**A Formal Report**

**For a**

**New Dentsply Natural Prophy Paste with NuPro Novamin Technology**

Prepared for

Dentsply Dental Supplies

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**INFORMATIVE ABSTRACT**

In the ever-progressing field of dentistry, there is a growing population of patients who are becoming fluoride-free and choosing natural ingredients. Moreover, it goes without saying that the general population is moving to a more holistic way of living, or a way of living that involves a reduced use of chemicals and every ingredient used offers healthy benefits to the mind and body.

While there are a few natural tooth polishes on the market, there is not, however, a natural prophy paste, made by a reputable dental supply company, in which dental professionals know and trust.

I understand that your product line, NUPRO® NUSolutions™ with NovaMin® is the newest Dentsply Professional prophy paste. As you have mentioned on your website, it is currently the only product powered by NovaMin, which has only recently been introduced in the dental industry and is made of a synthetic mineral containing sodium, calcium, phosphorous and silica—all elements found naturally in the body. (S. Wall) I am impressed by the clinical studies that have shown how these particles attach to the tooth surface and continue to release ions and remineralize the tooth surface after initial application. To date, there has been no other prophy paste product that can make this claim, which is why I see a successful natural prophy paste accepted by dentists from your reputable company. The potential for NovaMin as an ingredient in innovative dental products remains very positive. As the leading dental supply companies in the industry, I see the opportunity for this new product to finally gain confidence the critical eyes of dentists, and ultimately meets the needs of today’s growing ‘alternative’ clientele.

**INTRODUCTION**

**OVERVIEW**

In the few years that I have been working as a dental hygienist, I have used one general type of polishing paste, which has fluoride as well as several unnatural ingredients in it. I have also used prophy paste, which comes in several unnatural flavours like Piña colada or bubble gum or cotton candy etc. The majority find the taste repulsive and repeatedly ask if there is a more natural alternative, as well as a fluoride-free alternative. The following proposal addresses the concerns of a growing market of health-conscious patients and dental professionals requesting a safe, alternative (of chemical and fluoride-free) prophy paste used in their dental clinic.

**BACKGROUND**

Alternative or complementary medicine has been known as treatment and/or prevention, which *complements* mainstream medicine by contributing to a common whole, satisfying a demand not met by traditional medicine. In other words, it represents a group of diverse medical and healthcare practices, products, and systems that may not be considered to be part of traditional, western medicine. And more specifically, complementary medicine is used together with Western medicine while alternative medicine is used in place of. Aromatherapy, essential oils, herbal medicine, homeopathy, naturopathy are just some examples of complimentary medicine commonly used in health settings today. I intend to bring your attention to these specific examples, as they are the inspiration of the new product I am proposing to you now.

As the public demand for alternative and complimentary medicine grows strong, dental professionals are adapting their care planning to what their patients’ beliefs, values, experiences and opinions as a means of providing optimal and individualised care. Realising and understanding this trend is only a first step in developing a broader sense of how these and associated beliefs may affect treatment planning, public health programs, as well as oral health in general.

**STATEMENT OF PROBLEM**

In previous years, the standard of care for the dental hygienist performing a prophylaxis included coronal polishing until research discovered that polishing removed valuable enamel. The American Dental Hygienists' Association (ADHA) came on board with their position paper on polishing that stated the following:

* Polishing is viewed as a cosmetic procedure with little therapeutic value
* Thorough brushing and flossing can produce the same effect as polishing
* Continuous polishing can, over time, cause morphological changes by abrading tooth structure away
* Fluoride in the outer layers of enamel is removed through polishing (S. Wall)

Their main conclusion was that “polishing should be performed only as needed and not be considered a routine procedure.” In other words, rather than polishing every tooth surface, the dental hygienist should evaluate which teeth require it and then polish only those tooth surfaces.

With that said, I question whether it was appropriate for the ADHA to make a broad statement against polishing. Is polishing all of the teeth always detrimental or can there be possible benefits, in remineralizing the teeth, aiding in gum health, or even just providing the patient with an overall feeling of smooth and shiny teeth? I believe that every ingredient in the polish paste should have a proven, beneficial effect for the oral cavity, thus there is absolutely no harm done. Have dental hygienists, in general, adhered to the “selective polishing” concept? Probably not, since most dental hygienists include full mouth coronal polishing as an integral part of their prophylaxis procedure. This is just the reality! Patients expect it; if there is no polishing, they may feel shortchanged, not to mention, the treatment of polishing is undoubtedly favourited among the majority of patients. In the past, many would say there was no real benefit to full mouth polishing. But in the practice of today's dental hygiene, this is not the case. It is time to rethink where the profession of dental hygiene stands regarding this issue. I believe it is to the benefit of the patient and the dental hygiene practitioner to take a closer look.

Additionally, as I stated above, there are few natural prophy pastes on the market to appease the growing population of alternative patients who seek chemical and fluoride free-options, and even fewer to no products that meet the dental professionals standards of an FDA approved product. I am not saying that I am against the use of fluoride, but after years of altering my treatment plan to suite the needs of these patients, I am left with one last dilemma: the limiting amount of prophy pastes that are fluoride-free. My proposed product consists of natural and quality but cost-efficient ingredients including Redmond bentonite clay, calcium carbonate powder, xylitol, baking soda, and various carefully selected essential oils like lavender, peppermint, cinnamon, and sweet orange.

**NEED**

As a dental hygienist, the goal of my practice centers around providing preventative care, yet polishing currently aims only to treat the ‘symptom’ of stained teeth. I propose a prophy paste that not only removes unwanted stain, but also aids in gum health and prevents caries formation, and is made up of only natural ingredients, where each ingredient has a beneficial effect on the oral cavity. While there are a few natural tooth polishes on the market, there is not, however, a natural prophy paste made by a reputable dental supply company, and in individually packaged, ready-to-go prophy cups for a dental hygienist’s easy use. For a natural and chemical-free prophy paste to be used in dental clinics nationwide, it must gain FDA approval, adequate marketing, and the label of a reputable dental company.

**SCOPE**

To assess the feasibility of developing a market for “alternative”, natural prophy paste, I plan to pursue the following areas of inquiry:

1. Are dentists using any natural tooth polish products presently?
2. What factors may be limiting the use of natural prophy pastes used in dental offices today? FDA and NHP approval? Cost? Patient preference?
3. How large exactly is the demand for natural prophy paste? Is there a high enough demand to support the production costs?
4. What is the process of implementing a natural prophy paste?
5. What are the costs of retrieving and producing high quality natural prophy paste? What prices for the products can the market bear?

The following plan includes:

1. Methods for gathering data to support the purpose of this proposal
2. Phases for launching the New Dentsply Professional Natural Prophy Paste with NovaMin
3. Projected costs for product manufacturing, testing and FDA approval, marketing and distributing during the upcoming year
4. A demonstration of feasibility, showing the product demand
5. A summary of attitudes shared by interviewed personnel

**METHODS**

Qualitative research using survey questions and subsequent interviews were used to assess the feasibility of this proposal, which can be measures through an objective evaluation of product need vs. cost-effectiveness.

First questionnaire/interview: all patients (from October 31st – Nov 15th 2016) who volunteered to be part of the study and who have had the polish treatment were verbally asked to 8 questions during their dental appointment. Participants are representative of the general population, though the selection process was restricted by the small number of participants (N = ~40). No participants were eliminated.

Second additional, brief questionnaire/interview: was to dental professionals (dentists and dental hygienists, n=22) inquiring about their willingness to use natural prophy pastes in their office and any opposition towards its use.

Standard equipment used include generic prophy paste, standard dental polishing equipment, pen and paper to note answers.

**Summary of Collected Data**

Survey/interview questions (verbally asked during and/or after each patient’s appointment with their approval) was as follows:

1. How satisfied are you with the taste of the generic polish paste used by your dental hygienist today? (Fluoride with pepperment flavour).

The majority of patients (89%) were impartial to the pepperment flavour, and there was an equal smaller percentage of patients who either enjoyed the taste or severely disliked the taste.

1. Were you aware that this polish paste contains fluoride?

Surprisingly, all of the patients interviewed were not aware that there was fluoride in the polish, though about half said they were not surprised. One individual commented, “it seems that there’s fluoride in every dental paste” and a few patients opted out of the polish treatment upon learning this, while others agreed to have the polish treatment, though consequently opted out of having the fluoride treatment.

1. If there were other ingredients capable of remineralizing your teeth (like calcium), would you prefer them to fluoride or would you prefer your polish paste to contain fluoride?

56% of patients preferred an alternate option to remineralize their teeth, though they were unsure what else could be used. The other half were impartial and unaware that the polish treatment had the potential benefits of remineralizing the teeth.

1. Order the following flavours in the sequence that you would be most likely to try next (from most desirable to least desirable): cinnamon, sweet orange, or lavender.

Interestingly, all three flavours shared equal interest. One patient commented that they preferred cinnamon as long as it was not ‘spicy’, and a few patients were interested in sweet orange and lavender purely for the novelty of the experience.

1. Are you interested in complimentary or alternative medicine (natural and organic products as opposed to chemicals) being used in your dental treatment? Would you prefer an alternative, natural polish paste used today?

Over 90% of subjects replied a definite ‘yes’ to this question, with few patients remaining impartial and unconcerned about the ingredients as long as the polish was effective in whitening his teeth.

1. Do you have any apprehension towards any of the following ingredients being used in your polish paste: xylitol (a plant-derived sugar that naturally prevents cavities), baking soda (to smooth and whiten), calcium powder (to remineralize and whiten), essential oils (to add flavour, freshen the breath, and for added healing benefits), and Redmond Bentonite Clay (alkalizes, adds minerals, and removes toxins).

There was no oppositions to any of these ingredients being used, however, one client asked about using Stevia instead of xylitol, as she, as well as several others, questioned what xylitol was and its health benefits. Another suggested using charcoal to whiten and polish.

The list of interview questions (verbally asked) to dental professionals was as follows:

1. Are you aware of any patients in your office that would prefer a natural, chemical and fluoride-free prophy paste?

Most interviewed subjects responded with an absolute ‘yes’, few stated that they would assume so, but are not certain.

1. Are you aware of any natural, chemical and fluoride-free prophy pastes on the market today?

All but one subject responded no, who stated that they were unsure if this product was being used in dental clinics. One dentist reported using straight pumice and water as a natural prophy paste for his clients.

1. Would you consider buying and using a natural prophy paste in your office if it was the same price as regular prophy paste? If not, can you share why?

All subjects responded yes, but only if it was approved by the Canadian Dental Association or the FDA. And one hygienist admitted that her office has lost sales because clients from clients do not wish to polish because they see no added benefit from the procedure and refuse any fluoride intake.

**Working Definitions**

To **remineralize** - is to restore the depleted minerals to the teeth, which is generally through minerals such as calcium, phosphate, and fluoride.

**Prophy** - refers to oral prophylaxis treatment, which is a general term for a dental treatment or cleaning of the teeth by a dental professional. It includes the removal of plaque material, food debris, extrinsic stains, and sometimes calculus from the teeth and filling material. This is done as a preventative measure for the control of gingivitis (when plaque bacteria colonize on the gingival tissue, either above or below the gum line) and staining.

**Limitations of the Study**

Researcher bias can be attributed to this study as I, personally, asked my patients the questionnaire questions and recorded their answers. The limited amount of subjects that participated in these interviews can also be seen as a limitation of this study. Lastly, it would have been beneficial to have subject reviews of the natural prophy paste, however, due to legal issues, this was not permissible at this time.

**PROPOSED PLAN**

This plan is designed to create a new product that is safe, beneficial, and natural that will be accepted by both dentists and clients.

**Phases of the Plan**

We can meet our clients and dentists demands by taking these steps:

**Creating the Product/Materials.** The ingredients in this product can be purchased through large and reputable companies at wholesale prices. All of these ingredients have beneficial properties to oral cavity and overall well-being of the client, which include whitening and remineralizing the teeth, healing and cleansing gum tissues, and creating a relaxing aroma for the client. The selection of these ingredients is backed by evidence-based research. My primary proposed four ‘flavours’ include lavender, cinnamon, peppermint, and sweet orange. I have extensively researched and tested three main recipes for gum health, caries prevention, and desensitization. And with the addition of your active ingredient, of hydroxycarbonate apatite (HCA) in NovaMin®, this product would more efficiently and effectively aid in the remineralization of enamel and gain acceptance and approval in the critical eyes of dentists.

**Product testing to gain Food and Drugs Act (FDA) approval, or Natural Health Product (NHP) from Health Canada or Canadian Dental Association (CDA) Seal label.**  This is the essential step in making this product unique and widely accepted by all dental professionals. Market research by manufacturers has shown that CDA's Seal on a product directly influences the purchasing decisions of consumers and dental professionals. (#)

To get FDA approval, the manufacturers of this product must conduct lab and human clinical testing and submit the data to FDA, who will then review the data and approve the product if the agency determines that the benefits of the product outweigh the risks for the intended use. ("Dental Products Panel". *Fda.gov)*

To ensure this product comes with a NHP label, it must comply with the Labeling and Packaging requirements set out in the Natural Health Products Regulations (NHPR), as specified in Health Canada: Drugs and Health Products. **When preparing a label for a product license application,** t**he information provided on the label must be consistent with the information on the Product License Application form. If any advertising is to appear on the label, it must not the Food and Drugs Act.** Consequently, a Natural Health Product must gain its label in accordance with the set regulations, which follow the labeling requirements checklist and sent to Health Canada. ("Health Canada". *Hc-sc.gc.ca*.)

The CDA Seal Program is a symbol that identifies products that are of benefit to the oral health of consumers, which is designed to help the public and dental professionals make informed choices. ("CDA Seal Program". *Cda-adc.ca*)

The CDA's product recognition programs provide information to consumers and professionals on a wide range of dental products, as reviews submissions from manufacturers to verify the acceptability of research methodology and evidence that the statement of claim made by the manufacturer can be scientifically supported. These reviews include evaluation of the data from all clinical and laboratory tests mentioned in the submission. ("CDA Seal Program". *Cda-adc.ca*)

*The Application Process*

A manufacturer who applies for the seal must:

* Apply in writing, verifying product compliance with all requirements of Health Canada's Therapeutic Products Directorate;
* Demonstrate that the product meets specific CDA requirements by supplying supporting data (clinical or laboratory studies) attesting to the safety and efficacy of the product;
* Provide CDA with evidence that the product can be legally sold in Canada and belongs to a category specified by the Association;
* Assure the appropriate product recognition committee that the applicant's manufacturing and laboratory facilities comply with product specifications, and that product packaging and labelling are accurate;
* Submit product specification, ingredient lists and other pertinent information for review and approval.

The manufacturer may use the CDA Seal Program for three years, with a renewal option. An annual fee must be paid to CDA for each product that carries the Association's seal. ("CDA Seal Program". *Cda-adc.ca)*

**Marketing the new product.** I offer a few suggestions to market this product: a dental conventions, like the Pacific Dental Conference, dental education events, on your website, in dental product magazines and in advertisements in Health Journals. Additional funding would be essential here to encourage sales personnel to visit dental clinics in surrounding areas with free samples.

**Consumer evaluation of product.** Personnel are required to create and gather reviews from dental professionals as well as patients regarding their satisfaction of this product. This is necessary for the product success as consumer suggestions will advance the product in regards to splatter control, flavour preferences, frequency of use, and overall likeability.

**Costs**

My proposed budget is itemized in Table 1, but the main point is clear: If the product is to be incorporated into dental offices nationwide, increased funding is essential for meeting the projected costs. This is why I propose to add 15% to estimated budget costs, in order to successfully implement this project.

Table 1. Projected Costs and Requested Funding for New Dentsply Natural Prophy Paste

**PROJECTED COSTS**

**For first batch of this product**

|  |  |
| --- | --- |
|  |  |
| Ingredients  - Baking soda 50lbs  - Xylitol (GMO free) 5lb  - Calcium carbonate powder 150lbs  - Redmond Bentonite Clay 30lb  - peppermint Doterra essential oil  - lavender Doterra essential oil  - cinnamon Doterra essential oil  - sweet orange Doterra essential oil | $25  $35  $90  $120  $21  $21  $21  $11 |
| Total: | 344 x %15 = 395.60 |
| CDA Seal, NHP, or FDA Approval | $500-5000 |
| Total | x 15% = $575 - $5,750 |
| Personnel  - researcher  - product manufacturer | $500-$1,000  $500-$1,000 |
| Total: | $10,00-2,000 x %15 = $1,050-$,2300 |

Grand total: $2,020.60 - $8,445.60

**Personnel**

The success of this product placement ultimately depends on the willingness of your company to create, test, market, and distribute it, and of the dental clinics implement it.

**CONCLUSION**

The conclusions of this report including the two questionnaires indicate that clients are increasingly interested in an alternative polish paste, yet the lack of reputable and professional tested and approved options is one of the greatest barriers to its appropriate use in the clinical setting, which ultimately results in reduced sales among dental clinics, as well as dissatisfied clients. These findings demonstrate the importance for dental professionals to broaden their use of complimentary medicine and the growing need for more CDA and FDA approved products, collaboration among health professionals, as well as the implantation of alternative natural products in the clinic setting. This topic grows in significance alongside the growing population of those choosing alternative therapy over conventional approaches to their healthcare.

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