CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Action)

No.: 500-06-001004-197

(…) JEAN-FRANÇOIS BOURASSA

Plaintiff

v.

ABBOTT LABORATORIES, LIMITED *et al.*

Defendants

AMENDED APPLICATION BY DEFENDANT SANIS HEALTH INC. FOR LEAVE TO ADDUCE RELEVANT EVIDENCE (Art. 574 C.C.P.)

TO THE HONOURABLE GARY D.D. MORRISON, J.S.C., SITTING IN THE DISTRICT OF MONTREAL, AND DESIGNATED TO PRESIDE OVER THE PRESENT MATTER, DEFENDANT SANIS HEALTH INC. RESPECTFULLY SUBMITS AS FOLLOWS:

A. Introduction

1. Defendant Sanis Health Inc. ("**Sanis**") seeks leave to adduce relevant evidence in order to establish facts that are necessary to enable this Court to undertake an informed analysis, in light of the criteria set out in article 575 of the *Code of Civil Procedure* ("**CCP**"), regarding the authorization to institute class action proceedings sought by the Plaintiff.

2. In his *Re-Amended Application for Authorization to Institute a Class Action* dated (…) December 17, 2021 (the "**Application**"), (…) Mr. Jean-François Bourassa (**"Plaintiff"**) seeks this Court's authorization to bring a class action against Defendants on behalf of the following class:

> *All persons in Quebec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the Defendants between 1996 and the present day ("Class Period") and who suffer or have suffered from Opioid Use Disorder, according to the diagnostic criteria herein described.*
>
> *The Class includes the direct heirs of any deceased persons who met the above-mentioned description.*
>
> *The Class excludes any person's claim, or any portion thereof, subject to the settlement agreement entered into in the court file no (…). (…)*

200-06-000080-070, provided that such settlement agreement becomes effective as a result of the issuance of the requisite court approvals.

3. Plaintiff seeks to hold Defendants liable for the damages he alleges having suffered further to his use of opioids over a period of (…) eleven years. He claims that he was first prescribed opioids for pain management following (…) a fall from a roof on November 27, 2005, which caused multiple fractures to his left fibula and ankle.

4. Plaintiff further claims that (…) he has greatly suffered, and continues to suffer, from opioid use disorder and its side effects, which has caused him to miss important moments with his children, strained his marriage, and led to him being unable to work.

5. Article 574 CCP confers on this Court the power to authorize the presentation of relevant evidence to the analysis of the threshold authorization conditions in Article 575 CCP, including the production of documentary evidence.

6. As the Application sets forth a number of imprecise allegations and generalizations, Sanis should be afforded the opportunity to adduce evidence at the authorization stage that will bring more precision to the allegations contained in the Application as concerns Sanis and will inform the Court's assessment of whether the Application meets the threshold authorization conditions set out in Article 575 CCP.

B. The Evidence that Sanis Seeks to Adduce

7. The evidence which Sanis seeks leave to adduce is relevant, appropriate and proportional in respect of the assessment of the authorization conditions as concerns Sanis.

8. The sworn statement of Chris Potter which Sanis seeks leave to adduce (the "**Sworn Statement**") is attached hereto as **Schedule A**. The Sworn Statement brings clarity and precision to imprecise and general allegations contained in the Application by providing the Court with an overview of (a) Sanis' generic drug business and the extent of its activities in Quebec; (b) Sanis' consequent complete lack of promotional marketing efforts for its opioid products, and (c) the period of time during which Sanis was selling opioid products in Quebec, which is significantly shorter than the Class Period.

(a) Sanis Business Model

9. Plaintiff alleges that the Defendants competed with each other to increase their respective market shares and "generally acted in concert to promote the false and misleading narrative…concerning the safety and efficacy of opioids" in an effort to increase their prescription rate and sale of their drugs (paras 2.43 and 2.44).

10. These general allegations make no distinction as concerns manufacturers of generic drug products with limited opioid sales and no promotional marketing activities, such as Sanis. As more fully described in the Sworn Statement, Sanis' sales were only

made to two wholesalers and opioid sales represented a small share of Sanis' overall sales in any given year. Further, Sanis' market share has never exceeded 1% of overall opioid sales in Quebec, and the number of opioid products that Sanis produced was also small as compared to several other opioid manufacturers selling products in Quebec.

11. The allegations set out in paragraph 9 above therefore lack any factual basis in light of Sanis' business model, which was simply not focused on opioid sales or promotion. The evidence Sanis seeks leave to adduce will provide relevant and important clarifications to correct these allegations against Sanis.

(b) Lack of Marketing Efforts

12. Plaintiff alleges that in their promotional marketing efforts, the Defendants acted in concert to advance several misrepresentations, including but not limited to misrepresentations relating to the addictive nature of opioids, the efficacy of opioids over other pain relief treatments, the management of withdrawal from opioids, the tolerance developed to opioids, and the appropriateness and adverse effects of long term use of opioids (paras 2.46-2.81).

13. Plaintiff alleges that these misrepresentations were spread by the Defendants, who "engaged in aggressive marketing and sales practices which were entirely inappropriate for the distribution of dangerous, addictive drugs" (para 2.82) and engaged in aggressive sales tactics in order to spread these misrepresentations, to health care professionals, medical students, the public, and by funding patient advocacy groups (para 2.84).

14. These general allegations make no distinction as concerns manufacturers of generic drug products, such as Sanis. As is more fully exposed in the Sworn Statement, Sanis never engaged in any promotional marketing, never marketed its products to the public, pharmacists, or physicians, never had a sales force, and never funded any types of clinical trials, research or patient advocacy groups, or continuing professional education seminars or programs.

15. There is therefore no factual basis for the general and imprecise allegations described in paragraphs 12 and 13 above as regards Sanis, and the evidence which Sanis seeks leave to adduce provides the Court with relevant clarifications regarding same.

(c) Relevant Time Period

16. The Plaintiff seeks to bring a class action on behalf of persons in Quebec who were prescribed and consumed opioids manufactured, marketed, distributed, and/or sold by the Defendants between 1996 and the present day (defined as the Class Period in the Application).

17. Plaintiff alleges that his opioid addiction began (…) sometime after the above-described accident in 2005 following which he was prescribed opioids, and that it

persisted for eleven years before he sought treatment. He alleges that he continues to suffer from opioid use disorder and its side effects to this day (paras 2.212 to 2.220, 2.233).

18. As is more fully exposed in the Sworn Statement, Sanis began selling opioids to its only two customers in Quebec, namely Shoppers Drug Mart Inc. and McKesson Canada Corporation, in 2011, 15 years into the class period and (…) six years after the Plaintiff was first introduced to opioids. Further, Sanis is no longer manufacturing any of the opioid products that it sold to its two Quebec customers and the inventory of these products among its two customers has been depleted (except for a limited number of units of a particular type of Morphine).

19. The evidence that Sanis seeks leave to adduce therefore provides important precisions to the Plaintiff's allegations in respect of Sanis and the existence of a personal cause of action against Sanis.

C. Conclusion

20. The factual elements exposed in the Sworn Affidavit are central to the question of whether the criteria for authorization pursuant to art. 575 C.C.P. are met, specifically, whether the facts alleged in the Application appear to justify the conclusions sought against Sanis.

21. It appears from Plaintiff's Application that it contains several general, incomplete, vague or inaccurate allegations which are prejudicial to Sanis. (…) Other than alleging that Sanis manufactured certain opioids, the Application's only particularized allegation in respect of Sanis is that, as part of his treatment process for Opioid Use Disorder, Morphine SR manufactured by Sanis was prescribed to him for a period of 35 days.

21.1 The Application does not make any particularized allegations against Sanis outside of the withdrawal management process resulting from treatment sought by the Plaintiff, and therefore contains no allegations against Sanis with respect to the period during which the Plaintiff alleges that he became addicted to opioids and in which the alleged misrepresentations described in paragraphs 12 and 13 hereof would be relevant. This leaves before the Court overly broad and undue generalizations which purportedly apply to all Defendants. Sanis should be afforded the opportunity to adduce evidence which will fill this factual void and assist the Court in applying the criteria for authorization.

22. Indeed, the evidence which Sanis seeks to adduce will assist this Court in gaining a general understanding of the extent of Sanis' activities in Quebec, and in particular, who its customers were, its limited opioid sales in Quebec, the time period of its opioid sales in Quebec and its lack of any promotional marketing in Quebec or elsewhere.

23. The evidence which Sanis requests leave to adduce is limited to strictly circumscribed and precise subjects and facts, is consistent with the intendant nature of the

authorization process, and thus complies with the criteria of relevance, proportionality and reasonability provided at Articles 18 and 19 CCP.

24. In sum, the evidence which the Defendant Sanis seeks to adduce would enable this court to proceed with an efficient review of the criteria contained at Article 575 CCP, and would result in a more efficient hearing of the Application.

25. This Court should not prevent itself from having the benefit of evidence which could assist it in its analysis of the authorization criteria set forth in Article 575 CCP.

FOR THESE REASONS, MAY IT PLEASE THE COURT TO:

GRANT the present Amended Application for leave to adduce relevant evidence;

AUTHORIZE the Defendant Sanis to file a sworn statement of Chris Potter substantially similar to the document filed herewith as Schedule A;

THE WHOLE without costs, unless contested.

MONTREAL, (…) January 12, 2022

Osler, Hoskin & Harcourt

OSLER HOSKIN & HARCOURT LLP
1000 De La Gauchetière Street West, #2100
Montréal, Québec H3B 4W5
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Lawyers for Defendant
SANIS HEALTH INC.
Me Alexandre Fallon | Me Julien Morissette
afallon@osler.com | jmorissette@osler.com |
notificationosler@osler.com
Our file: 1201623

NOTICE OF PRESENTATION

To: **The service list**

TAKE NOTICE that the *Amended Application by Defendant Sanis Health Inc. for Leave to Adduce Relevant Evidence* will be presented for hearing and allowance before the Honourable Gary D.D. Morrison of the Superior Court of Québec, 1 Notre-Dame Street East, Montreal, Québec, at a time and place to be determined, or so soon thereafter as Counsel may be heard.

GOVERN YOURSELVES ACCORDINGLY.

MONTREAL, (…) January 12, 2022

Osler, Hoskin & Harcourt

OSLER HOSKIN & HARCOURT LLP
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Lawyers for Defendant
SANIS HEALTH INC.
Me Alexandre Fallon | Me Julien Morissette
afallon@osler.com | jmorissette@osler.com |
notificationosler@osler.com
Our file: 1201623

Schedule "A"

CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Action)

No.: **500-06-001004-197**

RICCARDO CAMARDA

Plaintiff

v.

ABBOTT LABORATORIES, LIMITED *et al.*

Defendants

SWORN DECLARATION OF CHRIS POTTER

I, Chris Potter, business executive, exercising my occupation at 1 President's Choice Circle, in the City of Brampton, in the Province of Ontario, L6Y 5S5, SOLEMNLY AFFIRM AS FOLLOWS:

1. I am the Senior Vice President, Healthcare Businesses of Sanis Health Inc. ("**Sanis**"). I have held this role since July 2019 and have worked for Sanis since July 2009. Prior to joining Sanis, I worked for a generic drug manufacturer. In my roles at Sanis I have been involved in Sanis' operations as they relate to opioid products. As such, I have personal knowledge of the facts and matters to which I depose, except where stated to be based upon information and belief, in which case I believe the information to be true.

2. I make this affidavit in support of Sanis' defence of the plaintiff's Amended application for authorization to institute a class action in this matter.

Sanis

3. Sanis is a licensed manufacturer of generic drug products. For the purposes of the *Food and Drugs Act*, RSC 1985, c F-27, a manufacturer means "a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug" (*Food and Drug Regulations*, CRC, c 870 at A.01.010).

4. Sanis contracts with generic drug manufacturers who cross licence their regulatory submissions to Sanis, which allows Sanis to obtain its own Health Canada approvals. The manufacturers granting the cross licence also fabricate, package and label the same generic drugs for Sanis under the Sanis branding, although Sanis also participates in the fabrication of certain of its drug products.

Sanis Opioid Products

5. Sanis has only ever manufactured and sold three types of opioid drugs: (i) Morphine, (ii) Oxycodone Hydrochloride/Acetaminophen, (iii) and Tramadol Hydrochloride/Acetaminophen. Within these three categories, Sanis has manufactured and sold the following opioid products (the "**Sanis Opioid Products**"):

Table 1 - Sanis Opioid Products

Exhibit	Product Name	DIN	DIN Date	DIN Status
"A"	MORPHINE SULF SR 15MG TAB 50's	02350815	May 6, 2010	Discontinued Dec-23-2020
"A"	MORPHINE SULF SR 30MG TAB 100's	02350890	May 6, 2010	Discontinued Mar-16-2021
"A"	MORPHINE SULF SR 60MG TAB 100's	02350912	May 6, 2010	Currently in force
"A"	MORPHINE SULF SR 100MG TAB 50's	02350920	May 6, 2010	Discontinued Aug-01-2014
"A"	MORPHINE SULF SR 200MG TAB 50's	02350947	May 6, 2010	Discontinued Aug-01-2014
"B"	TRAMADOL/ACET 37.5/325 TAB 100's	02426803	July 24, 2014	Discontinued Dec-16-2020
"C"	OXYCODONE/ACET 5/325MG TABS 100's	02361361	March 2, 2011	Discontinued Jan-7-2021
"C"	OXYCODONE/ACET 5/325MG TABS 500's	02361361	March 2, 2011	Discontinued Jan-7-2021

6. Sanis manufactured the Sanis Opioid Products pursuant to Health Canada authorizations generally referred to as "marketing authorizations". The marketing authorizations for the Morphine Sulfate and Tramadol/Acetaminophen products listed in Table 1 are recorded in Notices of Compliance attached as **Exhibits "A"** and **"B"** and dated May 6, 2010 and July 24, 2014 respectively. The marketing authorizations for the Oxycodone/Acetaminophen products listed in Table 1 are recorded in Health Canada's online Drug Product Database. A copy of the relevant Drug Product Database entry for

the Oxycodone/Acetaminophen products, accessed March 26, 2021, is attached as **Exhibit "C"**.

7. These Health Canada marketing authorizations are the only opioid-related marketing authorizations Sanis has ever held.

8. The Product Name, drug identification number ("**DIN**"), and DIN Date information listed in Table 1 is found in Exhibits "A", "B", and "C". The DIN Status for the Oxycodone/Acetaminophen products listed in Table 1 is also listed in Exhibit "C". The DIN Status for the remaining products listed in Table 1 are recorded in Health Canada's online Drug Product Database. Copies of the relevant Drug Product Database entries for the Morphine Sulfate and Tramadol/Acetaminophen products, accessed March 26, 2021, are attached as **Exhibit "D"**.

9. The period of time during which Sanis was authorized to manufacture and sell the Sanis Opioid Products is determined with reference to the product's DIN Date and DIN Status. The DIN Date is the date that Sanis received authorization to manufacture and sell the product from Health Canada. The product's DIN Status indicates whether Sanis continues to hold the DIN or whether it has been discontinued.

10. Sanis has discontinued the DINs of seven Sanis Opioid Products: Morphine Sulf SR 15MG TAB 50's, Moprhine Sulf SR 30MG TAB 100's, Morphine Sulf SR 100MG TAB 50's, Morphine Sulf SR 200MG TAB 50's, Oxycodone/Act 5/325MG TABS 100's, Oxycodone/Act 5/325MG TABS 500's, and Tramadol/Acet 37.5/325 TAB 100's. Sanis no longer manufactures or sells these products and has not manufactured or sold these products since the relevant DIN was discontinued.

11. Sanis continues to hold the DIN for one Sanis Opioid Product: Morphine Sulf SR 60MG TAB 100's. Sanis no longer manufactures this product.

Sanis Opioid Products Sold in Québec

12. Sanis sold each of the Sanis Opioid Products in Québec. Table 2 below lists the dates that the Sanis Opioid Products were (i) listed on the Québec List of medications (eligible for reimbursement under the public prescription drug insurance

plan) as a generic drug interchangeable with the corresponding brand drug, and (ii) first shipped to Québec.

Table 2 – Dates Sanis Opioid Products Listed in and Shipped to Québec

Product Name	First Listed on List of Medications	First Shipped to Québec Wholesaler
MORPHINE SULF SR 15MG TAB 50's	July 5, 2011	August 22, 2011
MORPHINE SULF SR 30MG TAB 100's	July 5, 2011	July 20, 2011
MORPHINE SULF SR 60MG TAB 100's	July 5, 2011	July 20, 2011
MORPHINE SULF SR 100MG TAB 50's	July 5, 2011	July 20, 2011
MORPHINE SULF SR 200MG TAB 50's	July 5, 2011	July 20, 2011
TRAMADOL/ACET 37.5/325 TAB 100's	October 1, 2014	September 22, 2014
OXYCODONE/ACET 5/325MG TABS 100's	September 30, 2011	October 12, 2011
OXYCODONE/ACET 5/325MG TABS 500's	September 30, 2011	October 12, 2011

13. I am informed by Jan Kuang, Manager, Strategic Procurement and Supply Planning, and believe that the dates in the column titled "First Listed in List of Medications" are the dates that the relevant product was first listed in the Québec List of medications. I am also informed by Ms. Kuang and believe that the dates in the column titled "First Shipped to Québec Wholesaler" are the dates that Sanis first shipped the relevant product to a wholesaler's warehouse (either located in Québec or located outside Québec but for onward distribution to Québec).

14. I am informed by Ms. Kuang and believe that the Sanis Opioid Products were not available for retail purchase in Québec until after each product was listed on the List of medications, as applicable.

15. Sanis sold Sanis Opioid Products to two customers in respect of the Québec market: Shoppers Drug Mart Inc. and McKesson Canada Corporation, both accredited wholesalers selling into Québec.

16. Sanis is no longer manufacturing any of the Sanis Opioid Products. Further, Sanis is no longer selling any of the Sanis Opioid Products to any Québec customers. As of the date of this affidavit, I am informed by Celia Williamson, Senior Manager, Sanis Supply Chain & Operations, and believe that the inventory of Sanis Opioid Products among Sanis' two Québec customers has been depleted except for a

limited number of units of Morphine Sulf SR 60MG TAB 100's (for which Sanis continues to hold a valid DIN).

17. Sanis did not sell Sanis Opioid Products directly to pharmacists or hospitals in Québec, however, pharmacists and hospitals were able to purchase Sanis Opioid Products through accredited wholesalers.

18. During the time Sanis sold the Sanis Opioid Products to customers in Québec, it had a very small share of the Québec opioids market. I am informed by Brian Vitola, Manager, Generic Procurement, and believe, that based on pharmaceutical sales data commercially acquired from IQVIA, Sanis' estimated Québec opioids market share relative to the broader Québec opioids market is as listed in the table below:

Table 3 - Sanis Opioid Products Estimated Québec Market Share

Year	Estimated Market Share
2012	0.17%
2013	0.15%
2014	0.29%
2015	0.76%
2016	0.76%
2017	0.90%
2018	0.96%
2019	0.88%
2020	0.42%

19. The Sanis Opioid Products sold by Sanis represented a small percent of Sanis' overall sales in Québec. I am informed by Brian Vitola, Manager, Generic Procurement, and believe that the estimated percentage of Sanis' overall sales in Québec to the sale of Sanis Opioid Products in Québec is as listed in the table below:

Table 4 - Sanis Opioid Products Estimated Share of Québec Sales

Year	Estimated Share of Québec Sales
2012	0.3%
2013	0.2%
2014	0.4%

2015	0.9%
2016	0.9%
2017	0.9%
2018	1.4%
2019	1.2%
2020	0.6%

No Marketing and No Funding of Research or Patient Groups

20. Sanis has never engaged in marketing, i.e. promoting or advertising the Sanis Opioid Products to the general public, pharmacists, or physicians. Sanis does not have a sales force. It does not fund or promote clinical trials or other research, nor patient advocacy groups. Similarly, Sanis has never funded or sponsored any continuing professional education seminars or programs.

21. Sanis has a publicly accessible website, www.sanis.com, but this website is not used as a promotional marketing tool. Its content is limited to providing the public with Sanis' contact information, a list of the products manufactured by Sanis, and patient information from product monographs, with Health Canada mandated content.

22. I note that advertising of the Sanis Opioid Products to the general public is prohibited by the restrictions on the advertising of narcotics contained in the *Narcotic Control Regulations* (CRC, c 1041) under the *Controlled Drugs and Substances Act*, SC 1996, c 19. At all times, Sanis has complied with its obligations under the law and has never advertised the Sanis Opioid Products to the general public.

23. On February 5, 2019, Ruth Moses, Director of Sanis Regulatory Affairs and Quality Assurance, responded to a request from Health Canada regarding the marketing and advertising of opioids by providing written confirmation that Sanis did not engage in any advertising or marketing to healthcare professionals. The confirmation in the email dated February 5, 2019 from Ms. Moses to Ed Morgan of Health Canada is attached as **Exhibit "E"**. Ms. Moses confirmed:

> "Sanis Health does not currently participate in any advertising or marketing to healthcare professionals. Any activities that may be

undertaken in the future, will fully comply with the terms and conditions on specific opioid products under authority of section C.01.014.21 of the Food and Drug Regulations."

24. Every year Sanis attends the Shoppers Drug Mart/Pharmaprix Conference. At this conference Sanis has a booth where it displays newly launched products. Sanis never displayed any of the Sanis Opioid Products at this conference and never profiled any of the Sanis Opioid Products at this conference. During the time period where Sanis manufactured and sold the Sanis Opioid Products, no Sanis employees or representatives attended any other conferences or trade shows on Sanis' behalf.

25. Lastly, I note that within the drug manufacturing industry, the word "marketing" can also refer to the process of simply 'going to market' or selling products to the market. Sanis does engage in this process, only in that it sells the Sanis Opioid Products to the market and holds "marketing authorization" from Health Canada for these products.

26. All of the facts alleged herein are true.

AND I HAVE SIGNED:

CHRIS POTTER

SOLEMNLY AFFIRMED BEFORE ME BY TECHNOLOGICAL MEANS, in LaSalle, Québec, on this 31st day of March 2021

Commissioner of Oaths for the Province of Québec

Health Canada / Santé Canada

Health Products and Food Branch / Direction générale des produits de santé et des aliments

NOTICE OF COMPLIANCE / AVIS DE CONFORMITÉ

MAI MAY 0 6 2010

Sponsor/Manufacturer:/ Promoteur/Fabricant: 9427-S3168\1-50

Sanis Health Inc.
333 Champlain Street, Suite 102
Dieppe NB
E1A 1P2

Submission Number/Numéro de présentation:	138027
Product Name/Nom du produit:	MORPHINE SR
Medicinal Ingredient(s)/Ingrédient(s) médicinal(aux):	Morphine Sulfate
Therapeutic Classification/Classification Thérapeutique:	Opioid Analgesic
Reason for Submission/Raison pour présentation:	New Manufacturer and Product Name
Drug Identification Number(s), Route(s), Form, Strength/ Identification Numérique de(s) drogue(s), Voie(s), Forme, Dosage :	02350815 (ORL,TER 15 mg) 02350890 (ORL,TER, 30 mg) 02350912 (ORL,TER, 60 mg) 02350920 (ORL,TER, 100 mg) 02350947 (ORL,TER, 200 mg)
Canadian Reference Product/Produit de référence canadien:	MS Contin, Purdue Pharma, Canada

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This is to notify you that, pursuant to section C.08.004 of the Food and Drug Regulations, the above abbreviated new drug submission complies with the requirements of sections C.08.002 and C.08.005.1 of the Regulations. As a manufacturer, you are further reminded of your obligations under C.08.002(1)(d), C.08.007 and C.08.008. These obligations are detailed on the reverse of this notice.

Ceci est pour vous aviser que, conformément à l'article C.08.004 du règlement sur les aliments et drogues, la présentation abrégée de drogue nouvelle citée en rubrique est conforme aux exigences des articles C.08.002 et C.08.005.1 des mêmes règlements. Nous vous rappelons vos obligations en tant que fabriquant aux termes de C.08.002(1)(d), C.08.007 et C.08.008. Ces obligations sont expliquées au verso du présent avis.

Supriya Sharma, MD MPH FRCPC
Director General / Directrice générale
Therapeutic Products Directorate / Direction des produits thérapeutiques

Enclosures: Drug Notification Form(s)
Product Monograph

Pièces jointes: Formule(s) de déclaration de(s) drogue(s)
Monographie du Produit

Canada

"Exhibit B"

Health Canada / Santé Canada

NOTICE OF COMPLIANCE

AVIS DE CONFORMITÉ

Sponsor/Manufacturer:/ Promoteur/Fabricant:

JUL 24 2014

Your file *Votre référence*

Our file *Notre référence*

9427-S3168\1-131

Sanis Health Inc.
333 Champlain Street, Suite 102
Dieppe, NB
E1A 1P2

Submission Number/Numéro de présentation:	175406
Product Name/Nom du produit:	TRAMADOL/ACET
Medicinal Ingredient(s)/Ingrédient(s) médicinal(aux):	Tramadol Hydrochloride, Acetaminophen
Therapeutic Classification/Classification Thérapeutique:	Centrally Acting Analgesic / Analgésique à action centrale
Reason for Submission/Raison pour présentation:	Administrative - licensing agreement between two companies / Administratif -accord de licence entre deux sociétés
Drug Identification Number(s), Route(s), Form, Strength/ Identification Numérique de(s) drogue(s), Voie(s), Forme, Dosage :	02426803 (oral, tablet, tramadol hydrochloride 37.5 mg, acetaminophen 325 mg)
Canadian Reference Product/Produit de référence canadien:	Tramacet, Janssen-Ortho Inc., Canada

This is to notify you that, pursuant to section C.08.004 of the Food and Drug Regulations, the above abbreviated new drug submission complies with the requirements of sections C.08.002 and C.08.005.1 of the Regulations. As a manufacturer, you are further reminded of your obligations under C.08.002(1)(d), C.08.007 and C.08.008. These obligations are detailed on the reverse of this notice.

Ceci est pour vous aviser que, conformément à l'article C.08.004 du règlement sur les aliments et drogues, la présentation abrégée de drogue nouvelle citée en rubrique est conforme aux exigences des articles C.08.002 et C.08.005.1 des mêmes règlements. Nous vous rappelons vos obligations en tant que fabriquant aux termes de C.08.002(1)(d), C.08.007 et C.08.008. Ces obligations sont expliquées au verso du présent avis.

Barbara J. Sabourin
Director General / Directrice générale
Therapeutic Products Directorate / Direction des produits thérapeutiques

Enclosures: Product Monograph

Pièces jointes: Monographie du Produit

Canada

"Exhibit C"

Government of Canada / Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Cancelled Post Market

Current status date:

2021-01-07

Original market date: [1]

2011-03-02

Lot number: [2]

35355920A & 35214887A

Expiry date: [2]

2023-10-31

Product name:

OXYCODONE/ACET

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02361361

Product Monograph/Veterinary Labelling:

Date: 2018-10-19

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet

Route(s) of administration:

Oral

Number of active ingredient(s):

2

Schedule(s):

Narcotic (CDSA I)

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.08 OPIATE AGONISTS , 28:08.92 MISCELLANEOUS ANALGESICS AND ANTIPYRETICS

Anatomical Therapeutic Chemical (ATC): [4]

N02AJ17 OXYCODONE AND PARACETAMOL

Active ingredient group (AIG) number: [5]

0215596001

List of active ingredient(s)

Active ingredient(s)	Strength
ACETAMINOPHEN	325 MG
OXYCODONE HYDROCHLORIDE	5 MG

Risk Management Plans [7]

A Canadian Specific Opioid targeted Risk Management Plan (CSO-tRMP) for this product was submitted.

Additional Risk Minimization Measures

Healthcare Professional Education

New search

Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

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- the second portion (5 digits) identifies the unique groups of active ingredients(s),
- the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.

7 Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.

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Date modified: 2021-03-15

"Exhibit D"

Government of Canada / Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Cancelled Post Market

Current status date:

2020-12-23

Original market date: [1]

2011-03-01

Lot number: [2]

35356038B

Expiry date: [2]

2022-01-31

Product name:

MORPHINE SR

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02350815

Product Monograph/Veterinary Labelling:

Date: 2018-12-06

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet (Extended-Release)

Route(s) of administration:

Oral

Number of active ingredient(s):

1

Schedule(s):

Narcotic (CDSA I)

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.08 OPIATE AGONISTS

Anatomical Therapeutic Chemical (ATC): [4]

N02AA01 MORPHINE

Active ingredient group (AIG) number: [5]

0104545009

List of active ingredient(s)

Active ingredient(s)	Strength
MORPHINE SULFATE	15 MG

Risk Management Plans [7]

A Canadian Specific Opioid targeted Risk Management Plan (CSO-tRMP) for this product was submitted.

Additional Risk Minimization Measures

Healthcare Professional Education

New search

Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

2 When a manufacturer decides to discontinue the sale of their drug, the date of discontinuation is the date of the last sale by the manufacturer. The DIN will be cancelled further to the receipt of a sale discontinuation notification from the manufacturer. The status of the DIN will be updated to “Cancelled (Post-Market)” in the online Drug Product Database. For DINs cancelled on or after March 14, 2017, the latest expiry date and lot number of the product distributed in Canada will be posted on the online Drug Product Database. Other parties in the health product distribution chain such as wholesalers, retailers, pharmacists and medical practitioners may still sell or distribute that drug after DIN cancellation if the expiry date of the drug lot has not passed. This may be acceptable so long as the DIN cancellation is not due to health and/or safety reasons.

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7 Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.

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Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

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Current status:

Cancelled Post Market

Current status date:

2021-03-16

Original market date: [1]

2011-03-01

Lot number: [2]

35357016A

Expiry date: [2]

2022-05-31

Product name:

MORPHINE SR

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02350890

Product Monograph/Veterinary Labelling:

Date: 2018-12-06

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet (Extended-Release)

Route(s) of administration:

Oral

Number of active ingredient(s):

1

Schedule(s):

Narcotic (CDSA I)

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.08 OPIATE AGONISTS

Anatomical Therapeutic Chemical (ATC): [4]

N02AA01 MORPHINE

Active ingredient group (AIG) number: [5]

0104545011

List of active ingredient(s)

Active ingredient(s)	Strength
MORPHINE SULFATE	30 MG

Risk Management Plans [7]

A Canadian Specific Opioid targeted Risk Management Plan (CSO-tRMP) for this product was submitted.

Additional Risk Minimization Measures

Healthcare Professional Education

New search

Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

2 When a manufacturer decides to discontinue the sale of their drug, the date of discontinuation is the date of the last sale by the manufacturer. The DIN will be cancelled further to the receipt of a sale discontinuation notification from the manufacturer. The status of the DIN will be updated to “Cancelled (Post-Market)” in the online Drug Product Database. For DINs cancelled on or after March 14, 2017, the latest expiry date and lot number of the product distributed in Canada will be posted on the online Drug Product Database. Other parties in the health product distribution chain such as wholesalers, retailers, pharmacists and medical practitioners may still sell or distribute that drug after DIN cancellation if the expiry date of the drug lot has not passed. This may be acceptable so long as the DIN cancellation is not due to health and/or safety reasons.

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Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Marketed

Current status date:

2014-10-17

Original market date: [1]

2011-03-02

Product name:

MORPHINE SR

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02350912

Product Monograph/Veterinary Labelling:

Date: 2018-12-06

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet (Extended-Release)

Route(s) of administration:

Oral

Number of active ingredient(s):

1

Schedule(s):

Narcotic (CDSA I)

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.08 OPIATE AGONISTS

Anatomical Therapeutic Chemical (ATC): [4]

N02AA01 MORPHINE

Active ingredient group (AIG) number: [5]

0104545010

List of active ingredient(s)

Active ingredient(s)	Strength
MORPHINE SULFATE	60 MG

Risk Management Plans [7]

A Canadian Specific Opioid targeted Risk Management Plan (CSO-tRMP) for this product was submitted.

Additional Risk Minimization Measures
Healthcare Professional Education

New search

Same active ingredient group number

Footnotes

1 The earliest marketed date recorded in the Drug Product Database.

3 The American Hospital Formulary Service permits an easy review of information on a group of drugs with similar activities and uses and allows the reader to determine quickly the similarities and differences among drugs within a group.

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- the last portion (3 digits) identifies the active ingredient group strength. The strength group has a tolerance of -2% to +10%.

7 Refer to the Health Canada Guidance Documents - "Submission of Risk Management Plans and Follow-up Commitments" as well as "Submission of targeted Risk Management Plans Follow-up Commitments for Prescription Opioid-containing Products" for additional details.

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Date modified: 2021-03-15

Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

The product monograph is developed by a drug sponsor according to guidelines published by Health Canada that provide direction on the content and format. The veterinary labelling is developed by the drug sponsor according to the Food and Drug Regulations. While Health Canada reviews the product monograph or the veterinary labelling as part of the drug review process, it remains the responsibility of the drug sponsor to ensure that the product monograph or the veterinary labelling is complete and accurate.

Current status:

Cancelled Post Market

Current status date:

2014-08-01

Original market date: [1]

2011-03-01

Product name:

MORPHINE SR

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02350920

Product Monograph/Veterinary Labelling:

Date: 2010-05-05

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet (Extended-Release)

Route(s) of administration:

Oral

Number of active ingredient(s):

1

Schedule(s):

Narcotic (CDSA I)

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.08 OPIATE AGONISTS

Anatomical Therapeutic Chemical (ATC): [4]

N02AA01 MORPHINE

Active ingredient group (AIG) number: [5]

0104545012

List of active ingredient(s)

Active ingredient(s)	Strength
MORPHINE SULFATE	100 MG

New search

Same active ingredient group number

Footnotes

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Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

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Current status:

Cancelled Post Market

Current status date:

2014-08-01

Original market date: [1]

2011-03-01

Product name:

MORPHINE SR

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02350947

Product Monograph/Veterinary Labelling:

Date: 2010-05-05

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet (Extended-Release)

Route(s) of administration:

Oral

Number of active ingredient(s):

1

Schedule(s):

Narcotic (CDSA I)

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.08 OPIATE AGONISTS

Anatomical Therapeutic Chemical (ATC): [4]

N02AA01 MORPHINE

Active ingredient group (AIG) number: [5]

0104545013

List of active ingredient(s)

Active ingredient(s)	Strength
MORPHINE SULFATE	200 MG

New search

Same active ingredient group number

Footnotes

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Government of Canada Gouvernement du Canada

Product information

From Health Canada

New search

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Current status:

Cancelled Post Market

Current status date:

2020-12-16

Original market date: [1]

2014-07-25

Lot number: [2]

RM1848

Expiry date: [2]

2022-04-30

Product name:

TRAMADOL/ACET

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section .

DIN:

02426803

Product Monograph/Veterinary Labelling:

Date: 2018-11-27

Product monograph/Veterinary Labelling (PDF version ~ 175K)

Company:

SANIS HEALTH INC
1 Presidents Choice Circle
Brampton
Ontario
Canada L6Y 5S5

Class:

Human

Dosage form(s):

Tablet

Route(s) of administration:

Oral

Number of active ingredient(s):

2

Schedule(s):

Prescription

Biosimilar Biologic Drug:

No

American Hospital Formulary Service (AHFS): [3]

28:08.92 MISCELLANEOUS ANALGESICS AND ANTIPYRETICS , 28:08.08 OPIATE AGONISTS

Anatomical Therapeutic Chemical (ATC): [4]

N02AJ13 TRAMADOL AND PARACETAMOL

Active ingredient group (AIG) number: [5]

0250601001

List of active ingredient(s)

Active ingredient(s)	Strength
ACETAMINOPHEN	325 MG
TRAMADOL HYDROCHLORIDE	37.5 MG

Risk Management Plans [7]

A Canadian Specific Opioid targeted Risk Management Plan (CSO-tRMP) for this product was submitted.

Additional Risk Minimization Measures

Healthcare Professional Education

New search

Same active ingredient group number

Footnotes

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MedEffect Canada

Adverse drug reaction - veterinary drugs

Notice of compliance database

Licensed natural health products database

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Technical support

Version 3.8.0

Date modified: 2021-03-15

From: Morgan, Ed (HC/SC) <ed.morgan@canada.ca>
Sent: February 8, 2019 11:05 AM
To: Ruth Moses (SNS)
Subject: [EXT] Marketing and Advertising of Opioids

Dear Mrs. Moses,

Thank you again for your correspondence in response to the January 31, 2019 letter from Health Canada, seeking your commitment in support of Canada's collective response to the opioid crisis by immediately suspending any and all marketing and advertising of opioids to health care professionals.

The Department will make your response available on Health Canada's Marketing and Advertising of Opioids webpage in the coming weeks.

Personal information provided to Health Canada during stakeholder communications will be governed in accordance with the Privacy Act. More information about how personal information is handled can be found on the Information and Privacy Notice for Specific Health Products and Food Branch Initiatives page.

Yours sincerely,

Ed Morgan
Director General / Directeur général
Policy, Planning & International Affairs Directorate (PPIAD) / Direction des politiques, de la planification et des affaires internationales (DPPAI)
Health Products and Food Branch (HPFB) / Direction générale des produits de santé et des aliments (DGPSA)
Health Canada / Santé Canada
Édifice Graham Spry Building, Room/pièce 538 (AL: 2005A)
250, avenue Lanark Avenue Ottawa, Ontario K1A 0K9
Tel.: 613.952.8149 BB: 613.462.4408
New email: ed.morgan@canada.ca

-------- Original message --------
From: "Ruth Moses (SNS)" <rmoses@sanis.com>
Date: 2019-02-05 1:38 PM (GMT-05:00)
To: "Morgan, Ed (HC/SC)" <ed.morgan@canada.ca>
Cc: "Kropp, Rhonda (HC/SC)" <rhonda.kropp@canada.ca>, "Chris Potter (SDM)" <cpotter@shoppersdrugmart.ca>
Subject: RE: Marketing and Advertising of Opioids / Le marketing et la publicité sur les opioïdes

Dear Mr. Morgan,

Please accept this letter as Sanis Health's acknowledgement of the correspondence received January 31, 2019 and our commitment to fully support the efforts to address Canada's opioid crisis. Sanis Health does not currently participate in any advertising or marketing to healthcare professionals. Any activities that may be

undertaken in the future, will fully comply with the terms and conditions on specific opioid products under authority of section C.01.014.21 of the *Food and Drug Regulations*.

Regards,

Ruth Moses
Director, Sanis Regulatory Affairs and Quality Assurance

243 Consumers Road, Toronto, Ontario M2J 4W8
C: 416-729-8309 | rmoses@sanis.com
SHOPPERS DRUG MART

From: Morgan, Ed (HC/SC) <ed.morgan@canada.ca>
Sent: Thursday, January 31, 2019 3:27 PM
To: Ruth Moses (SNS) <rmoses@sanis.com>
Cc: Kropp, Rhonda (HC/SC) <rhonda.kropp@canada.ca>; Chris Potter (SDM) <cpotter@shoppersdrugmart.ca>
Subject: [EXT] Marketing and Advertising of Opioids / Le marketing et la publicité sur les opioïdes

Please find enclosed correspondence regarding the marketing and advertising of opioids.

Vous trouverez ci-joint une correspondance concernant le marketing et la publicité sur les opioïdes.

Ed Morgan
Director General
Policy, Planning and International Affairs Directorate

No: 500-06-001004-197

SUPERIOR COURT
(Class Action)
DISTRICT OF MONTRÉAL

JEAN-FRANÇOIS BOURASSA

Plaintiff

v.

ABBOTT LABORATORIES, LIMITED *et al.*

Defendants

AMENDED APPLICATION BY DEFENDANT SANIS HEALTH INC. FOR LEAVE TO ADDUCE RELEVANT EVIDENCE (Art. 574 C.C.P.) and SCHEDULE A

ORIGINAL

OSLER, HOSKIN & HARCOURT LLP
(Me Alexandre Fallon, Me Julien Morissette,
Me Deborah Glendinning and Me Kevin O'Brien)
1000 de La Gauchetière St. West, Suite 2100
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Tél: 514.904.8100 Téléc.: 514.904.8101
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Code : BO 0323 Our file: 1201623

Boulais, France

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Envoyé: 12 janvier 2022 11:26
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Objet: NOTIFICATION BY EMAIL – Jean-François Bourassa v. Abbot Laboratories, Ltd. & al., 500-06-001004-197 – Amended Application by Defendant Sanis Health Inc. for Leave to Adduce Relevant Evidence and Schedule A
Pièces jointes: Amended Application by Defendant Sanis Health Inc. for leave to adduce relevant evidence and Schedule A (Jan 12 2022).PDF; Service List - Sanis 2022-01-12.PDF

NOTIFICATION BY EMAIL
(Art. 134 CCP)

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Date of transmission:	January 12, 2022
Number of pages transmitted:	65 pages attached
Type of documents:	AMENDED APPLICATION BY DEFENDANT SANIS HEALTH INC. FOR LEAVE TO ADDUCE RELEVANT EVIDENCE (Art. 574 C.C.P.) and SCHEDULE A
Court file number:	500-06-001004-197

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PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL
N°: 500-06-001004-197

S U P E R I O R C O U R T
(Class Action)

JEAN-FRANÇOIS BOURASSA

Plaintiff

v.

ABBOTT LABORATORIES CO. et al.

Defendants

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