Federal Court  Cour fédérale

Date: 20120830

Docket: T-768-11

Citation: 2012 FC 1044

Ottawa, Ontario, August 30, 2012

PRESENT: The Honourable Mr. Justice O'Keefe

BETWEEN:

NORTH AMERICAN NUTRICEUTICAL INC.

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application pursuant to subsection 18.1(1) of the *Federal Courts Act*, RSC 1985, c F-7 for judicial review of a reconsideration decision made by the Natural Health Products Directorate (the Board), dated April 19, 2011, wherein the applicant's product licence application for its natural health product TherapeutxTM "Maori Miracle" Joint Health Companion was refused. This conclusion was based on the Board's finding that there was inadequate information on the safety of the ingredient Kolla2 used in the applicant's product.

[2] The applicant requests that the decision be set aside and that the matter be referred back for reconsideration.

Background

[3] The applicant, North American Nutriceutical Inc., manufactures natural health products, one of which is called TherapeutxTM "Maori Miracle" Joint Health Companion (the product). One of the ingredients in this product is an avian sternal cartilage powder known as Kolla2. This application pertains to the safety of Kolla2 and the collagen used therein.

[4] The Board is the division of Health Canada responsible for licencing and regulating natural health products in accordance with the *Natural Health Products Regulations*, SOR/2003-196 (the Regulations). These Regulations came into force on January 1, 2004.

[5] Pursuant to sections 4 and 5 of the Regulations, producers of natural health products must submit a product licence application (PLA) to the Board and have it approved before the natural health product can be sold. On April 11, 2005, the applicant submitted a PLA for its product. On June 24, 2005, the Board acknowledged receipt of the applicant's PLA and issued file and submission numbers for the product. In accordance with practice, the Board, upon issuing the submission number, carried out a completeness review to ensure all necessary documentation was provided. At this administrative stage, no review was conducted of the ingredients or the content of the evidence.

[6] On November 5, 2007, the Board issued an initial information request notice (IRN) to the applicant (IRN#1). IRNs are used to request clarification on specific information in applications. In IRN#1, the Board informed the applicant that the PLA was deficient in evidence on safety and efficacy. With regards to collagen, the Board noted:

> The evidence in support of collagen consists mostly of either book excerpts or articles taken from sources of low credibility as per Chapter 5.1 of the Evidence for Safety and Efficacy of Natural Health Products and does not support the recommended conditions of use in the Product License Application. The Hauselmann et al. 1998 study shows that collagen can actually increase the disease activity in the rheumatoid arthritis patients.

[7] Some correspondence was then exchanged between the parties regarding the issues raised in IRN#1.

[8] Subsequently, on January 8, 2008, the applicant submitted a response to IRN#1. This response included Schedules A to G. In its response, the applicant explained that several of the issues raised in IRN#1 pertained to differences between the policy document, Product Licensing – A Step by Step Guide (2004) that was distributed at a Health Canada seminar that the applicant attended in 2006 and the current PLA policy titled Evidence for Safety and Efficacy of Finished Natural Health Products (2006). The applicant stated that it was provided assurances at the Health Canada seminar that PLAs submitted under the old policy would be processed according to the guidance provided therein. The applicant noted that the two policies differed on the acceptability of abstracts, animal studies, book articles, suppliers, manufacturers, websites and experts as evidence of safety.

[9] With regards to Kolla2, the applicant explained in its IRN#1 response that the Häuselmann et al (Häuselmann) study explored whether the therapeutic effect of methotrexate on arthritis could be sustained when replaced by collagen type II. The results were negative. However, the applicant submits that this was not indicative of collagen type II causing or contributing to arthritis; rather, it merely showed that collagen type II could not replace the benefits of methotrexate. The applicant submits that it provided a depth of other studies, qualified expert opinions and a long term safety record that clearly supported a positive safety consideration of collagen type II.

[10] On July 2, 2008, the Board issued a second IRN (IRN#2) with a similar finding of deficient evidence of the safety and efficacy of the applicant's product. Here, the Board highlighted the following deficiencies on type II collagen:

> In the references by Bishop (2003) and Trentham (1993), the medicinal ingredient evaluated is "native" collagen and the doses used are considerably lower. It is unknown if the collagen used in the formulation is native collagen. Furthermore, even in the case where the collagen used in the formulation is native, studies have demonstrated that higher amounts of native collagen have an inflammation-inducing effect. Therefore, this reference is not sufficient to support the safety and efficacy of this ingredient.
>
> […]
>
> The reference by Hauselmann showed a significant increase in disease activity.

[11] The Board noted that several references were: abstracts and not full studies; animal or in-vitro investigations unsupported with human evidence; and references without citation information. The Board also requested more information on non-hydrolyzed type II collagen (Kolla2) to determine if it was comparable to the medicinal ingredients mentioned in the references.

[12] In July 2008, the parties exchanged correspondence on the issues raised in IRN#2. The Board responded to several of the applicant's concerns in a letter dated July 25, 2008. With regards to abstracts, the Board noted:

> […] according to current assessment practice, abstracts will be considered if they are submitted, but they may not be considered until after the applicant has already demonstrated sufficient safety and efficacy through full-text evidence or other evidence as per Ch 5 of the Evidence for Safety and Efficacy of Finished Natural Health Products […] It is recommended that any evidence that applicants wish NHPD to examine in-depth be submitted in **full-text** format.

[13] On animal and in vitro evidence, the Board explained:

> Current assessment practice is to delay review of animal and in vitro evidence until after safety and efficacy have been demonstrated through **human** use evidence. […] the use of animal data is still valuable in understanding the nature of the ingredient, the mechanisms of action and the trends towards efficacy or safety.

[14] On expert opinion, the Board explained that "expert opinion reports should focus on the conditions of use". It noted that those submitted by the applicant "do not refer to specific doses, durations of use or healthy subpopulations". Further, the Board noted its difficulty in comparing the identity of collagen used in the product compared to that used in the Häuselmann study; particularly in terms of the processing method. Thus, it was recommended that additional detail be provided on the characteristics of Kolla2 to allow better certainty in interpreting the study results.

[15] Finally, in response to the applicant's concern about the different versions of the PLA Guide, the Board stated:

> NHPD recognizes that "Maori Miracle" was submitted in 2005 and that the 1st assessment IRN was not sent until 2007. During this

> period, there have been guidance document revisions, communiques providing clarifications, and changes in assessment practice. It is sincerely hoped that despite past, present and future changes, NHPD is moving towards a "fair playing field" (ie transparent assessment criteria) for all stakeholders. It is hoped that applicants recognize that the intent of assessment IRNs is to ensure that the products sold to Canadians are safe, effective and of high quality. To this end, NHPD encourages applicants to respond to the IRNs to the greatest extent possible and to provide comments and rationales when they feel that the criteria [*sic*] not well thought out or unclear.

[16] In a letter dated August 15, 2008, the applicant committed to submitting full-text copies of the abstracts (these were subsequently filed in October 2008) and reiterated its previous submissions regarding the lack of usefulness of the Häuselmann study. The applicant noted that the animal and in vitro studies it had filed were merely submitted as supporting evidence and were not central determinatives of its submissions. Finally, the applicant informed the Board that it had increased the recommended daily dosage of the product from three capsules to four to eight capsules.

[17] On June 12, 2009, the Board issued a notice of refusal pursuant to subsection 7(a) of the Regulations (the first refusal). This decision was based on insufficient evidence to support the safety of ""unhydrolyzed type II collagen from chicken sternum cartilage" (Kolla2 (600 – 1200 mg per day))". The Board deemed the evidence insufficient for the following reasons:

1. No additional full text evidence to support "unhydrolyzed type II collagen from chicken cartilage";

2. The manufacturer Collagen Neutraceuticals stated that the types of collagen used in Bishop (2003) and Trentham (1993) were not comparable to Kolla2 because it was not "native type II collagen";

3. No evidence was provided showing why the safety of unhydrolyzed Kolla2 would be different from native type II chicken sternum collagen;

4. Hunter (2003) was an animal study and was insufficient to support safety;

5. Moskowitz (2000) used hydrolyzed gelatin collagen, which was not representative of the dose or characterization of Kolla2; and

6. Just stating that Kolla2 is not native collagen did not prove that it would not be associated with a worsening of symptoms in subjects with arthritis (Cazzola (2000) and Barnet (1996)).

[18] Finally, the Board stated in the first refusal that:

> Evidence provided (Kalden and Sieper 1998, Bishop 2003; Hauselmann et al. 1998; Cazzola et al. 2000) showed that high doses of native collagen II could actually worsen the effects of arthritic disease in at least some subjects with arthritis. Since no additional evidence was provided for unhydrolyzed collagen supplementation, it has not been adequately demonstrated that the Kolla2 at 900 mg/d would have an improved safety over native collagen when being used in subjects with rheumatoid or osteoarthritis or related musculoskeletal disorders.

[19] Over the ensuing period, the parties exchanged correspondence regarding the reasons for the first refusal and on a reconsideration thereof. The Board directed the applicant to its guidance document on the reconsideration process, which specified that reconsideration is limited to the information and material upon which the original decision was made; thus, no new evidence would be considered at the reconsideration stage. The applicant raised concerns about the Cazzola et al (Cazzola) study which it had not filed with the Board. In response, the Board explained that it consulted this study in reviewing the applicant's application.

[20] On July 16, 2009, the applicant submitted a request for reconsideration of the first refusal (the reconsideration package). In Schedule A of this reconsideration package, the applicant provided a thorough summary of the dose, type of collagen used and excerpts from the studies highlighted by the Board in the first refusal. Based on this review, the applicant submitted that the Trentham (1993), Bishop (2003), Cazzola (2000), Kalden and Sieper (1998) Häuselmann (1998) and Barnett (1996) studies were not representative of the dose, characterization or molecular structure of the Kolla2 collagen used in the applicant's product. The applicant thus held that this evidence did not support the safety concerns identified by the Board.

[21] In Schedule B of the reconsideration package, the applicant referred to other evidence that it had filed in support of the safety of Kolla2. This included: scientific studies; expert evidence; excerpts from Health Canada's website; use of Kolla2 in LaKota's arthritic formula sold in Canada for several years; book excerpts; U.S. patent for Kolla2; certificates of analysis; advance ruling on tariff classification; letters from manufacturers; and product formula.

[22] On August 6, 2009, the Board issued a reconsideration decision (the final refusal) upholding its first refusal. It briefly stated:

> Evidence to support safety and efficacy of a product must be provided for the medicinal ingredient as manufactured. The evidence provided does not support that Kolla2 has an established safety profile. Evidence for similar collagen products is insufficient to support safety.

[23] In coming to this decision, the assessment officer noted on August 4, 2009:

> As Kolla2 is not comparable to "native type II collagen" the safety concerns associated with "native type II collagen" in relation to

> arthritis may not be relevant to Kolla2. However no data has been provided to support this assumption.

[24] Subsequently, further correspondence was exchanged between the parties regarding reasons for the refusal and steps forward for a new submission.

[25] On February 17, 2010, the applicant commenced a judicial review application of the final refusal. On March 21, 2011, with consent of both parties, the Board's final refusal was quashed and the matter was remitted for a new reconsideration decision (the consent order).

[26] On April 19, 2011, the Board issued a new reconsideration decision upholding its first refusal. This new reconsideration decision is the subject of this application.

Board's Decision

[27] In its decision dated April 19, 2011, the Board upheld its previous refusal of the applicant's PLA based on its finding of inadequate information regarding the safety of Kolla2 used in the product at the recommended daily dose of 600 to 1,200 mg. In coming to this finding, the Board stated that it considered the applicant's reconsideration package.

[28] The Board reviewed the scientific studies submitted by the applicant. It distinguished the findings presented therein from the use of Kolla2 in the product for the following reasons:

1. Different manufacturing process and dose (i.e., studies pertained to undenatured (native) type II collagen that had been acid solubilised by limited enzymatic digestion): Bishop

(2003), Cazzola (2000), Barnett (1998), Häuselmann (1998), Kalden and Sieper (1998), Barnett (1996) and Trentham (1993);

2. Different or unspecified type of collagen: Moskowitz (2000), Duarte (date unknown), Clouatre (date unknown), and book chapter from unknown reference; and

3. Insufficient details on primary data: book chapter by Quadri S. and U.S. Patent No. 768141.

[29] The Board also discussed three abstracts submitted by the applicant: Toda (2000), Choy (2001) and Kalman (2004). It found that all three provided insufficient detail. The Choy and Kalman reports also pertained to different types of collagen; namely, collagen of a differently sourced material and hydrolyzed collagen, respectively.

[30] Turning to the applicant's reference to the Board's policy documents, the Board noted that the product licencing guidance document did not provide any information on the safety of any medicinal ingredients or imply that these were authorized by Health Canada. The Board also noted that previous marketing experience alone was insufficient to obtain approval for natural health products in Canada.

[31] The Board noted the conclusion in the Häuselmann study that oral collagen type II was not capable of sustaining the methotrexate-induced anti-inflammatory effect in patients. Although the Häuselmann study did not conclude that the observed increase in disease activity was caused by collagen, the Board noted it had evidence before it that there was a possibility of increased disease activity from oral collagen administration. Specifically, in the Cazzola study, a small number of

patients experienced worsening of the disease after receiving oral chicken type II collagen. None of the patients that were given a placebo in that study had the same experience. The Board noted the authors' conclusion that more studies might be justified and that their results raised the possibility that, in a sub-group of patients, oral collagen administration might induce disease flares. The Board observed that it remained unclear what type of type II collagen might cause a worsening of disease activity. However, as the applicant did not provide any scientific studies specific to Kolla2, the Board was unable to conclude that the possibility of increased disease activity would not occur after the administration of Kolla2.

[32] The Board acknowledged that in its first refusal, it should have specified 600 - 1,200 mg/d as the dosage. It also acknowledged that Hunter (2003) should not have been included in the first refusal as it pertained to a different ingredient. Finally, the Board noted that details on the characterization of Kolla2, including the physiochemical characteristics of the collagen used therein, were not provided in the PLA. Such a characterization was necessary for the Board to complete its assessment of the ingredients. Once the assessment of the ingredients was complete, the Board could proceed with the assessment of the product as a whole.

Issues

[33] The applicant submits the following points at issue:

1. Whether or not the Board's decision to uphold its notice of refusal to licence the applicant's product was rational based on relevant considerations.

2. Did the Board avoid irrelevant considerations and follow principles of procedural fairness and fundamental justice in coming to its decision?

[34] I would rephrase the issues as follows:

1. What is the standard of review?

2. Did the Board err by basing its decision on irrelevant considerations and ignoring evidence before it?

3. Was there a breach of procedural fairness?

Applicant's Written Submissions

Standard of Review

[35] The applicant submits that the appropriate standard of review of the Board's decision is correctness. In support, the applicant notes that the legislation is relatively new and there is thus insufficient evidence of the Board's expertise. This is demonstrated by the number of revised versions of the Board's PLA guidance document. The applicant also notes that the Regulations do not have a privative clause and that the decision is extremely important to it.

Political Motivation

[36] The applicant submits that the Board's decision was politically motivated to reduce the backlog of applications. The applicant notes that immediately following the Minister of Health's

public announcement promising the elimination of the PLA backlog, the applicant's PLA was dismissed without clear reasons.

Collagen

[37] The applicant submits that the brand name Kolla2 is inconsequential as all chicken type II collagen is the same regardless of how it is produced. Conversely, collagens differ when they have been hydrolyzed, acid purified or obtained from a non-avian source. The collagen used in the applicant's product is unhydrolyzed. Nevertheless, all forms of collagen have been consumed by humans for dozens of years and are known to be extremely safe.

[38] The applicant also submits that it is accepted industry terminology that collagens put through a hydrolysis process are specifically referred to as hydrolyzed; where this is not specified, the collagen is unhydrolyzed. Thus, the term collagen means unhydrolyzed collagen and the term chicken type II collagen means unhydrolyzed chicken type II collagen. As such, the actual brand name of Kolla2 is irrelevant.

Evidence

[39] The applicant submits that all relevant evidence known to the Board prior to rendering its decision, including all information contained in the applicant's affidavit material in this file, should have been taken into account in the decision. The applicant submits that the lack of direction in the

consent order indicates that the new decision should not be limited to the information contained in the reconsideration package.

[40] With regards to the safety of chicken type II collagen, the applicant highlights the following:

1. The chicken type II collagen listed as a medical ingredient on the Board's website is sourced from sternum cartilage, which is the same source of the collagen in the applicant's product;

2. Unhydrolyzed chicken type II collagen is included in the Board's Natural Health Products Ingredient Database for approved medical ingredients and is listed as a medical ingredient in Schedule 1 of the Regulations;

3. The Board has issued exemption numbers and product licences allowing the sale of products containing the same form and similar dose of chicken type II collagen as used in the applicant's product;

4. The safety of chicken type II collagen has been well documented;

5. Chicken type II collagen has been on the market for several years and has been consumed by millions worldwide without any known adverse events; and

6. Kolla2 has patents in the United States, Europe and Canada.

[41] The applicant criticizes the Board's treatment of the various studies by qualified researchers. The applicant submits that the Board either ignored or wrongly dismissed them. The applicant notes that several of the studies have been accepted by the Board on other occasions. With regards to the abstracts that it submitted, the applicant explains that at the time that it filed its PLA, abstracts were acceptable.

[42] The applicant submits that the Board ignored Dr. Trentham's statement that chicken type II collagen has a high degree of safety and the long use of collagen formulations for health purposes noted in the Bishop (2003) study.

[43] The applicant also criticizes the Board's characterization of the material by Dr. Quadri and Dr. Darrow as an "unreferenced consumer-orientated publication that does not provide any detailed primary evidence". The applicant submits that these authors are qualified practitioners who support the safety of the Kolla2 chicken type II collagen in the applicant's product. Similarly, the applicant submits that the Board ignored the statements made by experts Dr. Stokes, Dr. Lunney, John Croft, Dr. Wei Lei and Dr. Michael F. Nassar who all attested to the safety of the collagen in the applicant's product. The applicant highlights Dr. Nassar's statement that Kolla2 is not "native" collagen type II.

[44] The applicant also notes that the Board dismissed the study by Dr. Duarte as pertaining to collagen that was not comparable to the collagen in the applicant's product. However, in his article, Dr. Duarte referred to chicken type II collagen, sourced from chicken sternal cartilage, from chicks six to eight weeks old. This was precisely how Kolla2 was described in the patent information submitted with the applicant's PLA. The applicant also submits that the Board dismissed the research of Dr. Clouatre supporting the safety of chicken type II collagen, even though Dr. Clouatre is aptly qualified and his article was published in the Vitamin Retailer magazine.

[45] The applicant submits that the Board erred by basing its conclusions on the Häuselmann (1998) report, whose conclusions it admits were incorrect and on the Cazzola (2000) study, that the

parties had agreed is not comparable to the applicant's product. Both of these studies pertained to acid solubilised collagen by limited enzymatic digestion, which was not comparable to the applicant's collagen. The applicant also notes that the collagen used in the Cazzola study was the same as that used in the Trentham study, which the Board had previously acknowledged used a collagen that was not relevant to that used in the applicant's product. As such, the applicant submits that the Board based its decision on irrelevant considerations. Nevertheless, the applicant highlights that the researchers in Cazzola concluded that their findings of a worsening of disease activity should be considered anecdotal and no such findings have been reported before or since then.

[46] The applicant also questions how knowing the average molecular weight of collagen will help determine its safety. The applicant notes that the Board did not request information on physiochemical characteristics in IRN#1, IRN#2 or in the first refusal.

[47] The applicant submits that although the individual pieces of evidence may not alone be sufficient to support a finding of safety, collectively the evidence does support such a finding. This evidence is thus incapable of supporting the Board's factual determination.

[48] The applicant submits that by requiring it to demonstrate not only the safety of collagen, but also that the collagen in its product will not cause an increase in disease activity, the Board is imposing a higher licencing standard on it compared to other applicants. That level of proof would be a never-ending and impossible hurdle to meet.

[49] At the hearing, the applicant noted that the primary purpose of scientific studies is efficacy, not safety. Further, no researcher will conduct safety research of an ingredient, such as collagen, that has a proven safety record evidenced by long-term consumption without any adverse effects.

Procedural Fairness

[50] The applicant submits that the decision was important to it and therefore clear written reasons for the notice of refusal should have been provided. The applicant submits that the Board did not provide clear reasons; instead, the reasons were vague and overbroad.

[51] The applicant notes that key personnel involved in the review of the applicant's PLA did not read critical studies that were relied on in support of the decision which may account for the errors made.

[52] Further, the applicant notes that the Board did not previously communicate the need for physiochemical characteristics to it and the applicant was thereby not provided an opportunity to comply with such a requirement. As such, the Board violated procedural fairness. Nevertheless, the applicant did provide the physiochemical characteristics of its collagen even though this information has little, if any, correlation to the safety of an ingredient.

[53] Similarly, without explaining its meaning, the Board stated that complete characterization of the medical ingredient was necessary. The applicant submits that it did provide certificates of analysis, finished product testing and manufacturing details; it is unclear what more would be

required to satisfy this requirement. The applicant notes that none of the Board's publications require this information.

[54] Finally, the applicant submits that where, as in this case, the respondent is the regulator and the applicant is a member of the regulated class, the respondent owes the applicant special consideration. At a minimum, this entails clearly answering the applicant's questions regarding the reasons for the decision so that the applicant can know what needs to be established to obtain product licence approval.

Respondent's Written Submissions

Standard of Review

[55] The respondent submits that the standard of review is correctness for procedural fairness and reasonableness on the alleged errors in the decision.

Political Motivation

[56] The respondent submits that there was no summary dismissal of the applicant's product as a measure to reduce backlog. Rather, the decision was based on insufficient evidence and evidence that was not appropriate to the product at issue. The respondent submits that March 31, 2010 was chosen as an internal date to address outstanding PLAs, which meant issuing a product licence,

notice of refusal, IRN or the withdrawal of an application. That date was not designed to systemically eliminate PLAs.

Evidence

[57] At the outset, the respondent notes that the consent order does not explicitly state that the new decision is to be based on the information contained in the reconsideration package. However, the respondent submits that applicant's counsel explicitly stated that he did not want to file a new package. Thus, the new decision is limited to the information contained in the reconsideration package.

[58] The respondent submits that the applicant bears the responsibility of filing evidence that demonstrates that the benefit of a product outweighs any identified risks. To do so, the applicant must provide sufficient evidence of the safety of the product at its recommended conditions of use. The evidence must also show that no risks, such as an increase in disease activity, would occur from the use of the ingredient or that such risks are mitigated in an acceptable manner.

[59] The respondent notes that this Court is not an academy of science. Accordingly, it should not be concerned with scientific disagreements on conclusions reached in the decision. It is not the Court's role to weigh or interpret such evidence. Nevertheless, the respondent submits that the studies filed by the applicant were all insufficient to support the safety of Kolla2 in its intended conditions of use.

[60] The respondent submits that a decision is only subject to review on an erroneous finding of fact where there is no evidence upon which a decision maker could have reached its conclusion. In this case, the Board's decision was within the range of acceptable outcomes based on the evidence before it. The respondent submits that the applicant provided insufficient evidence on the safety of the specific type of collagen (Kolla2) at its recommended use and dose in its product.

[61] The respondent notes that there is a presumption that the Board considered all the evidence. In accordance with both the reconsideration policy and the consent order, the decision was limited to the information submitted in the original submission, in response to the IRNs and in the reconsideration package. Thus, any other evidence would only be considered in a new submission filed after the notice of refusal. In its decision, the Board did specifically mention the reconsideration package. Further, the Board provided the applicant with comments from its review of the studies, which will permit it to answer outstanding questions in future resubmissions.

[62] The respondent submits that the opinion evidence put forth by the applicant from Dr. T. Stokes, Dr. Wei Lei, Dr. James Lunney and Dr. Nassar is not relevant as it was not submitted by the applicant as part of its original submission, in response to an IRN, or as part of its reconsideration package. The applicant has also not properly established a basis for that evidence and it is not in accordance with Rule 52 of the *Federal Courts Rules*, SOR/98-106. The applicant's submissions regarding this evidence should thus be struck.

[63] The respondent notes that the Board considers marketing history insufficient to indicate, on its own, the safety of an ingredient. Thus, such evidence can supplement other evidence, but it cannot establish on its own the safety of an ingredient.

[64] The respondent also notes that the listing of an ingredient on the Board's Natural Health Products Ingredient Database is not indicative of its safety. Rather, products are posted there based on their classification as a natural health product. Applicants are still required to submit evidence to support the safety of ingredients in their products according to the specific conditions of use. The respondent also highlights that contrary to the applicant's submission, unhydrolyzed chicken type II collagen is not listed as a medical ingredient on Schedule 1 of the Regulations.

[65] The respondent submits that inclusion of an ingredient on the product licencing guidance document does not indicate that it is safe; in fact in this case, it was merely used as an example on how to correctly fill in a PLA form. Similarly, the issuance of an exemption number does not indicate that a product is safe. These numbers are issued to authorize certain natural health products for sale while awaiting a final decision. Nevertheless, no exemption number was issued to the applicant for its product.

[66] The respondent submits that the issuance of product licences to other products containing collagen does not indicate that the applicant's product is safe. In this case, the applicant did not submit evidence linking Kolla2 to the licences listed in the Board's database. In addition, the existence of patents for Kolla2 does not imply safety of the applicant's product. Patents do not include sufficient details on clinical studies conducted on the ingredient; details that the Board

requires to determine whether an ingredient is safe at the product's intended conditions of use and dose.

[67] The respondent notes that rather than pertaining to the safety of Kolla2 in the applicant's product, the decision was based on the lack of evidence of the safety of Kolla2. The respondent highlights that Kolla2 contains not only collagen, but also other substances. The Board's decision indicates that it has concerns with "native collagen/acid solubilised collagen" as the applicant did not provide information indicating that the collagen in its product would not behave the same way as the similar "native collagen/acid solubilised collagen". As the applicant did not provide information on an identical ingredient to Kolla2, it was obliged to explain scientifically why the adverse reaction for the similar ingredient was not going to occur for its ingredient; which it failed to do.

[68] With regards to the abstracts submitted by the applicant, the respondent notes that both the initial and the current versions of the Board's policy titled Evidence for Safety and Efficacy of Finished Natural Health Products set out that abstracts are not acceptable as they provide insufficient study details to determine whether an ingredient is safe and effective. The respondent further notes that both versions of this policy state that although in vitro and in vivo (animal studies) may be considered when evidence in humans is lacking or insufficient, such studies cannot be the basis for approval of an application.

[69] The respondent further notes that expert opinion reports may be used to provide information that is not available in the literature or to support a new use for a previously approved ingredient.

However, they cannot be the sole source of evidence to support the safety and efficacy of a natural health product.

[70] The respondent notes that the studies of Dr. Bishop and Dr. Trentham pertain to native type II collagen, different manufacturing processes and different doses than the applicant's use of Kolla2 in its product. The studies from Dr. Duarte, Dr. Clouatre and Dr. Darrow are expert opinion and can therefore not solely be relied upon. They are also not in compliance with the Board's policy on expert reports, which require scientific review or contain critical medical and descriptive information on the ingredient.

[71] With regards to the Cazzola study, the respondent notes that the Board considered it potentially relevant because it raised concern about a specific type of collagen. The applicant did not provide clear information on what type of collagen was used in its product. Without such information and in light of the similarity between the ingredients in the Cazzola study and the applicant's product, the Board was unable to conclude that the concern raised in the Cazzola study would not also be a concern for other types of unhydrolyzed chicken type II collagen.

[72] Finally, the respondent highlights that the Board was unable to determine from the scientific papers whether the collagen studied was hydrolyzed or unhydrolyzed and native or not. Information on the molecular weight of the collagen would have permitted the Board to characterize the collagen and thereby draw information on its safety from a comparison of the ingredients used in the studies with those used in the applicant's product. The respondent notes that many of the comments in the IRNs, notice of refusal and decision highlighted the need for clarifications on specifics of the

applicant's product. The respondent also highlights that none of the physiochemical characteristics information that the Board suggested in the decision is necessarily a requirement that would result in a refusal if not provided.

Procedural Fairness

[73] The respondent submits that procedural fairness was not breached in this case. Although the applicant contends that the Board told it that it was "free to go to the market", the respondent submits that at that time no submission number had yet been issued for the product. Thus, no preliminary review would yet have been conducted on the safety of the product. The respondent submits that this communication could therefore not have created a legitimate expectation because such an expectation cannot conflict with a statutory duty.

[74] The respondent also submits that the fairness of the Board's policy not to accept new evidence at the reconsideration stage cannot be challenged on judicial review as the Board is a master of its own internal administrative policy. The respondent notes that the applicant had sufficient opportunity to submit evidence as part of its initial application or in response to either of the IRNs.

[75] Further, the respondent notes that Alison Ingham was not the assessment officer who reviewed the file. Her testimony that she did not read critical studies was therefore irrelevant as that was not her role as supervisor. Rather, supervisors rely on reading critical information to confirm conclusions of assessment officers.

[76] Finally, the respondent submits that reasons were provided in the decision. These were adequate and provided an explanation to the applicant. As such, there was no breach of procedural fairness.

Analysis and Decision

[77] **Issue 1**

What is the standard of review?

Where previous jurisprudence has determined the standard of review applicable to a particular issue before the court, the reviewing court may adopt that standard (see *Dunsmuir v New Brunswick*, 2008 SCC 9, [2008] 1 SCR 190 at paragraph 57).

[78] As noted by the respondent, it is established jurisprudence that the appropriate standard of review in judicial review of decisions on questions of fact and the exercise of discretion by Health Canada under the *Food and Drug Regulations*, CRC c 870, is reasonableness (see *Wellesley Therapeutics Inc v Canada (Minister of Health)*, 2010 FC 573, [2010] FCJ No 680 at paragraph 31). The Regulations at issue in this case are enacted under the same enabling statute as the *Food and Drug Regulations*: namely, the *Food and Drugs Act*, RSC 1985, c F-27. Although pertaining to different types of products, the regulators' mandates under the two regulatory schemes both entail determining whether a proposed new product meets standards of safety and efficacy. Decisions on questions of fact and the exercise of discretion by the regulators are thus entitled to similar levels of deference. The Board's decision in this case is therefore reviewable on a reasonableness standard.

[79] In reviewing the Board's decision on the reasonableness standard, the Court should not intervene unless the Board came to a conclusion that is not transparent, justifiable and intelligible and within the range of acceptable outcomes based on the evidence before it (see *Dunsmuir* above, at paragraph 47; and *Canada (Citizenship and Immigration) v Khosa*, 2009 SCC 12, [2009] SCJ No 12 at paragraph 59). It is not up to a reviewing Court to substitute its own view of a preferable outcome, nor is it the function of the reviewing Court to reweigh the evidence (see *Khosa* above, at paragraphs 59 and 61).

[80] Conversely, the appropriate standard of review for issues of procedural fairness is correctness (see *Wang v Canada (Minister of Citizenship and Immigration)*, 2008 FC 798, [2008] FCJ No 995 at paragraph 13; and *Khosa* above, at paragraph 43). No deference is owed to the Board on these issues (see *Dunsmuir* above, at paragraph 50).

Rule 81

[81] At the hearing, the applicant argued that the respondent's affidavits were not in accordance with Rule 81(1) of the *Federal Courts Rules*, SOR/98-106. Rule 81 states:

81. (1) Affidavits shall be confined to facts within the deponent's personal knowledge except on motions, other than motions for summary judgment or summary trial, in which statements as to the deponent's belief, with the grounds for it, may be included.	81. (1) Les affidavits se limitent aux faits dont le déclarant a une connaissance personnelle, sauf s'ils sont présentés à l'appui d'une requête – autre qu'une requête en jugement sommaire ou en procès sommaire – auquel cas ils peuvent contenir des déclarations fondées sur ce que le déclarant croit être les faits, avec motifs à l'appui.
(2) Where an affidavit is made on belief, an adverse inference may be drawn from the	(2) Lorsqu'un affidavit contient des déclarations fondées sur ce que croit le

failure of a party to provide evidence of persons having personal knowledge of material facts.	déclarant, le fait de ne pas offrir le témoignage de personnes ayant une connaissance personnelle des faits substantiels peut donner lieu à des conclusions défavorables.

[82] Applicant's counsel was particularly concerned with Alison Ingham's number 1 affidavit. In that affidavit, Ms. Ingham stated that she "verily believe it to be true, that the Applicant's Company's representative, Walter Anderson, indicated that he did not wish to submit a new reconsideration package and so by agreement the new decision would be based upon the existing comprehensive reconsideration package received on July 22nd, 2009" (at paragraph 2).

[83] Applicant's counsel submits that this statement is both hearsay and false. In response, respondent's counsel notes that Prothonotary Lafrenière already ruled on the hearsay issue and found that there was no breach of the hearsay rules with respect to what Ms. Ingham was evidencing in her affidavit material. Respondent's counsel also notes that the applicant did not file a further reconsideration package, reinforcing the general understanding that the decision would be based on the applicant's reconsideration package.

[84] The consent order does not specify what material the decision maker should have considered. However, in making its decision, the Board explicitly stated that it considered the applicant's reconsideration package. Thus, the decision was ultimately based on the reconsideration package. This is in accordance with the Board's reconsideration policy, which clearly states that reconsiderations "will be based only on the information and material upon which the original decision was made".

[85] At the hearing, applicant's counsel explained that the relevant evidence on this issue was that related to products containing Kolla2 that have been licenced by the respondent and studies supporting the safety of collagen that are posted on the respondent's website. However, the Board ultimately rendered its decision based on its view that it did not have data before it to support a finding that the safety concerns identified in some of the studies on collagen would not arise from the use of Kolla2 in the applicant's product. In addition, throughout the decision making process, the Board repeatedly highlighted the lack of information on the type and dose of collagen used in the scientific studies submitted by the applicant and requested more information on the type of collagen used in the applicant's product so that it could determine if it was comparable to the medicinal ingredients mentioned in the studies.

[86] I would also highlight that in Schedule A of its reconsideration package, the applicant provided summaries of research studies on collagen. All the studies focused on the same type of collagen as used in the Trentham study; a type of collagen that the applicant acknowledged was not representative of the collagen used in its product. These studies were therefore reasonably deemed insufficient by the Board for the purposes of evaluating the safety of the collagen in the applicant's product.

[87] With regards to the other evidence relied on by the applicant, I note that, contrary to the applicant's submission, unhydrolyzed chicken type II collagen is not listed as a medical ingredient on Schedule 1 of the Regulations. The listing of an ingredient on the Board's Natural Health Products Ingredient Database is also clearly insufficient to support a safety finding of that ingredient at a specified condition of use in a particular product. Similarly, the use of the ingredient as an

example on how to fill in a form in the product licencing guidance document clearly does not indicate its safety at the specific conditions of use in the applicant's product.

[88] In summary, I do not find that the applicant's submissions on Rule 81 support a finding that the Board erred in its decision.

[89] **Issue 2**

Did the Board err by basing its decision on irrelevant considerations and ignoring evidence before it?

Under subsection 5(g) of the Regulations, applicants must include in the PLA for their product: "information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use". In this case, the applicant submits that the Board erred in assessing the safety and efficacy of Kolla2 in its product firstly, by basing its decision on irrelevant considerations and secondly, by failing to consider the evidence before it.

[90] The issue of irrelevant considerations must be considered by the Court when reviewing a decision on the standard of reasonableness. As explained by Mr. Justice Yvon Pinard in *3651541 Canada Inc v Canada (Attorney General)*, 2007 FC 1255, [2007] FCJ No 1605 (at paragraph 18):

> Review of a decision on the standard of reasonableness requires that the Court not intervene in a decision unless it is "not supported by any reasons that can stand up to a somewhat probing examination" (*Cartier-Smith v. Canada (Attorney General)*, 2006 FC 1175, 2006 D.T.C. 6707 at para. 19). This can occur, for example, if the Minister has taken account of irrelevant considerations, or failed to take account of relevant considerations.

[91] In this case, the applicant submits that by relying on the scientific studies by Cazzola and Häuselmann, both of which pertained to different types of collagen than that used in its product, the Board based its decision on irrelevant considerations. Conversely, the respondent submits that the Board did not rely purely on these studies in rendering its decision, but rather on the lack of evidence distinguishing the behaviour of collagen in Kolla2 from that of native and acid-solubilised collagen used in those studies and the health risks reported therein.

[92] In evaluating these two positions, a review of the Board's correspondence with the applicant is warranted. Initially, in IRN#1 and IRN#2, the Board gave significant weight to the study as evidence of a risk of increased illness from the use of collagen. However, as highlighted by the applicant, the Häuselmann study clearly focused on determining whether the beneficial effect of methotrexate on rheumatoid arthritis patients could be sustained when replaced with collagen type II. The results were negative, indicating that without methotrexate treatment disease activity increased in the patients. There was no suggestion that this increase in disease activity was caused by the collagen; rather, the study merely indicated that the replacement of methotrexate with collagen did not maintain the beneficial effects in the patients.

[93] Later, in its first refusal, the Board again referenced the Häuselmann study, but also mentioned other studies as evidence of high doses of native collagen II worsening the effects of arthritic disease in some patients. In particular, the Board relied on the Cazzola study. This study had not been submitted by the applicant, but was nonetheless identified as relevant by the Board based on its research into the safety of collagen.

[94] After the applicant filed its reconsideration package, the Board issued its final refusal. In coming to this decision, the Board acknowledged the differences between the collagen used in Kolla2 and that used in the studies where safety concerns were identified. However, the Board reiterated that it did not have data before it to support a finding that the same safety concerns would not arise from the use of Kolla2 in the applicant's product.

[95] In its most recent decision, which is the subject of this application, the Board acknowledged that the Häuselmann study did not cause the observed increase in disease activity to collagen. Conversely, the Cazzola study did raise a possibility of increased disease activity from oral collagen administration. The Board noted that it remained unclear what type of type II collagen might cause a worsening of disease activity and without any scientific studies specifically on Kolla2 or any information on the physiochemical characteristics of the collagen used therein, it was unable to conclude that this possibility of increased disease activity would not also occur from the administration of Kolla2.

[96] It is also notable that previously in IRN#2, the Board highlighted the lack of information on the type and dose of collagen used in the scientific studies submitted by the applicant. It therefore requested more information on the type of collagen used in the applicant's product so that it could determine if it was comparable to the medicinal ingredients mentioned in the studies. Similar concerns were repeated in the Board's letter dated July 25, 2008 and in its first refusal.

[97] Thus, as indicated, the Board did not rely in its most recent decision on the Häuselmann and Cazzola studies as evidence of increased disease activity caused by Kolla2. Rather, it based its

decision on the lack of evidence distinguishing Kolla2 from the collagen used in Cazzola. This was particularly important in light of the Board's finding that there was insufficient evidence before it on the safety of Kolla2 and the conditions of use and dose in the applicant's product.

[98] This latter finding was also criticized by the applicant, who submits that the Board ignored and wrongly dismissed evidence before it on the safety of Kolla2. Specifically, the applicant submits that the Board ignored or wrongly dismissed expert evidence, scientific studies and other supporting evidence such as: the inclusion of type II collagen in the Regulations and on the Board's website and database; past marketing experience; patents; and existing exemption numbers and product licences. Conversely, the respondent submits that this evidence was either wrong (for example, collagen type II is not included in the Regulations) or insufficient to support a safety finding of Kolla2 in the product at its recommended conditions of use.

[99] The respondent also objects to the applicant's reference to the expert evidence as it submits that the applicant did not file it appropriately and it was not before the Board when it rendered its original decision. The Board's reconsideration policy does clearly state that reconsiderations "will be based only on the information and material upon which the original decision was made". Thus, I find no error in the Board limiting its reconsideration to the reconsideration package and the materials previously filed by the applicant. With regards to the abstracts submitted by the applicant, the Board's original Product-Licencing – A Step by Step Guide clearly states that, "Please note that abstracts will not be accepted as key references; however, they may be included as part of evidence".

[100] In Schedule A of its reconsideration package, the applicant provided summaries of research studies on collagen. All the studies focused on the same type of collagen as used in the Trentham study; a type of collagen that the applicant acknowledged was not representative of the collagen used in its product. These studies were therefore reasonably deemed insufficient by the Board for the purposes of evaluating the safety of the collagen in the applicant's product.

[101] Insufficient evidence was also provided in the expert reports. For example, Dr. Duarte stated that "if collagen type II is derived from chicken sternal cartilage, from chicks six to eight weeks old, it contains the greatest number of anti-inflammatory and joint supporting proteoglycans". This information is insufficient to support a finding of safety and efficacy of the product "when it is used in accordance with the recommended conditions of use", as per subsection 5(g) of the Regulations.

[102] Turning to the other evidence relied on by the applicant, it is notable at the outset that contrary to the applicant's submission, unhydrolyzed chicken type II collagen is not listed as a medical ingredient on Schedule 1 of the Regulations. The listing of an ingredient on the Board's Natural Health Products Ingredient Database is also clearly insufficient to support a safety finding of that ingredient as a specified condition of use in a particular product. Similarly, the use of the ingredient as an example on how to fill in a form in the product licencing guidance document clearly does not indicate its safety at the specific conditions of use in the applicant's product. It is also notable that no exemption number was issued to the applicant for its product.

[103] Further, neither the patents nor the advanced tariff ruling provide information on the physiochemical characteristics of Kolla2 that could be used to compare it with the collagen tested in

the scientific studies; studies that identified a potential risk of increased disease from using collagen. Similarly, although the laboratory certificates of manufacture and analysis provide some information on the manufacturing of Kolla2 and its composition, this information was insufficient for the purpose of comparing Kolla2 to the collagen tested in the scientific studies.

[104] In summary, the record indicates that the Board repeatedly found that it had insufficient evidence before it on the safety and efficacy of Kolla2 at the recommended conditions of use in the applicant's product. The studies relied on by the applicant pertained to different types of collagen than that used in Kolla2. Although the applicant did file supplementary evidence, collectively it remained insufficient to support a safety finding. The key missing link remained information specifically on the safety of Kolla2 at the recommended conditions of use in the applicant's product. I find that the Board came to a reasonable finding that this evidence was deficient and its decision was therefore within the range of acceptable outcomes based on the evidence before it.

[105] **Issue 3**

Was there a breach of procedural fairness?

The applicant submits that the Board breached procedural fairness by issuing inadequate reasons and by not previously informing it of the need to provide physiochemical characteristics of Kolla2, thereby not providing it with an opportunity to comply.

[106] On review, the Board's decision clearly indicates that it was based on a continued concern with the lack of information on the safety of Kolla2 at the recommended conditions of use in the applicant's product. As discussed above, this was a reasonable finding based on the evidence before

it. Further, throughout its previous correspondence with the applicant, the Board highlighted its uncertainty about the type of collagen used in the applicant's product compared to that tested in the scientific studies submitted. Although the certificates of analysis provided some information on the content of Kolla2, this information was insufficient to allow comparison with the type of collagen tested in the scientific studies. I therefore do not find that the Board breached procedural fairness on either of these issues raised by the applicant.

[107] Finally, the applicant also submits that the Board's decision was politically motivated to reduce the backlog of PLAs. In support, the applicant refers to evidence on the backlog in the system. However, the applicant does not provide any evidence of the Board, or its staff, issuing the decision based on ill-intent. Further, as indicated, the decision itself provides sufficient reasons rather than providing a mere dismissal of the applicant's PLA. I would therefore also dismiss this allegation as not indicative of a breach of procedural fairness.

[108] In summary, I find that the Board came to a reasonable decision based on the evidence before it and did not violate procedural fairness in so doing. I would therefore dismiss this application, with costs to the respondent.

JUDGMENT

THIS COURT'S JUDGMENT is that the application for judicial review is dismissed with costs to the respondent.

"John A. O'Keefe"
Judge

ANNEX

Relevant Statutory Provisions

Federal Courts Act, RSC 1985, c F-7

18.1 (1) An application for judicial review may be made by the Attorney General of Canada or by anyone directly affected by the matter in respect of which relief is sought.	18.1 (1) Une demande de contrôle judiciaire peut être présentée par le procureur général du Canada ou par quiconque est directement touché par l'objet de la demande.

Federal Courts Rules, SOR/98-106

52.1 (1) A party to a proceeding may name an expert witness whether or not an assessor has been called on under rule 52.	52.1 (1) Une partie à une instance peut désigner un témoin expert même si les services d'un assesseur ont été retenus en application de la règle 52.
(2) Two or more of the parties may jointly name an expert witness.	(2) Deux parties ou plus peuvent conjointement désigner un témoin expert.
52.2 (1) An affidavit or statement of an expert witness shall	52.2 (1) L'affidavit ou la déclaration du témoin expert doit :
(a) set out in full the proposed evidence of the expert;	a) reproduire entièrement sa déposition;
(b) set out the expert's qualifications and the areas in respect of which it is proposed that he or she be qualified as an expert;	b) indiquer ses titres de compétence et les domaines d'expertise sur lesquels il entend être reconnu comme expert;
(c) be accompanied by a certificate in Form 52.2 signed by the expert acknowledging that the expert has read the Code of Conduct for Expert Witnesses set out in the schedule and agrees to be bound by it; and	c) être accompagné d'un certificat, selon la formule 52.2, signé par lui, reconnaissant qu'il a lu le Code de déontologie régissant les témoins experts établi à l'annexe et qu'il accepte de s'y conformer;
(d) in the case of a statement, be in writing, signed by the expert and accompanied by a solicitor's certificate.	d) s'agissant de la déclaration, être présentée par écrit, signée par l'expert et certifiée par un avocat.
81. (1) Affidavits shall be confined to facts within the deponent's personal knowledge except on motions, other than motions for	81. (1) Les affidavits se limitent aux faits dont le déclarant a une connaissance personnelle, sauf s'ils sont présentés à

summary judgment or summary trial, in which statements as to the deponent's belief, with the grounds for it, may be included.

l'appui d'une requête – autre qu'une requête en jugement sommaire ou en procès sommaire – auquel cas ils peuvent contenir des déclarations fondées sur ce que le déclarant croit être les faits, avec motifs à l'appui.

(2) Where an affidavit is made on belief, an adverse inference may be drawn from the failure of a party to provide evidence of persons having personal knowledge of material facts.

(2) Lorsqu'un affidavit contient des déclarations fondées sur ce que croit le déclarant, le fait de ne pas offrir le témoignage de personnes ayant une connaissance personnelle des faits substantiels peut donner lieu à des conclusions défavorables.

Natural Health Products Regulations, SOR/2003-196

4. (1) Subject to subsections (2) and (3), no person shall sell a natural health product unless a product licence is issued in respect of the natural health product.

4. (1) Sous réserve des paragraphes (2) et (3), il est interdit de vendre un produit de santé naturel à moins qu'une licence de mise en marché n'ait été délivrée à son égard.

(2) No product licence holder, manufacturer, importer or distributor of a natural health product for which a product licence is issued shall sell the natural health product during any period that the sale of that natural health product is directed to be stopped under section 17.

(2) Il est interdit au titulaire de la licence de mise en marché, au fabricant, au distributeur et à l'importateur, durant toute période de cessation de vente ordonnée aux termes de l'article 17, de vendre un produit de santé naturel à l'égard duquel une licence de mise en marché a été délivrée.

(3) No person shall sell a natural health product for which a product licence is issued

(3) Il est interdit de vendre un produit de santé naturel à l'égard duquel une licence de mise en marché a été délivrée à l'un ou l'autre des moments suivants :

(a) during the period of any suspension of the licence under section 18 or 19; or

a) durant toute période de suspension de la licence ordonnée aux termes des articles 18 ou 19;

(b) after cancellation of the licence under paragraph 20(b).

b) après l'annulation de la licence ordonnée aux termes de l'alinéa 20b).

5. An application for a product licence shall be submitted to the Minister and shall contain the following information and documents:

(a) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

(b) if the address submitted under paragraph (a) is not a Canadian address, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant's representative in Canada to whom notices may be sent;

(c) for each medicinal ingredient of the natural health product,

(i) its proper name and its common name,

(ii) its quantity per dosage unit,

(iii) its potency, if a representation relating to its potency is to be shown on any label of the natural health product,

(iv) a description of its source material, and

(v) a statement indicating whether it is synthetically manufactured;

(d) a qualitative list of the non-medicinal ingredients that are proposed for the natural health product and for each ingredient listed, a statement that indicates the purpose of the ingredient;

(e) each brand name under which the natural health product is proposed to be sold;

(f) the recommended conditions of use for the natural health product;

5. La demande de licence de mise en marché est présentée au ministre et comporte les renseignements et documents suivants :

a) le nom, l'adresse, le numéro de téléphone et, le cas échéant, le numéro de télécopieur et l'adresse électronique du demandeur;

b) si l'adresse visée à l'alinéa a) est un lieu situé à l'extérieur du Canada, le nom, l'adresse, le numéro de téléphone et, le cas échéant, le numéro de télécopieur et l'adresse électronique du représentant du demandeur au Canada à qui les avis peuvent être expédiés;

c) pour chacun des ingrédients médicinaux contenus dans le produit :

(i) son nom propre et son nom usuel,

(ii) sa quantité par unité posologique,

(iii) son activité, si l'une des étiquettes du produit comporte une déclaration à l'égard de celle-ci,

(iv) une description de sa matière d'origine,

(v) une mention indiquant s'il s'agit d'un ingrédient fabriqué synthétiquement;

d) une liste qualitative des ingrédients non médicinaux qu'on se propose d'incorporer au produit de santé naturel ainsi que, pour chacun de ces ingrédients, une mention indiquant à quelles fins l'ingrédient serait incorporé au produit;

e) chacune des marques nominatives sous lesquelles le produit est destiné à être vendu;

f) les conditions d'utilisation recommandées du produit;

(g) information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use;

g) les renseignements montrant l'innocuité et l'efficacité du produit lorsqu'il est utilisé selon les conditions d'utilisation recommandées;

(h) the text of each label that is proposed to be used in conjunction with the natural health product;

h) le texte à utiliser sur chacune des étiquettes du produit;

(i) a copy of the specifications to which the natural health product will comply; and

i) un exemplaire des spécifications auxquelles le produit devra se conformer;

(j) one of the following attestations, namely,

j) l'une des attestations suivantes :

(i) if the natural health product is imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3, or

(i) dans le cas d'un produit de santé naturel importé, une attestation du demandeur établissant que le produit de santé naturel sera fabriqué, emballé, étiqueté, importé, distribué et entreposé conformément aux exigences prévues à la partie 3 ou à des exigences équivalentes,

(ii) if the natural health product is not imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, distributed and stored in accordance with requirements set out in Part 3.

(ii) dans le cas d'un produit de santé naturel qui n'est pas importé, une attestation du demandeur établissant que le produit de santé naturel sera fabriqué, emballé, étiqueté, distribué et entreposé conformément aux exigences prévues à la partie 3.

7. The Minister shall issue or amend a product licence if

7. Le ministre délivre ou modifie la licence de mise en marché si les conditions suivantes sont réunies :

(a) the applicant submits an application to the Minister that is in accordance with section 5 or subsection 11(2), as the case may be;

a) le demandeur présente au ministre une demande conforme à l'article 5 ou au paragraphe 11(2), selon le cas;

(b) the applicant submits to the Minister all additional information or samples requested under section 15;

b) le demandeur fournit au ministre les renseignements complémentaires ou les échantillons demandés en vertu de l'article 15;

(c) the applicant does not make a false or

c) le demandeur ne fait pas de déclaration

misleading statement in the application; and

(d) the issuance or amendment of the licence, as the case may be, is not likely to result in injury to the health of a purchaser or consumer.

8. (1) The Minister shall assign a product number to each natural health product in respect of which a product licence is issued.

(2) In the case of a natural health product that is a drug for which a drug identification number is assigned in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*, the product number required under subsection (1) shall be the drug identification number.

9. (1) If the Minister refuses to issue or amend a product licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.

(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(a) give the applicant an opportunity to be heard in respect of the application; and

(b) reconsider the application after giving the applicant that opportunity.

10. (1) After reconsidering the application, the Minister shall issue or amend the product licence if the requirements of section 7 are met.

fausse ou trompeuse dans sa demande;

d) la délivrance ou la modification de la licence ne risque pas de causer un préjudice à la santé de l'acheteur ou du consommateur.

8. (1) Le ministre assigne un numéro d'identification à chaque produit de santé naturel à l'égard duquel une licence de mise en marché est délivrée.

(2) Dans le cas d'un produit de santé naturel qui est une drogue faisant l'objet d'une identification numérique conformément au paragraphe C.01.014.2(1) du *Règlement sur les aliments et drogues*, le numéro d'identification assigné conformément au paragraphe (1) consiste en l'identification numérique en cause.

9. (1) Lorsque le ministre refuse de délivrer ou de modifier la licence, il envoie au demandeur un avis exposant les motifs du refus.

(2) Le demandeur peut, dans les trente jours suivant l'envoi de l'avis, demander au ministre de reconsidérer la demande de licence.

(3) Lorsque le demandeur présente une demande selon le paragraphe (2), le ministre, à la fois :

a) donne au demandeur la possibilité de se faire entendre;

b) reconsidère la demande de licence après avoir donné au demandeur la possibilité de se faire entendre.

10. (1) Après avoir reconsidéré la demande de licence, le ministre délivre ou modifie la licence si les conditions de l'article 7 sont réunies.

(2) If the Minister again refuses to issue or amend the product licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.

(2) Si le ministre refuse à nouveau de délivrer ou de modifier la licence, il envoie au demandeur un avis final exposant les motifs du refus.

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

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