tasting, which could lead the public to perceive them in a similar way to a food product like hard candy. Similarly, the use of cherry, lemon and mint flavouring agents are flavours of food at their base, which increases the likelihood that the public will perceive or associate the Lozenges to satisfy a desire for taste or flavour; and

(iv) *Product representation* – The Lozenges are represented with descriptors that increase the likelihood the public would perceive them as satisfying a desire for taste or flavour. Importantly, according to Health Canada, lozenges are not commonly consumed sublingually, and the Lozenges' shape and size "are not typical to rest comfortably" under the tongue;

(kk) In addition to these factors, Health Canada also noted that it considered (without specifying) all information that was made available to it in reaching the Decision;

Post-Decision Correspondence between the Parties

(ll) On March 3, 2023, after issuing the Decision, Health Canada published and communicated to the industry a *Compliance promotion statement on the classification of edible cannabis*, which sets out the factors that Health Canada considers in determining if a cannabis product is edible cannabis;

(mm) On March 6, 2023, the Applicant wrote to Health Canada to reiterate its request from January 2023 to speak with legal counsel at Health Canada regarding the legal analysis that factored into the classification and related allegations of non-

compliance. In addition, the Applicant requested a reasonable extension of the deadline of March 7 pending resolution of the matter;

(nn) On March 8, 2023, Health Canada rejected the Applicant's request on the basis that discussions with legal counsel would not result in a change in the department's position. Health Canada also denied the Applicant's request for a call and an extension, advising that they will continue with written correspondence. Health Canada provided an extension until March 10, 2023 to respond to point ii) of the Decision, but required confirmation of point i) by the end of the day;

(oo) On March 8, 2023, the Applicant wrote to Health Canada to confirm that it had paused production of new lots of the Jolts in their current format of 100 mg THC per immediate container as of March 7, 2023;

(pp) On March 10, 2023, the Applicant wrote to Health Canada in response to point ii) of the Decision. The Applicant advised that it remains of the view that the Jolts are compliant with the *Regulations* and was considering its legal options with respect to the request to cease all sales by May 31, 2023. The Applicant requested that its external counsel be connected with Health Canada's counsel to determine next steps and any pathway forward that would avoid the need for litigation. Health Canada has not acknowledged or responded to this correspondence as of the date of filing this Application;

Reviewable Errors in the Decision

(qq) In rendering the Decision and concluding that the Lozenges are edible cannabis, Health Canada acted unreasonably, including

by erring in law and basing its Decision on erroneous findings of fact unsupported by the material before it, for at the least the following reasons:

(i) Health Canada selectively, inconsistently and incorrectly relied on its internal policies such as the *Guide*, and external guidance such as the *Codex Alimentarius General Standard for Food Additives* and the *Labelling requirements for confectionery, chocolate and snack food products*, to support the findings in the Decision;

(ii) The Decision is wholly inconsistent with classifications made of other products, including but not limited to lozenges and cannabis oils. Reliance on the fact that the Lozenges are consumed by way of ingestion as indicative of them being cannabis edibles is misplaced, unfounded and incorrect. Several other cannabis extracts (e.g., cannabis oil) are consumed by way of “ingestion”. In addition, this ignores Health Canada’s guidance regarding cannabis extracts for ingestion, and the definition of “ingestion” in the *Regulations* which specifically contemplates the administration of a cannabis extract by “absorption in the mouth”;

(iii) Health Canada failed to consider and give weight to certain provisions of the *Regulations*, including but not limited to section 101.3, which identifies the permissible ingredients for a cannabis extract;

(iv) Health Canada incorrectly and disproportionately focused on the use of oligofructose in the Lozenges, despite acknowledging the Applicant’s rationale for using the dietary fibre (which is not prohibited by the *Regulations*) in

producing the Lozenges two years earlier on March 1, 2021;

(v) The Decision is wholly unsupported by the record and is premised on several unfounded generalizations and bald and conclusory statements that lack a legal basis and are unsubstantiated by any evidence presented or disclosed by Health Canada, including but not limited to:

(1) The Lozenges are “sweet tasting” which the public “would perceive as or associate with food”;

(2) The use of oligofructose and glycerin “could lead the public to perceive the products in a similar way to a food product, such as hard candy”;

(3) The use of flavouring agents “increases the likelihood that the public will perceive or associate the [Lozenges] to satisfy a desire for taste or flavour”;

(4) Certain product descriptors “increase the likelihood that the public would perceive the [Lozenges] as being intended … to satisfy a desire for taste or flavour”;

(5) “Lozenges are not commonly consumed by keeping them under the tongue”;

(6) The products’ “size and shape are not typical to rest comfortably in those cavities compared to sublingual format”; and

(7) Individuals “may” not follow the instructions provided;

(vi) The Decision is internally incoherent and contains flaws in logic. In particular, the Decision disproportionally and inconsistently relies on the four factors used in classifying natural health products and food, whereas the threshold question based on the cannabis regulatory scheme (as established by the *Regulations*) is whether the Lozenges are "intended to be consumed in the same manner as food". The Decision does not assert, and Health Canada has provided no evidence that the Lozenges are intended to be consumed in the same manner as food. Rather, the Decision focuses on the classification of products, and Health Canada's analysis is restricted to what is "food" without considering the definition of edible cannabis and/or ingestion. Health Canada's failure to adhere to certain provisions of the *Regulations*, including section 101.3 and the definitions of "edible cannabis" and "ingestion" in section 1 of the *Regulations*, also results in an illogical decision and outcome;

(vii) The Decision improperly asserts that the Jolts pose a potential risk to public harm, without providing evidence of actual risk. In addition, the Decision ignores the demonstrated evidence of actual risk associated with high potency cannabis products that are available in the illicit market, and fails to acknowledge the risk of harm associated with removing the Jolts from the Canadian market (i.e., consumers returning to the illicit market for alternatives to Jolts, where products are not tested, are not quality-controlled and are packaged in a manner that is appealing to youth and without child-resistant closures);

(rr) Furthermore, in reaching the Decision, Health Canada failed to observe and provide the Applicant with the requisite level of procedural fairness for at least the following reasons:

(i) Health Canada failed to provide the Applicant with adequate notice. In particular, Health Canada failed to provide the Applicant with adequate and sufficient disclosure, which materially impeded the Applicant's ability to know and to respond to the case against it. Information and evidence that was not disclosed to the Applicant but otherwise known to Health Canada includes the evidence implicitly relied upon by Health Canada to reach the purported conclusions listed in paragraph 3(qq)(v) above, and "all the information made available to [Health Canada]" beyond and excluding representations made by the Applicant on January 6 and 13, 2023;

(ii) Health Canada's failure to provide the Applicant with adequate notice also extends to its reliance on novel arguments that were not included in the notice dated January 3, 2023 or at any time prior. These new arguments were raised for the first time in the Decision, notwithstanding that Health Canada and the Applicant had been engaging on the same issues for over two years prior. Examples include:

(1) Reliance on the *Codex Alimentarius General Standard for Food Additives* and the *Labelling Requirements for confectionery, chocolate and snack food products;*

(2) Stating that lozenges without health claims would be regulated as a hard candy;

(3) Reliance on product sensory characteristics, including the public's perception as to the alleged sweetness, taste and flavour of the Lozenges; and

(4) Objections relating to the size and shape of the Lozenges, including its suitability for sublingual and buccal administration.

(iii) Health Canada's failure to provide any response for a 12-month period following to the Applicant's detailed written submissions in reply to Health Canada's first correspondence in 2021 led the Applicant to reasonably believe it had satisfied Health Canada's concerns. Accordingly, the Applicant reasonably committed considerable resources to pursue further research and development, manufacturing and distribution of the Jolts, only to be informed more than a year and a half later that Health Canada disagreed with the Applicant's analysis; and

(iv) The Decision was made prior to the release of any Health Canada guidance specific to the classification of cannabis edibles and cannabis extracts. Such guidance was released three days *after* the Decision in the form of the Compliance promotion statement. Thus, the Applicant was not privy to the framework used by Health Canada to formulate the Decision, which materially impaired its ability to respond to the case against it;

(ss) Sections 2, 18, 18.1, 18.2, 18.4 of the *Federal Courts Act*;

(tt) Rule 3 and Part 5 (Rules 300 –334) of the *Federal Court Rules*;

(uu) Sections 1, 101.2, 101.3, 102 and 102.7 of the *Cannabis Regulations*;

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

(ww) Section B.01.001 of the *Food and Drug Regulations*;

(xx) Sections 1 and 2 of the *Marketing Authorization for Food Additives That May Be Used as Sweeteners*, including the *List of Permitted Sweeteners* referred to therein;

(yy) Health Canada's *Guide on composition requirements for cannabis products* and *Classification of edible cannabis*;

(zz) Such further and other grounds as are set out in the affidavit(s) and memorandum to be filed in support of the within Application; and

(aaa) Such further and other grounds as counsel may advise and this Honourable Court may permit.

4. This Application will be supported by the following material:

(a) The affidavit(s) to be filed in support of the within application and the exhibits thereto;

(b) Such materials as may be provided pursuant to the Applicant's request below, made pursuant to Rule 317, as may be included in the Application Record; and

(c) Such further and other material as counsel may advise and this Honourable Court may permit.

The Respondent requests, pursuant to Rules 317 and 318 of the *Federal Courts Rules* that Health Canada send a certified copy of the following material

that is not in the possession of the Applicant but is in the possession of Health Canada to the Applicant and to the Registry:

1. Any non-privileged documents or records that relate to the Decision (other than the Decision itself, and guidance and/or policy documents referred in any correspondence from Health Canada to the Applicant), including but not limited to any facts, information, notes, minutes, memoranda, reports, articles, internal and/or external correspondence, complaints and any policies or guidelines i) pertaining to the Applicant or, more broadly, the issue of classifying cannabis products between cannabis edible and cannabis extract, or ii) referred to or relied on by Health Canada in reaching the Decision, and which was not otherwise disclosed or communicated to the Applicant.

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March 31, 2023

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