CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000609-129

(Class Action)
SUPERIOR COURT

A. CHARLES

Plaintiff / Class Representative

-vs.-

BOIRON CANADA INC., legal person duly constituted, having its principal place of business at 1300 René-Descartes, City of Saint-Bruno de Montarville, Province of Quebec, J3V 0B7

Defendant

APPLICATION TO INSTITUTE PROCEEDINGS
(Arts. 141 and following and arts. 583 and following C.C.P.)

TO THE HONOURABLE MADAM JUSTICE CLAUDINE ROY, J.S.C., SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PLAINTIFF/ CLASS REPRESENTATIVE STATES AS FOLLOWS:

I. INTRODUCTION

1. By judgment dated October 26, 2016[1] (the "Authorization Judgment"), the Honourable Court of Appeal authorized the Plaintiff/ Class Representative to institute a class action against the Defendant on behalf of the following group:

> "all residents in Canada who have purchased Oscillococcinum and Children Oscillococcinum ["Oscillo Products"] since April 13, 2009";

2. The Defendant, Boiron Canada Inc. is the company that designed, manufactured, marketed, distributed, imported and/or sold Oscillo Products throughout Canada, including the Province of Quebec;

3. The present action involves the Defendant having marketed the Oscillo Products as being an effective treatment for cold and flu symptoms.

[1] Application for Leave to Appeal denied by the Supreme Court of Canada on May 4, 2017.

Specifically, the Oscillo Products have been promoted by the Defendant as a clinically-proven natural medicine that "reduces the severity and duration of flu-like symptoms such as feeling run down, headache, body aches, chills and fever" and that the Oscillo Products "nips symptoms in the bud" with "clear improvement" and even "complete resolution within 48 hours" – when it is nothing more than a sugar pill;

4. The purported active ingredient, *Anas Barbariae Hepatis et Cordis Extractum* (i.e. Muscovy duck liver and heart), is: (a) not active in combatting the flu and (b) not actually an ingredient in the final product. In fact, some of the product labelling even states that the non-medicinal ingredients are "0,85g of sucrose and 0,15g of lactose", which adds up to 1,00g, leaving no room for any other ingredient, whether medicinal or otherwise. Consequently, and contrary to some of the product's labelling, the "medicinal ingredients" in the Oscillo Products are not even "ingredients" in the final product;

5. Had Class Members known of the above-summarized characteristics of the Oscillo Products during the class period, they would certainly not have purchased them;

6. In the Authorization Judgment, the Honourable Court of Appeal identified the principle questions of fact and law to be treated collectively as the following:

   a) Did the defendant engage in unfair, false, misleading, or deceptive acts or practices regarding the marketing and sale of its Oscillo Products?

   b) Is the defendant liable to the class members for reimbursement of the purchase price of the Oscillo Products as a result of their misconduct?

   c) Should an injunctive remedy be ordered to prohibit the defendant from continuing to perpetrate their unfair, false, misleading, and/or deceptive conduct?

   d) Is the defendant responsible to pay compensatory and/or punitive damages to class members and in what amount?

II. THE DEFENDANT

7. The Defendant, Boiron Canada Inc. ("Boiron"), is a Canadian company with its head office in Saint-Bruno-de-Montarville, Quebec. Boiron designed, manufactured, marketed, distributed, imported and/or sold the Oscillo Products throughout Canada, including within the province of Quebec, the whole as appears more fully from copies of extracts from the *Registraire des enterprises* dated April 13, 2012 and July 31, 2017, produced herein *en liasse* as **Exhibit P-1**;

8. Boiron is the Canadian contingent of the non-party French corporation, Boiron Inc., which has an operating presence in 59 countries worldwide. It is the largest manufacturer of homeopathic products in the world. It is a $730 million public company with 4,000 employees in more than 80 countries;

9. On February 5, 2009, the Defendant obtained approval from Health Canada to place Children Oscillococcinum onto the market under product number 8009268 and on October 21, 2009, the Defendant obtained approval from Health Canada to place Oscillococcinum onto the market under product number 80014156, the whole as appears more fully from copies of the Product Licenses, produced herein *en liasse* as **Exhibit P-2**;

III. THE SITUATION

A. Influenza (the Flu) and the Common Cold

10. Influenza or the flu, is an extremely contagious respiratory illness caused by influenza A or B viruses that infects the nose, throat and lungs. It can cause mild to severe illness and, at times, can even lead to death. Some symptoms of the flu include, but are not limited to fever/ feverish chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, fatigue, and vomiting and diarrhea, the whole as appears more fully from a copy of the Centers for Disease Control and Prevention article entitled “Key Facts About Influenza (Flu)”, produced herein as **Exhibit P-3**;

11. Most people who get influenza will recover in several days to less than two weeks, but some people will develop complications as a result of the flu. A wide range of complications can be caused by influenza virus infection of the upper respiratory tract (nasal passages, throat) and lower respiratory tract (lungs). While anyone can get sick with the flu and become severely ill, some people are more likely to experience severe flu illness such as young children, adults aged 65 years and older, pregnant women, and people with certain chronic medical conditions, the whole as appears more fully from a copy of the Centers for Disease Control and Prevention article entitled “Flu Symptoms & Complications”, produced herein as **Exhibit P-4**;

12. Both the flu and the common cold are contagious viral infections of the respiratory tract and, although the symptoms can be similar, the flu is far more severe. While a cold will affect just the upper respiratory tract (nose and throat), the flu additionally affects the lower respiratory tract (the lungs). While both the flu and the common cold more generally involve congestion, sore throat, sneezing, coughing, headache, and chest discomfort, the flu often also involves a fever, body aches, fatigue, and weakness, the whole as appears more fully from a copy of the WebMD article entitled “What is the Flu?”, from a copy of the Government of Canada article entitled “Symptoms of flu

(influenza)", and from a copy of the Government of Canada brochure entitled "Is it a cold or the flu?" produced herein *en liasse* as **Exhibit P-5**;

13. The Public Health Agency of Canada estimates that the flu infects millions of Canadians every year and that flu cases result in approximately 12,200 hospitalizations and, on average, 3,500 deaths in Canada each year (although as many as 8,000 Canadians die of influenza and its complications annually, depending on the severity of the season), the whole as appears more fully from copies of reports from the Public Health Agency of Canada dated April 13, 2012 and July 31, 2017, produced herein *en liasse* as **Exhibit P-6**;

14. In the end of April 2009, the virulent influenza A virus colloquially known as "swine flu" or "H1N1" spread fear across North America. On June 11, 2009, the World Health Organization declared the outbreak to be a pandemic, the whole as appears more fully from a copy of the World Health Organization article entitled "The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010" dated June 16, 2010 and from a copy of the World Health Organization Press Release entitled "World now at the start of 2009 influenza pandemic" dated June 11, 2009, produced herein *en liasse* as **Exhibit P-7**;

15. On August 10, 2010, the H1N1 influenza virus was announced to be in the post-pandemic period by the World Health Organization, despite the likelihood of localized outbreaks to continue, the whole as appears more fully from a copy of the World Health Organization Press Briefing entitled "Pandemic (H1N1) 2009", produced herein as **Exhibit P-8**;

16. Since then, flu outbreaks have been relatively less devastating, but the public's fear of flu infection has fueled the emergence of various alternative medicines, including homeopathic "remedies" such as the Oscillo Products;

B. <u>The Defendant's Marketing of the Oscillo Products</u>

17. The Defendant has taken advantage of the widespread nature of the flu and the public's fear of it by making false claims about the purported efficacy characteristics of the Oscillo Products in order to drive enormous sales of the worthless product. As an example, the front of the product's packaging places in bold letters the name of the product – Oscillococcinum – directly below the statements "Fever", "Chills", "Body Aches", and "Headaches", as illustrated below;


DIN-HM 80014156
Reduces the duration of flu symptoms
FLU-LIKE SYMPTOMS
Body aches • Headache
Fever • Chills
Oscillococcinum®
HOMEOPATHIC MEDICINE
Non-drowsy
Adults and children
Family pack
30 doses
BOIRON
DOSES OF GLOBULES
1 g each


Réduit la durée des symptômes de la grippe
ÉTATS GRIPPAUX
Courbatures • Maux de tête
Fièvre • Frissons
Oscillococcinum®
MÉDICAMENT HOMÉOPATHIQUE
Sans somnolence
Adultes et enfants
Format familial
30 doses
BOIRON

18. The Oscillo Products are sold in most retail pharmacies across the country, through online retailers, and are also available directly from the Defendant through its website, www.boiron.ca;

19. Oscillococcinum is available for purchase in three different package dosages; 6 doses for $13.99, 12 doses for $20.99, or 30 doses for $34.99, the whole as appears more fully from a copy of a checkout cart from the Defendant's website at www.boiron.ca, produced herein as **Exhibit P-9**;

20. In order to give its claims an appearance of legitimacy, the Defendant claims on its website that "four clinical studies, including two which have been published in peer-reviewed journals, show that the Oscillo Products reduce the severity and duration of flu-like symptoms such as feeling run down, headache, body aches, chills and fever", and that the Oscillo Products "nips symptoms in

the bud" with "clear improvement" and even "complete resolution within 48 hours", the whole as appears more fully from a copy of an extract from the Defendant's website www.oscillo.com, produced herein as **Exhibit P-10**;

21. Boiron advertises the Oscillo Products as an effective treatment and cure for the symptoms of seasonal flu, also known as the common cold, by indicating that "at the first sign of flu symptoms, take OSCILLO®!" and that "OSCILLO® is recommended by Graham Rynbend, head athletic therapist for the Montreal Canadiens". The Defendant now claims on its website that "Oscillococcinum reduces the duration of flu-like symptoms such as body aches, headaches, fever and chills. It does not cause drowsiness", the whole as appears more fully from copies of extracts from the Defendant's website www.boiron.ca, produced herein *en liasse* as **Exhibit P-11**;

22. The product labeling of Oscillococcinum states:

> "Nature's #1 Flu medicine
>
> SYMPTOMS OF FLU
> Fever, Chills, Body Aches and Pains
>
> INDICATIONS:
> For relief of symptoms of flu such as fever, chills, body aches and pains.
>
> DIRECTIONS
> At the onset of flu like symptoms, take one dose and repeat for 2 more doses at 6 hour intervals (3 doses total)
>
> Established flu symptoms, take one dose morning and evening for 3 days. One dose consists of the entire contents of one tube to dissolve in the mouth.
>
> Will not cause drowsiness"

The whole as appears more fully from copies of the product labels for Oscillococcinum, produced herein *en liasse* as **Exhibit P-12**. Copies of Oscillococcinum Children's product label are produced herein *en liasse* as **Exhibit P-13**;

23. In fact, the Oscillo Products are composed of nothing more than sugar pellets onto which minute quantities of water have been absorbed. Thus, the Oscillo Products contain no active ingredients, and can therefore not have any effect on the flu, on colds or on any their symptoms;

24. The purported active ingredient - an extract or preparation of the heart and liver of a duck – is not actually present in the sugar that is sold to consumers due to enormous dilutions used in the Oscillo Products' preparations;

> "Since 1925, Oscillococcinum has been prepared as follows. Into a one litre bottle, a mixture of pancreatic juice and glucose is poured. Next a Canard de Barbarie is decapitated and 35 grams of its liver and 15 grams of its heart are put into the bottle… After 40 days in the sterile bottle, liver and heart autolyse (disintegrate) into a kind of goo, which is then "potentized" with the Korsakov method…. Oscillococcinum's manufacturer (Boiron) uses "ultrapure water" from the first step on. Oscillococcinum is designated as "200K"—which means that the original amount is subjected to 200 Korsakov dilutions—and the resulting fluid is used to moisten small 5 milligram balls of milk sugar. Some packages have been labeled "200CK." ("C" is the abbreviation for centesimal, which means 1-to-100 dilution, and "CK" stands for "centesimal Korsakovian.") Other packages have been labeled 200C, which does not specify which dilution method was used".

The whole as appears more fully from a copy of the article entitled "The True Story of Oscillococcinum" dated August 27, 2003, produced herein as **Exhibit P-14**;

25. At the stupendously high dilutions used to prepare the Oscillo Products, they can have no effect of any kind in humans because the odds are astronomically high that not even a single molecule derived from the original "extract" could be present in the solution used to soak the tiny balls of lactose mixed with sucrose which constitute the product sold to consumers;

26. Oscillo 200C does not contain a single molecule of the duck organs that serve as the raw materials for the production of the final "remedy." The designation "C" represents an initial dilution of 1 to 100, and 200C means repeating this 200 times. "C" is confusing to the consumer because a larger number actually means a smaller dose (contrary to what a reasonable person would think) and further the term does not conform to the *Weights and Measures Act*[2] at section 7 and schedules I and II;

27. It has been noted that in order to obtain even a single molecule of the original fermented Muscovy duck, a volume of tablets greater that the mass of the entire universe would need to be consumed. In other words, it is mathematically impossible that there is any of the original product in final product sold, the whole as appears more fully from a copy of the Science-Based Pharmacy article entitled "Remedy Regulation: Homeopathy in Canada" dated April 14, 2010, produced herein as **Exhibit P-15**;

[2] *Weights and Measures Act* (R.S.C., 1985, c. W-6).

28. Even if this purported active ingredient were present in any significant way, it has no known impact on the human body whatsoever and it is nothing more that Muscovy Duck Liver and Heart, which French cooks use to prepare duck breast;

29. The active ingredient, *Anas Barbariae Hepatis et Cordis Extractum*, is neither active in combatting the flu nor is in actually an ingredient in the final product. In fact, some of the product's labeling even states that the non-medicinal ingredients are "0,85g of sucrose and 0,15g of lactose", which adds up to 1, leaving no room for any other ingredient. Consequently, and contrary to some of the product's labeling the "medicinal ingredients" in the Oscillo Products are not even "ingredients" in the final product;

30. The Defendant is fully aware that there is no active ingredient in the Oscillo Products stating "of course its safe. There's nothing in it", the whole as appears more fully from a copy of the article entitled "Flu Symptoms? Try Duck" dated February 9, 1997, produced herein as **Exhibit P-16**;

31. On its website, www.boiron.ca, the Defendant assures the consumer that the Oscillo Products do not "cause drowsiness" (Exhibit P-11), which is clear as there is no ingredient in the pill that could cause much of anything, whether positive or negative;

32. The Oscillo Products have also been criticized by Dr. Joe Schwarcz as being nothing more than a placebo, the whole as appears more fully from a copy of the article entitled "Homeopathy - Delusion through Dilution" dated June 5, 2012, produced herein as **Exhibit P-17**;

33. In addition, the expert report of Dr. Lynn Willis (who has studied the scientific literature related to the Oscillo Products) explains the contents of the Oscillo Products quite succinctly, including the enormous dilutions involved in its preparation. Following are some relevant excerpts from the report:

> "40. In the final analysis, no compelling scientific evidence exists to show that homeopathy results in anything more than a placebo effect. (Ernst, 2000; Ernst, 2010; Linde, 1999) Indeed, homeopathic theory and practice are contrary to what modern scientific research in pharmacology and therapeutics has established.
>
> …
> 44. The source of Roy's oscillococci (which modern bacteriologists believe don't exist at all) was, for reasons no one understands, the Muscovy duck. […]
>
> …
> 45. The 200C dilution of Oscillococcinum® goes well past the point at which even a single molecule of the original digestate of duck organs

could be expected to be present. [...] To put the magnitude of a 200C dilution into perspective, consider that a 200C dilution of 1 cubic centimeter, or cc, of a given “mother tincture” is equivalent to putting that single cc of fluid into 10400 cc of water (i.e., 10 followed by 400 zeroes). The planet Earth has a volume of approximately 1027 cc; accordingly, the volume needed to contain 10400 cc would be nearly 15 times the volume of a sphere the size of planet Earth (i.e., 400 ÷ 27).

46. Any effort to validate the therapeutic efficacy of Oscillococcinum® must be exerted in the context of a bacterium that no one but Joseph Roy has ever reported seeing, and which is administered in such extreme dilution that not one molecule of the starting material remains in the final product; indeed, no such molecules would have been present in the diluted fluid after the first 30 dilutions.

…

49. Oscillococcinum has been subjected to clinical trials for the prevention and treatment of flu-like syndromes. In 2006, Vickers and Smith published a meta-analysis of those studies, seven in all, from which they concluded 1) that there was not enough evidence to recommend “the use of Oscillococcinum-like medicines to prevent influenza and influenza-like syndrome,” and 2) that “the evidence is not strong enough to make a general recommendation to use Oscillococcinum for routine treatment” of flu-like symptoms. In 2012, Mathie et al. published an updated review of essentially the same studies as were reviewed by Vickers and Smith, and reached the same conclusions with respect to the prevention and treatment of flu-like symptoms with Oscillococcinum.

…

53. Although all of these effects were reported by Ferley et al. and Papp et al. as statistically significant, Vickers and Smith judged the effects merely as “moderate,” and of insufficient magnitude to warrant recommending Oscillococcinum as an effective treatment of flu and flu-like symptoms.

…

55. Indeed, given that flu-like symptoms usually last 5-7 days, the notion that a 7-hour reduction of that time counts as a “reduced duration of flu-like symptoms,” as is claimed on the Oscillococcinum® package label and websites, strikes me as ludicrous.

…

70. I concur with the judgment of Drs. Vickers and Smith, and I believe, based on the data discussed in this Declaration, that more such studies

> of Oscillococcinum are both unnecessary and unwarranted…In my view, such minimal prospects for improvement render Oscillococcinum no better than placebo, and therefore of insufficient clinical or therapeutic significance to be offered for sale to consumers at all.
>
> …
> 73. Based on my preceding analysis and critique of the clinical evidence that Boiron presents to support this claim, i.e., the studies of Ferley et al. and Papp et al., and on the overall review of the Oscillococcinum literature by Vickers and Smith and Mathie et al., I conclude that there is insufficient scientific support to justify any of these marketing statements or claims for Oscillococcinum.
>
> 74.Both of the most rigorous clinical trials of Oscillococcinum available (Ferley et al. and Papp et al.) have demonstrated that the ability of Oscillococcinum to relieve flu-like symptoms is only slightly better than the effects of placebo treatment. Accordingly, it is my opinion that Oscillococcinum lacks clinical relevance and utility for the treatment of flu-like symptoms."

The whole as appears more fully from a copy of the Expert Report of Dr. Lynn Willis dated April 12, 2013, produced herein as **Exhibit P-18**;

34. In a study conducted in January 2005 to determine whether the Oscillo Products or similar homeopathic medicines are more effective than placebo in the prevention and treatment of influenza and influenza-like syndromes, it was determined that there was no evidence that homoeopathic treatment can prevent influenza-like syndrome and that "current evidence does not support a preventive effect of Oscillococcinum-like homeopathic medicines in preventing influenza and influenza-like syndromes". While the study focused more on the ability of the Oscillo Products to prevent influenza, it still finds application in the present context as to its overall efficacy, the whole as appears more fully from a copy of the Respiratory Medicine study entitled "Preventing influenza: An overview of systematic reviews" dated June 14, 2005, produced herein as **Exhibit P-19**;

35. There is simply no compelling evidence that the Oscillo Products have any effect beyond placebo in the treatment of influenza or influenza-like illness, the whole as appears more fully from a copy of the Cochrane Database of Systematic Reviews study entitled "Homeopathic Oscillococcinum® for preventing and treating influenza and influenza-like illness" dated January 28, 2015, produced herein as **Exhibit P-20**;

36. Even Wikipedia states the following about the Oscillo Products: "Oscillococcinum (or Oscillo) is a homeopathic preparation marketed to relieve influenza-like symptoms. It does not provide any benefit beyond that of sugar pills" and that "there is no compelling scientific evidence that Oscillococcinum

has any effect beyond placebo. None of its active ingredient is present in a dose of the final product, nor is there any credible evidence that duck liver is effective in relieving (or causing) flu symptoms in the first place", the whole as appears more fully from a copy of the Wikipedia page for the Oscillo products at https://en.wikipedia.org/wiki/Oscillococcinum, produced herein as **Exhibit P-21**;

37. Due to the Defendant's failure to inform consumers of the truth regarding the Oscillo Products and their purported active ingredient, consumers are unknowingly spending millions of dollars every year while receiving no results and remaining sick longer than necessary, exposing themselves to greater risk of complications;

38. Given that a significant factor in a consumer's decision to purchase a cold and flu remedy is the presence of an effective active ingredient, the Defendant's misrepresentations and omissions of material fact induced consumers to purchase the product;

39. Boiron utilized false claims regarding the alleged presence of the active ingredient of the Oscillo Products to persuade consumers to believe that it would significantly reduce, if not completely cure, their cold and flu symptoms;

40. The advertisements and representations made by the Defendant as set forth herein were, and are, false or misleading. The acts and practices of the Defendant as alleged herein constitute unfair or deceptive acts or practices and the making of false advertisements;

41. The Defendant's false and misleading representations allowed it to reap millions of dollars of profit at the expense of the consumers it has misled into believing that the homeopathic "remedy" in the Oscillo Products has the ability to cure the flu and/or the common cold;

C. Health Canada's Licensing Process and Labelling Requirements

42. In Canada, all commercial homeopathic products are subject to the *Food and Drugs Act* [3] and its regulations, including the *Natural Health Products Regulations*. The *Natural Health Products Regulations*[4] require that prior to placing a homeopathic product into the stream of commerce, a Health Canada license must be obtained;

43. This means that before a homeopathic product may be placed onto the market, a company must submit documents to Health Canada for review to show that the product is safe and effective. Non-scientific information is accepted to demonstrate efficacy, for example, texts that demonstrate historical use of the

[3] *Food and Drugs Act* (R.S.C., 1985, c. F-27).
[4] *Natural Health Products Regulations* (SOR/2003-196).

product would suffice, the whole as appears more fully from a copy of the Government of Canada article entitled “Consulting Canadians on the regulation of self-care products in Canada”, produced herein as **Exhibit P-22**;

44. When the homeopathic product is licensed by Health Canada, it is assigned a Homeopathic Medicine Number (DIN-HM), which then appears on the product labelling, giving consumers peace of mind knowing that the particular product has been authorized and approved for sale;

45. On March 13, 2015, CBC Marketplace aired an approximate twenty-two (22) minute exposé about the homeopathic product market and the procedure that must be followed in order to obtain a Health Canada license which allows manufacturers to make efficacy claims to consumers, the whole as appears more fully from a copy of the DVD copy of the CBC/Radio Canada Marketplace television episode entitled “Drugstore remedies: Licence to Deceive”, which was broadcasted in Canada on March 13, 2015, attached hereto as **Exhibit P-23**;

46. The CBC Marketplace episode revealed journalists who had created a fever and pain “remedy” for children called Nighton (an anagram for “nothing”). They applied for a Health Canada licence using only a few photocopied pages from a homeopathic reference book printed in 1902 to prove the product would provide effective relief for fever, pain and inflammation in children – That was all it took for Health Canada to approve those claims for Nighton’s label. Pictured below is Nighton’s label:

47. The months-long investigation revealed that the bar in order to obtain Health Canada approval for a homeopathic product, such as the Oscillo Products, was exceedingly low; all that was required was to send Health Canada a

completed application and photocopies of old homeopathic encyclopedia pages – no scientific proof whatsoever was necessary;

48. Dr. Matthew Stanbrook MD PhD, deputy editor of the Canadian Medical Association Journal has stated that it is "frustrating that the government standards are not protecting the public the way they should be" and that this is "lending to the veneer of approval to something that really hasn't demonstrated the science". Dr. Stanbrook also has stated that Health Canada's licensing of Nighton "really makes a joke of the regulatory process", the whole as appears more fully from a copy of the CBC News article entitled "Health Canada licensing of natural remedies 'a joke', doctor says" dated March 12, 2015, produced herein as **Exhibit P-24**;

49. The only real bar to obtaining Health Canada's approval to market a homeopathic product is that it not contain substances in either schedules I to V of the *Controlled Drugs and Substances Act* or schedule C of the *Food and Drugs Act* (Radiopharmaceuticals), the whole as appears more fully from a copy of Health Canada's Evidence for Homeopathic Medicines: Guidance Document dated July 2015, produced herein as **Exhibit P-25**;

50. Soon after the broadcast, Health Canada advised that it would be introducing certain labelling changes to certain homeopathic products that fall under the *Natural Health Product Regulations* as the labelling "may not provide Canadians with the information they need to make informed choices". These labelling changes applied to certain nosode[5] products as well as homeopathic cough, cold, and flu products for children aged 12 and under, the whole as appears more fully from a copy of the Health Canada Alert entitled "Nosodes and children's cough, cold and flu homeopathic products Labelling Changes" dated July 31, 2015, attached hereto as **Exhibit P-26**;

51. These labelling changes included Health Canada no longer allowing companies to make specific health claims on homeopathic products for cough, cold, and flu for children 12 and under, unless those claims were supported by scientific evidence;

52. Although manufacturers were given until March 31, 2017 to ensure that their labels meet the new federal standard, an informal Marketplace survey of several drugstores in Toronto and Vancouver conducted in the last week of April found only one of the four most prominent brands (Hyland's, Homeocan, Similasan and Boiron) has done so. Many products are still making the same old promises — all with Health Canada's stamp of approval on their label, the whole as appears more fully from a copy of the CBC Marketplace article

[5] Nosodes are homeopathic preparations made from bodily tissues and fluids (including faeces, blood, pus, discharges, and saliva) taken from patients suffering from a disease (e.g. measles, anthrax, tuberculosis).

entitled “Unproven homeopathic remedies for kids still promising relief despite new label rules” dated May 9, 2017, produced herein as **Exhibit P-27**;

53. Further, the new rules themselves have been criticized as they only applied to homeopathic products for children and not for adults making them inconsistent. Dr. Joe Schwarcz has stated the following:

> “I don't think it makes any kind of sense to draw a line at age 12 and to require evidence for children’s products but not to have the same criteria for products that are sold to adults.”

The whole as appears more fully from a copy of the CBC News article entitled “Health Canada's new rules for homeopathic products for kids should apply to adults, expert says” dated August 6, 2015, produced herein as **Exhibit P-28**;

54. Health Canada itself has stated (Exhibit P-28):

> “Health Canada is concerned that there has been confusion for consumers because of the similarity between the packaging and marketing of homeopathic and non-prescription drug products. This can lead consumers to the conclusion that homeopathic products are similar to or the same as health products that meet more scientific standards of evidence to demonstrate their effectiveness”

55. With Health Canada’s lax regulations, manufacturers of homeopathic products have been able to exploit the public’s difficulty in distinguishing between over-the-counter drugs with scientifically-proven therapeutic benefits, from homeopathic preparations and supplements that often make similar health claims with little or no evidence, the whole as appears more fully from a copy of Dr. Matthew Stanbrook’s Editorial entitled “Natural health products should be sold separately from drugs” dated June 26, 2017, produced herein as **Exhibit P-29**;

56. One main cause of this is that in pharmacies, supermarkets and convenience stores across Canada, the homeopathic products are placed side-by-side with the nonprescription drugs, both of which tout their approval by Health Canada. This approval goes a long way with consumers who believe that efficacy and safety claims on the packaging;

57. The issue is that Health Canada’s regulation of nonprescription drugs involves careful scrutiny of scientific evidence, while its “regulation” of homeopathic products involves minimal requirements and is effectively a rubber stamp. Thus, there is a certain lowered bar for efficacy for homeopathic products – otherwise, they would never obtain approval to market;

58. As has been succinctly stated (Exhibit R-15):

Health Canada has implemented a regulatory system for homeopathy that seeks to adapt a system of sympathetic magic into a structured, scientific process. To do so, it has essentially eliminated the requirement that homeopathy be supported by credible evidence. This regulation has led to a licensing framework that is fundamentally unfair to consumers, as it does not disclose that most homeopathic products don't contain a single molecule of the product that is named on the label. Further, it allows centuries-old anecdotal evidence as justification for "recommended uses". Finally, it reinforces homeopathy's legitimacy by assigning distinct numbers (actually calling them homeopathic "medicine" numbers) to indistinguishable sugar pills.

Health Canada's current framework for regulating homeopathic products wastes resources and compromises the regulator's credibility. Why bother regulating homeopathy? There is no more of a need to regulate homeopathy than there is to regulate the tools of psychics, ghost hunters, wizards or astrologists.

An evidence-based, science-based approach would mean Health Canada would forbid all treatment statements ("recommended uses") with homeopathic remedies, as none have been substantiated. An appropriate regulatory framework would consider the following:

If a remedy is not sufficiently dilute, it can have medicinal effects. These products should therefore be treated as drugs, and subject to the same regulatory standards, where persuasive, objective, clinical trial evidence must be produced before specific "recommended uses" are allowed. Approved products would then be assigned drug identification numbers.

If homeopathy is sufficiently dilute, it contains no active ingredients and is not a health-related product. For these products, Health Canada adds no value by regulating homeopathy, and, in fact, unnecessarily legitimize the products in the process. Regulations and safety standards are already in place for selling table sugar and drinking water – and these are adequate to protect Canadian consumers who elect to use homeopathy.

D. <u>The Merits of Homeopathy – the Placebo Effect</u>

59. It is a popular misconception to equate herbal or natural medicine with homeopathy. Homeopathy is an alternative medicine system that was invented in the 1796 by Samuel Hahnemann and involves three main concepts; (i) the law of similar (like-cures-like – what causes a symptom can

cure a symptom), (ii) the law of infinitesimals (less-is-more – water has memory, and substances that are progressively diluted become stronger, not weaker), and (iii) the law of succession (rigorous shaking increases potency), the whole as appears more fully from a copy of the 10:23 Campaign article entitled “What is Homeopathy”, produced herein as **Exhibit P-30**;

60. If homeopathy worked, what is known about science, biology, chemistry, physics, and pharmacology is wrong. Upon rigorous examination, there is no convincing evidence that homeopathy triggers anything more than placebo effects (Exhibit R-15);

61. The placebo effect (also called the placebo response) has been defined as “a remarkable phenomenon in which a placebo -- a fake treatment, an inactive substance like sugar, distilled water, or saline solution -- can sometimes improve a patient's condition simply because the person has the expectation that it will be helpful”, the whole as appears more fully from a copy of an extract from the Medicinenet website www.medicinenet.com, from a copy of the Harvard Health Publication entitled “The power of the placebo effect” dated May, 2017, and from a copy of the Vox article entitled “The weird power of the placebo effect, explained” dated July 7, 2017, produced herein *en liasse* as **Exhibit P-31**;

62. Thus, the mind plays an important role in the process of healing and the reasons that a person recovers from an ailment can range from being mentally positive to the simple passing of time whereby the ailment would have subsided in the absence of any additional factors;

63. It is important to not commit the logical error of *post hoc*, *ergo propter hoc* (“after and therefore because of”) – the simple fact of a person recovering from an ailment does not in and of itself indicate that that the specific treatment is effective – the efficacy of a treatment must be tested scientifically in order to accredit it with having either improved or cured a particular ailment;

64. In 1997, an editorial was published In the New Science Journal that revealed the following:

    - Of the 180 or more controlled trials that have been published in the past 30 years, fewer than 30 meet the highest standards. And when the dodgier trials are excluded from the analysis, the bottom line is scarcely one you would stake your life on: there is no single illness for which homeopathy’s efficacy compared with a placebo rises above statistical noise.

    - [Homeopathic efficacy] can be explained without rewriting the laws of science or invoking magic. A few teams failing to publish a negative trial; a few researchers claiming they tested the remedy blind when in fact they were well aware which patients were getting the remedy and which the

placebo, and, hey presto, homeopathy nudges ahead in the pooled analysis.

- The problem for homeopathy and other alternative therapies is that extraordinary claims require extraordinary evidence.

- In the unlikely event that the tools of science do, in the final analysis, prove that homeopathy works, then the laws of chemistry will be in for a thorough rethink.

The whole as appears more fully from a copy of the New Science editorial entitled “The power of magic – Using science to prove homeopathy works will destroy the essence of its appeal” dated September 27, 1997, produced herein as **Exhibit P-32**;

65. On July 23, 1999, the Gaia Research Institute presented the following findings to the Medicines Control Council in Pretoria, South Africa:

- Pseudo-scientific homoeopathic product manufacturing companies are hiding behind false advertising and prejudicing the established scientific health and therapeutic potential of nutritional and herbal products, to fraudulently peddle their placebo products as medicines, with serious unsubstantiated indications and efficacy claims, with state sanction, and at taxpayer's expense.

- Whereas considerable real scientific validation exists for nutritional and herbal substances, and this expands chrono-exponentially, the opposite pertains to homoeopathic medicines, which are still struggling with hypothetical therapeutic rationale, and have yet to convincingly establish significant therapeutic efficacy for a single clinical condition.

- The laws of chemistry state that there is a limit to the dilution that can be made without losing the original substance altogether, (Avogadro's number), which corresponds to homeopathic potencies of 12C or 24D(X). A 30X dilution means that the original substance has been diluted 1,000,000,000,000,000,000,000,000,000,000 times. To get even one molecule of the substance in the most common 30X pills, would necessitate taking two billion of them, about a thousand tons of lactose tablets (or one hundred tons of drops).

- After evaluating all scientific reviews of homoeopathic trials to date, even though the remedy 'appears' in many cases to perform beyond mere placebo, one has to conclude that the spontaneous remission / placebo complex, commonly and hereafter simply termed placebo (nothing), in the final analysis, is at work rather than the actual remedy itself.

- There is insufficient evidence for the efficacy of homoeopathic medicines for even a single clinical condition.

- It is the absence of proof, rather than the absence of disproof that matters.

- Previous articles in this series proved quite conclusively that homoeopathic remedies are worthless beyond their singular ritualistic value. The local homoeopathic fraternity were invited to present any evidence to the contrary, but either declined or subsequently withdrew their efforts as the strength of this thesis became evident. Similarly, the threats of legal action evaporated as the truth of this position set in.

- It was originally the intention to expose only the monopolistic and fraudulent acts being perpetrated by the big homoeopathic companies from behind a sickening charade of public beneficence, but subsequent denial by homoeopaths themselves and refusal to consider evidence led to the publication of proof of their delusion.

- Dr Andrew Weil M.D. points out that “in 1842 Oliver Wendell Holmes (echoing Voltaire) wrote that the fact of homeopathic cures should not be admitted as evidence, because 90% of cases commonly seen by a physician would recover sooner or later, with more or less difficulty, provided that nothing were done to interfere seriously with the efforts of nature”. Weil adds: “In other words, most sick people will get better no matter what you do, as long as you do not actively make them worse, a strong argument, consistent with the experience of most observers of illness, (and concludes that) we may quibble over the percentage of cases that will recover anyway, but it is certainly high, and may well be as high as 90%”.

- The placebo effect is an unpopular topic. In complementary medicine the ‘aura of quackery’, linked to any discussion of the placebo effect is for many, too close for comfort. At a recent conference titled “Placebo: Probing the Self-Healing Brain” Lawrence Sullivan, a historian of religion at Harvard Divinity School noted: "Nobody wants to own it. Even shamans and witch doctors would be offended by the idea that their healing powers depended on the placebo effect”. Harvard Medical School anthropologist Arthur Kleinman asked: “Why is the placebo regarded as pejorative? Is it threatening to medicine?” (19) The author of this and associated reports has no gripe with homoeopathic practitioners using the homoeopathic placebo to good effect for self-limiting conditions and minor conditions under their supervision. It is however considered criminal to treat serious conditions thus, and to sell otc’s to this end.

- “treatment with ineffective therapy, will result in unnecessary progression of disease and adverse effects. Some homoeopaths claim that there is a

duration of action from certain potencies, even up to a year after a single dose. The author has seen cases in which individuals with chronic illness, such as gingivitis and gall bladder disease, have been told to wait for the full duration of action of the remedy, resulting in continued suffering".

The whole as appears more fully from a copy of the presentation by the Gaia Research Institute to the full council of the Medicines Control Council entitled "Homoeopathy: A critique" dated May, 1999, produced herein as **Exhibit P-33**;

66. In 2002, the Department of Complementary Medicine at the University of Exeter in the United Kingdom published an article conveying the lack of effectiveness of homeopathy based on systematic reviews. In particular, they found that there was no condition which responds convincingly better to homeopathic treatment than to placebo or other control interventions. Similarly, there was no homeopathic remedy that was demonstrated to yield clinical effects that are convincingly different from placebo. It concluded that the best clinical evidence for homeopathy available to date does not warrant positive recommendations for its use in clinical practice, the whole as appears more fully from a copy of the article entitled "A systematic review of systematic reviews of homeopathy" dated 2002, produced herein as **Exhibit P-34**;

67. In August 2005, a study from the Department of Social and Preventive Medicine at the University of Berne, in Switzerland, concluded that homeopathy had no effect beyond placebo. It concluded that positive findings of trials of homeopathy are due to the presence of biases and then when account was taken for biases in the analysis of homeopathy as well as conventional medicine, there was weak evidence for a specific effect of homeopathic remedies, but strong evidence for specific effects of conventional interventions, the whole as appears more fully from a copy of the Lancet article entitled "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy" dated August 27, 2005, produced herein as **Exhibit P-35**;

68. In November 2005, an article was published in Trends in Pharmacological Sciences indicating that any implausible benefits of homeopathy do not outweigh the potential for harm that his approach can cause. Specifically, there is no conclusive evidence that highly dilute homeopathic remedies are different from placebos and that homeopathy is not entirely devoid of risk, the whole as appears more fully from a copy of the Trends in Pharmacological Sciences article entitled "Is homeopathy a clinically valuable approach?" dated November 11, 2005, produced herein as **Exhibit P-36**;

69. In November 2007, a review was conducted in order to assess the evidence of the effectiveness of complementary and alternative therapies for the prevention and treatment of influenza and influenza-like illness. Fourteen

randomized controlled trials testing seven preparations were included including Oscillococcinum. The review concluded that the effectiveness of these types of therapies is not established beyond a reasonable doubt and that the evidence is found to be sparse and limited by "small sample sizes, low methodological quality, or clinically irrelevant effect sizes", the whole as appears more fully from a copy of The American Journal of Medicine article entitled "Complementary Medicine for Treating or Preventing Influenza or Influenza-like Illness" dated November 2007, produced herein as **Exhibit P-37**;

70. In November 2009, The American Journal of Medicine published an article stating that although some alternative medicines may have some basis in science, homeopathy is absurd and nonscientific. Specifically, homeopathy is based in obsolete or metaphysical concepts[6] and its supporters, who have a "conflict of interest more powerful than the requirement for scientific integrity" will not subject their interventions to scientific scrutiny. The following are excerpts from the article:

- Homeopathy is among the worst examples of faith-based medicine that gathers shrill support of celebrities and other powerful lobbies in place of a genuine and humble wish to explore the limits of our knowledge using the scientific method.

- If homeopathy is correct, much of physics, chemistry, and pharmacology must be incorrect. To put it more strongly, in the parallel universe of homeopathy, life, as we know it, would be inconceivable, and the alien creatures that might dwell in that hostile environment are hard to envisage.

- We should start from the premise that homeopathy cannot work and that positive evidence reflects publication bias or design flaws until proved otherwise. If not, we must believe that water has a selective memory, recalling the 1×10^{-9} molecule of the mother tincture in favor of the multitude of molecules that are likely to be present in concentrations orders of magnitude greater.

- So far homeopathy has failed to demonstrate efficacy in randomized controlled trials and systematic reviews of well designed studies. Homeopathic physicians seem to clutch onto the straws of a series of poorly designed or underpowered studies to retain their credibility or claim that the randomized controlled trial is an inappropriate methodology to assess their belief system in the name of postmodern relativism.

[6] Metaphysics might include the study of the nature of the human mind, the definition and meaning of existence, or the nature of space, time, and/or causality.

- After more than 200 years, we are still waiting for homeopathy "heretics" to be proved right, during which time the advances in our understanding of disease, progress in therapeutics and surgery, and prolongation of the length and quality of life by so-called allopaths have been breathtaking. The true skeptic therefore takes pride in closed mindedness when presented with absurd assertions that contravene the laws of thermodynamics or deny progress in all branches of physics, chemistry, physiology, and medicine.

The whole as appears more fully from a copy of The American Journal of Medicine article entitled "Should We Maintain an Open Mind about Homeopathy?" dated November 2009, produced herein as **Exhibit P-38**;

71. In February 2010, the House of Commons' Science and Technology Committee in London assessed the evidence for and against homeopathy. It concluded that homeopathy was not more effective than a placebo and called for the complete withdrawal of National Health Service (NHS) funding and official licensing of homeopathy. They also accused homeopaths of having no credible evidence to support their remedies. Subsequently, the U.K. government considered their report and agreed with the verdict, but nevertheless felt that, if patients want homeopathy, they must have it on the NHS, the whole as appears more fully from a copy of the House of Commons Report entitled "Evidence Check 2: Homeopathy" dated February 22, 2010, produced herein as **Exhibit P-39**;

72. In December 2012, The International Journal of Clinical Practice conducted a systematic review of all relevant case reports and case series in order to evaluate the evidence regarding the adverse effects of homeopathy. The review concluded that homeopathy has the potential to harm patients and consumers in both direct and indirect ways and that clinicians should be aware of its risks and advise their patients accordingly, the whole as appears more fully from a copy of The International Journal of Clinical Practice article entitled "Adverse effects of homeopathy: a systematic review of published case reports and case series" dated December 2012, produced herein as **Exhibit P-40**;

73. In March 2015, the National Health and Medical Research Council of Australia analyzed over 200 academic research papers and concluded that homeopathy is not an effective treatment for any disease or condition. In undertaking an assessment of the evidence of the effectiveness of homeopathy, it concluded that "there was no reliable evidence from research in humans that homeopathy was effective for treating the range of health conditions considered: no good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment". In addition, it determined that people who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence

of safety and effectiveness, the whole as appears more fully from a copy of the Australian Government National Health and Medical Research Council's Information Paper entitled "NMHRC Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions" dated March 2015, attached hereto as **Exhibit P-41**;

74. In addition, the paper (Exhibit P-41) concluded the following:

> "Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective.
>
> Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness. People who are considering whether to use homeopathy should first get advice from a registered health practitioner. Those who use homeopathy should tell their health practitioner and should keep taking any prescribed treatments."

75. As has been succinctly stated:

> Homeopathy is an elaborate placebo system of "remedies" with no active ingredients. Based on the prescientific notion of "like cures like", proponents of homeopathy believe that any substance can be an effective remedy if it's diluted enough: raccoon fur, the sunlight reflecting off Saturn, and even pieces of the Berlin Wall can all be homeopathic remedies. The 30C "potency" is common – it's a ratio of 10-60. With this remedy, you would have to give two billion homeopathic doses per second, to six billion people, for 4 billion years, to deliver a single molecule of the original material

The whole as appears more fully from a copy of the Skeptic North article entitled "Mass Homeopathic Overdose Kills No One: Victory Declared" dated January 30, 2010, produced herein as **Exhibit P-42**;

E. <u>The United States</u>

76. On January 14, 2011, a class action complaint was filed in the United States District Court for the Central District of California alleging that another of Boiron, Inc.'s homeopathic products, Children's Coldcalm, had been falsely advertised in terms of efficacy on the product packaging. On August 24, 2011, the class action was certified by the Honourable Judge Josephine Staton Tucker, United States District Judge, the whole as appears more fully from a copy of the "Order Granting Plaintiff's Motion for Class Certification and

Denying as Moot Plaintiff's Motion to Strike and Defendant's Motion to Strike" dated August 24, 2011 in *Delarosa* v. *Boiron, Inc. et al.*, Case No. 8:10-cv-1569-JST (CWx), produced herein as **Exhibit P-43**;

77. On April 16, 2013, a class action settlement was reached between the parties involving modification of the labelling and packaging for Children's Coldcalm as well as refunds of the purchase price of the product. On November 6, 2013, the settlement agreement was approved by the court, the whole as appears more fully from a copy of the Class Action Settlement Agreement dated April 13, 2013 and from a copy of the "Order and Judgment Granting Motion for Approval of Class Action Settlement" dated November 6, 2013 in *Delarosa* v. *Boiron, Inc. et al.*, Case No. 8:10-cv-1569-JST (CWx), produced herein *en liasse* as **Exhibit P-44**;

78. On September 2, 2011, a class action complaint was filed in the United States District Court for the Southern District of California alleging substantially similar allegations albeit without going too far into the merits. On February 6, 2012, the class action complaint was amended, the whole as appears more fully from a copy of the Class Action Complaint and from a copy of the First Amended Complaint in *Gallucci et al.* v. *Boiron Inc. et al*., under case no. 11-cv-02039-JAH-NLS, produced herein *en liasse* as **Exhibit P-45**;

79. On February 27, 2012, a settlement agreement was reached between the parties whereby class members were able to recover the full price of their purchase and which also included injunctive relief by way of modification of the label and packaging for the Oscillo Products in the following manner:

    (a) FDA Disclaimer: the following language on the same outer label or package panel that bears the Drug Facts box, would include "These 'Uses' have not been evaluated by the Food and Drug Administration";

    (b) Dilution Disclaimer: The back panel of each product's outer label or package would be modified to include the following language in close proximity to the Drug Facts: "C, K, CK, and X are homeopathic dilutions" with a link to a website for further information;

    (c) Modification of the Defendants' webpages;

    The whole as appears more fully from a copy of the Settlement Agreement dated February 27, 2012 in *Gallucci et al.* v. *Boiron Inc. et al*., under case no. 11-cv-02039-JAH-NLS, produced herein as **Exhibit P-46**;

80. On April 25, 2012, the Honourable Judge John A. Houston of the United States District Court for the Southern District of California granted preliminary approval of the class action settlement and on October 31, 2012, the court granted final approval to the settlement agreement, the whole as appears more

fully from a copy of the "Order (1) Granting Preliminary Approval of Class Action Settlment *[sic]*, (2) Certifying Settlement Class, (3) Appointing Class Representatives and Lead Class Counsel, (4) Approving Notice Plan, and (5) Setting Final Approval Hearing" dated April 25, 2012 and from a copy of the "Final Judgment and Order: (1) Approving Class Action Settlement, (2) Awarding Class Counsel Fees And Expenses, (3) Awarding Class Representatives Incentives, (4) Permanently Enjoining Parallel Proceedings, And (5) Dismissing Action With Prejudice" dated October 31, 2012, produced herein *en liasse* as **Exhibit P-47**;

81. On December 13, 2016, the United States Federal Trade Commission issued an enforcement policy whereby homeopathic companies must either prove the efficacy of their products before making efficacy claims or include a disclaimer on the packaging that says that there is no scientific evidence that the product works and that the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts, the whole as appears more fully from a copy of the United States Federal Trade Commission Press Release entitled "FTC Issues Enforcement Policy Statement Regarding Marketing Claims for Over-the-Counter Homeopathic Drugs" dated November 15, 2016 and from a copy of the Federal Register/ Vol. 81, No. 239 – Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs, produced herein *en liasse* as **Exhibit P-48**;

F. <u>The Fault</u>

82. The claimed active ingredient, *Anas Barbariae Hepatis et Cordis Extractum* (i.e. an extract/ preparation of the heart and liver of a duck), is not medicinal in that it does not alleviate flu symptoms and further, even if it had any medicinal properties (which it does not), it is not even an ingredient in the Oscillo Products due to unfathomably high dilutions in the preparation of the product;

83. Despite this, the Defendant falsely and misleadingly advertises and represents the Oscillo Products as containing a medicinal ingredient that relieves symptoms of the flu such as fever, chills, body aches and pains;

84. In fact, the Oscillo Products are nothing more than placebos; sugar pellets onto which minute quantities of water have been absorbed;

85. In falsely advertising the Oscillo Products as being capable of combatting the flu and/or flu-like symptoms, the Defendant put human health at risk as consumers were led to reject or to delay safe and effective treatments for their illnesses. This reality is all the more exacerbated by the fact that there are many thousands of hospitalizations and deaths each year in Canada due to the influenza virus, making it vital that consumers make informed choices on how to heal when afflicted and this, as soon as possible;

IV. THE EXAMPLE OF THE PLAINTIFF/ CLASS REPRESENTATIVE

86. In the late fall of 2011/ winter of 2012, the Plaintiff/ Class Representative purchased Oscillococcinum and Children Oscillococcinum from Jean Coutu at 3347 Boulevard des Sources, in Dollard-des-Ormeaux, Quebec for approximately $15.49 plus taxes each;

87. The Plaintiff/ Class Representative believed, after reading the Defendant's labelling, that the Oscillo Products would help herself and her child, who was 5 at the time, to fight the flu and relieve their symptoms which included fever, chills, body aches and pains;

88. The Plaintiff/ Class Representative and her child used the product as directed, but it did not live up to its promised results, having no noticeable effect on their flu symptoms;

89. The Plaintiff/ Class Representative has since discovered that the ingredients in Oscillococcinum and Oscillococcinum Children have no proven health benefit and that these ingredients are so diluted that they are not even present in the final product;

90. In consequence, the Plaintiff/ Class Representative feels that she has been misled by Boiron and that had she known the true facts, she would not have purchased the Oscillo Products;

91. The Plaintiff/ Class Representative's damages are a direct and proximate result of the Defendant's conduct;

92. In consequence of the foregoing, Plaintiff/ Class Representative is justified in claiming damages:

V. THE DAMAGES

93. Every member of the Class has purchased one or more of the Defendant's Oscillo Products;

94. Each member of the Class is justified in claiming damages in the amount of the purchase price of the Oscillo Products that they purchased as well as any other related damages that they suffered as a result of the purchase and punitive damages;

95. All of the damages to the Class Members are a direct and proximate result of the Defendants' conduct;

96. In consequence of the foregoing, members of the Class are justified in claiming damages, which will be calculated when further information is available so as to better evaluate the number of Class Members in Canada:

FOR THESE REASONS, MAY IT PLEASE THIS HONOURABLE COURT TO:

GRANT the class action of the Representative Plaintiff and each of the members of the Class.

ORDER the Defendant to cease from continuing its unfair, false, misleading, and/or deceptive conduct.

DECLARE the Defendant liable for the damages suffered by the Representative Plaintiff and each of the members of the Class.

CONDEMN the Defendant to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums.

CONDEMN the Defendant to pay each of the members of the Class, punitive damages, and ORDER collective recovery of these sums.

CONDEMN the Defendant to pay legal interest and additional indemnity on the above sums from the date of service of the application to authorize a class action.

ORDER the Defendant to deposit in the office of the court the totality of the sums which forms part of the collective recovery, with interest, additional indemnity and legal costs.

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation.

CONDEMN the Defendant to bear the costs of the present action including expert and notice fees.

RENDER any other order that the court shall determine and that is in the interest of the members of the Class.

Montreal, August 4, 2017

(s) Andrea Grass

_____

CONSUMER LAW GROUP INC.
Per: Me Andrea Grass
Attorneys for the Plaintiff / Class Representative

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SUMMONS
(Arts. 145 and following C.C.P.)

TO: **BOIRON CANADA INC.**
1300 René-Descartes
Saint-Bruno-de-Montarville
Quebec, J3V 0B7

TAKE NOTICE that the Plaintiff/ Class Representative filed the present application in the office of the Superior Court, in the judicial district of Montreal.

YOU MUST answer this application in writing, personally or through a lawyer, at the Montreal Courthouse (the Palais de Justice) situated at 1 Notre Dame East, Montreal, Quebec, H2Y 1B6, Canada within 15 days of service of this Application or if you have no domicile, residence, or establishment in Quebec, within 30 days thereof. The answer must be notified to the Plaintiff/ Class Representative's lawyer.

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgment may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the cases required by the Code, cooperate with the Plaintiff/ Class Representative in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

You may ask the court to refer the application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the Plaintiff/ Class Representative.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the

immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

In support of the Application to institute proceedings, the Plaintiff/ Class Representative discloses the following exhibits:

P-1: Copies of extracts for the Defendant from the *Registraire des enterprises* dated April 13, 2012 and July 31, 2017, *en liasse*;

P-2: Copies of the Product Licenses for the Oscillo Products, *en liasse*;

P-3: Copy of the Centers for Disease Control and Prevention article entitled “Key Facts About Influenza (Flu)”;

P-4: Copy of the Centers for Disease Control and Prevention article entitled “Flu Symptoms & Complications”;

P-5: Copy of the WebMD article entitled “What is the Flu?”,

Copy of the Government of Canada article entitled “Symptoms of flu (influenza)”,

Copy of the Government of Canada brochure entitled “Is it a cold or the flu?” *en liasse*;

P-6: Copies of reports from the Public Health Agency of Canada dated April 13, 2012 and July 31, 2017, *en liasse*;

P-7: Copy of the World Health Organization article entitled “The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010” dated June 16, 2010,

Copy of the World Health Organization Press Release entitled “World now at the start of 2009 influenza pandemic” dated June 11, 2009, *en liasse*;

P-8: Copy of the World Health Organization Press Briefing entitled “Pandemic (H1N1) 2009”;

P-9: Copy of a checkout cart from the Defendant’s website at www.boiron.ca;

P-10: Copy of an extract from the Defendant’s website www.oscillo.com;

P-11: Copies of extracts from the Defendant’s website www.boiron.ca, *en liasse*;

P-12: Copies of the product labels for Oscillococcinum, *en liasse*;

P-13: Copies of Oscillococcinum Children’s product label, *en liasse*;

P-14: Copy of the article entitled “The True Story of Oscillococcinum” dated August 27, 2003;

P-15: Copy of the Science-Based Pharmacy article entitled “Remedy Regulation: Homeopathy in Canada” dated April 14, 2010;

P-16: Copy of the article entitled “Flu Symptoms? Try Duck” dated February 9, 1997;

P-17: Copy of the article entitled “Homeopathy - Delusion through Dilution” dated June 5, 2012;

P-18: Copy of the Expert Report of Dr. Lynn Willis dated April 12, 2013;

P-19: Copy of the Respiratory Medicine study entitled “Preventing influenza: An overview of systematic reviews” dated June 14, 2005;

P-20: Copy of the Cochrane Database of Systematic Reviews study entitled “Homeopathic Oscillococcinum® for preventing and treating influenza and influenza-like illness” dated January 28, 2015

P-21: Copy of the Wikipedia page for the Oscillo products at https://en.wikipedia.org/wiki/Oscillococcinum

P-22: Copy the Government of Canada article entitled “Consulting Canadians on the regulation of self-care products in Canada”;

P-23: Copy of the DVD copy of the CBC/Radio Canada Marketplace television episode entitled “Drugstore remedies: Licence to Deceive”, which was broadcasted in Canada on March 13, 2015;

P-24: Copy of the CBC News article entitled “Health Canada licensing of natural remedies ‘a joke’, doctor says” dated March 12, 2015;

P-25: Copy of Health Canada’s Evidence for Homeopathic Medicines: Guidance Document dated July 2015;

P-26: Copy of the Health Canada Alert entitled “Nosodes and children’s cough, cold and flu homeopathic products Labelling Changes” dated July 31, 2015;

P-27: Copy of the CBC Marketplace article entitled “Unproven homeopathic remedies for kids still promising relief despite new label rules” dated May 9, 2017;

P-28: Copy of the CBC News article entitled “Health Canada's new rules for homeopathic products for kids should apply to adults, expert says” dated August 6, 2015;

P-29: Copy of Dr. Matthew Stanbrook’s Editorial entitled “Natural health products should be sold separately from drugs” dated June 26, 2017;

P-30: Copy of the 10:23 Campaign article entitled “What is Homeopathy”;

P-31: Copy of an extract from the Medicinenet website www.medicinenet.com,

Copy of the Harvard Health Publication entitled “The power of the placebo effect” dated May, 2017,

Copy of the Vox article entitled “The weird power of the placebo effect, explained” dated July 7, 2017, *en liasse*;

P-32: Copy of the New Science editorial entitled “The power of magic – Using science to prove homeopathy works will destroy the essence of its appeal” dated September 27, 1997;

P-33: Copy of the presentation by the Gaia Research Institute to the full council of the Medicines Control Council entitled “Homoeopathy: A critique” dated May, 1999;

P-34: Copy of the article entitled “A systematic review of systematic reviews of homeopathy” dated 2002;

P-35: Copy of the Lancet article entitled “Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy” dated August 27, 2005;

P-36: Copy of the Trends in Pharmacological Sciences article entitled “Is homeopathy a clinically valuable approach?” dated November 11, 2005;

P-37: copy of The American Journal of Medicine article entitled “Complementary Medicine for Treating or Preventing Influenza or Influenza-like Illness” dated November 2007;

P-38: Copy of The American Journal of Medicine article entitled “Should We Maintain an Open Mind about Homeopathy?” dated November 2009;

P-39: Copy of the House of Commons Report entitled “Evidence Check 2: Homeopathy” dated February 22, 2010;

P-40: Copy of The International Journal of Clinical Practice article entitled “Adverse effects of homeopathy: a systematic review of published case reports and case series” dated December 2012;

P-41: Copy of the Australian Government National Health and Medical Research Council’s Information Paper entitled “NMHRC Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions” dated March 2015;

P-42: Copy of the Skeptic North article entitled “Mass Homeopathic Overdose Kills No One: Victory Declared” dated January 30, 2010;

P-43: Copy of the “Order Granting Plaintiff’s Motion for Class Certification and Denying as Moot Plaintiff’s Motion to Strike and Defendant’s Motion to Strike” dated August 24, 2011 in *Delarosa* v. *Boiron, Inc. et al.*, Case No. 8:10-cv-1569-JST (CWx);

P-44: Copy of the Class Action Settlement Agreement dated April 13, 2013,

Copy of the “Order and Judgment Granting Motion for Approval of Class Action Settlement” dated November 6, 2013 in *Delarosa* v. *Boiron, Inc. et al.*, Case No. 8:10-cv-1569-JST (CWx), *en liasse*;

P-45: Copy of the Class Action Complaint,

Copy of the First Amended Complaint in *Gallucci et al.* v. *Boiron Inc. et al*., under case no. 11-cv-02039-JAH-NLS, *en liasse*;

P-46: Copy of the Settlement Agreement dated February 27, 2012 in *Gallucci et al.* v. *Boiron Inc. et al*., under case no. 11-cv-02039-JAH-NLS;

P-47: Copy of the "Order (1) Granting Preliminary Approval of Class Action Settlment [sic], (2) Certifying Settlement Class, (3) Appointing Class Representatives and Lead Class Counsel, (4) Approving Notice Plan, and (5) Setting Final Approval Hearing" dated April 25, 2012,

Copy of the "Final Judgment and Order: (1) Approving Class Action Settlement, (2) Awarding Class Counsel Fees And Expenses, (3) Awarding Class Representatives Incentives, (4) Permanently Enjoining Parallel Proceedings, And (5) Dismissing Action With Prejudice" dated October 31, 2012, *en liasse*;

P-48: Copy of the United States Federal Trade Commission Press Release entitled "FTC Issues Enforcement Policy Statement Regarding Marketing Claims for Over-the-Counter Homeopathic Drugs" dated November 15, 2016,

Copy of the Federal Register/ Vol. 81, No. 239 – Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs, *en liasse*.

These exhibits are available on request.

Montreal, August 4, 2017

(s) Andrea Grass

_____
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Per: Me Andrea Grass
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(Class Action)
SUPERIOR COURT
DISTRICT OF MONTREAL

A. CHARLES

Plaintiff/ Class Representative

-vs.-

BOIRON CANADA INC.

Defendant

APPLICATION TO INSTITUTE PROCEEDINGS
(Arts. 141 and following and arts. 583 and following C.C.P.)

COPY

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Me Andrea Grass (ext. 3)
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