CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211580Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	November 15, 2018
Application Type and Number:	NDA 211580
Product Name and Strength:	Spy Agent Green (indocyanine green) for injection, 25 mg/vial
Total Product Strength:	25 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novadaq Technologies ULC.
Panorama #:	2018-26498814
DMEPA Safety Evaluator:	Casmir Ogbonna, PharmD, MBA, BCPS, BCGP
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Spy Agent Green, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Novadaq Technologies ULC submitted an external Brand Name study, conducted by (b) (4), for this proposed proprietary name.

1.1 REGULATORY HISTORY

Novadaq Technologies ULC previously submitted the proposed proprietary name, Spy Agent Green*** on June 26, 2018 under NDA 211580. However, we found the name, Spy Agent Green*** unacceptable due to due to the Office of Prescription Drug Promotion (OPDP) objection.[1]

Thus, Novadaq Technologies ULC re-submitted the name, Spy Agent Green, for reconsideration on October 10, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 10, 2018.

- Intended Pronunciation: [spahy] [ey-juh nt] [green]
- Active Ingredient: indocyanine green
- Indication of Use:
    - Fluorescence imaging of blood flow and tissue perfusion during: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgeries, including general minimally invasive surgical procedures. (b) (4)
    - Fluorescence imaging of lymph nodes and delineation of lymphatic vessels in the cervix and uterus during lymphatic mapping in patients with solid tumors for which this procedure is a component of intraoperative management. (b) (4)
- Route of Administration: Intravenous, Interstitial
- Dosage Form: for injection
- Strength: 25 mg/vial

[1]Rychlik, I. Proprietary Name Review for Spy Agent Green*** (NDA 211580). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 AUG 07. Panorama No. 2018-24067287.

- Dose and Frequency:
  - [redacted] Blood Flow and Tissue Perfusion: The recommended dose for a single image sequence is 1.25 mg – 5 mg Spy AGENT Green. For visualization of perfusion in extremities through the skin, the recommended dose is 3.75 mg - 10 mg. [redacted].
  - Imaging Extrahepatic Biliary Ducts: The recommended dose [redacted]
  - Imaging of Lymph Nodes and Lymphatic Vessels During Lymphatic Mapping: The recommended dose is four 1.25 mg injections for a total dose of 5 mg.
- How Supplied: Spy AGENT™ Green (Indocyanine Green) is supplied [redacted]

  Spy Elite Kit containing [redacted] 25 mg Spy AGENT Green (Indocyanine Green) vial, one 10 mL Sterile Water for Injection, USP plastic vial, one sterile drape, [redacted]

  PINPOINT® Kit [redacted] one 25 mg Spy AGENT Green (Indocyanine Green) vial, one 10 mL Sterile Water for Injection, USP plastic vial, two x 3 ml syringes (sterile), 2 x 10 ml syringes (sterile), one 3-way stopcock (sterile), two 18G, 1 inch needles (sterile), [redacted]

  PINPOINT Lymphatics [redacted] Kit [redacted] one 25 mg Spy AGENT Green (Indocyanine Green for Injection, USP) vial, two 10 mL Sterile Water for Injection, USP plastic vials, [redacted] x 10 ml syringes (sterile), [redacted] luer-lock 10 ml syringes with controlled handle (sterile), [redacted] spinal needles 22G, 3.5 inch (sterile), [redacted]
- Storage: 20°C to 25°C (68°F to 77°F)

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Spy Agent Green.

2.1 MISBRANDING ASSESSMENT

On October 26, 2018, the Office of Prescription Drug Promotion (OPDP) rescinded their previous OPDP objection of Spy Agent Green and determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Medical Imaging Products (DMIP) concurred with the findings of OPDP's assessment for Spy Agent Green.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Spy Agent Green.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[2].

2.2.2 Components of the Proposed Proprietary Name

Novadaq Technologies ULC indicated in their submission that the proposed proprietary name, Spy Agent Green, is derived from the term 'SPY' which refers to Novadaq/Stryker fluorescence imaging medical devices, which have been available on the US market since 2005 and currently include the SPY Fluorescence Imaging System (SPY Elite) and the Pinpoint Endoscopic Fluorescence Imaging System (Pinpoint), collectively the SPY Fluorescence Imaging Systems. The term 'AGENT' refers to Imaging Agents and the product's classification. And the term 'GREEN refers to Indocyanine Green. SPY AGENT GREEN (b) (4) This proprietary name is comprised of multiple words that does not contains a component (a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 26, 2018 e-mail, the Division of Medical Imaging Products (DMIP) did not forward any comments or concerns relating to Spy Agent Green at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Fifty-one (51) practitioners participated in DMEPA's prescription studies for Spy Agent Green. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[3] identified 161 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, and external study conducted by (b) (4) These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3

[2] USAN stem search conducted on October 30, 2018.

[3] POCA search conducted on October 29, 2018 in version 4.3.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	148
Low similarity name pair: combined match percentage score ≤54%	161

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 312 names contained in Table 1 determined none of the names will pose a risk for confusion with Spy Agent Green as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Medical Imaging Products (DMIP) via e-mail on November 15, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Medical Imaging Products (DMIP) on November 15, 2018, they stated no additional concerns with the proposed proprietary name, Spy Agent Green.

3 CONCLUSION

The proposed proprietary name, Spy Agent Green, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO NOVADAQ TECHNOLOGIES ULC.

We have completed our review of the proposed proprietary name, Spy Agent Green, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on October 10, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [4]

[4] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[5]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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[5] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Spy Agent Green Study (Conducted on July 6, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Spy Agent Green Unpuse 2.5 mg (1 mL)	Spy Agent Green Inject 2 mg intravenously today
Outpatient Prescription: Spy Agent Green Provide to Hospital for imaging 1 Vial	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Spy Agent Green

As of Date 11/5/2018

309 People Received Study

51 People Responded

Study Name: Spy Agent Green

Total	16	14	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
BI AGENT GREEN	0	2	0	2
BIAGENT GREEN	0	3	0	3
BI-AGENT GREEN	0	1	0	1
BY AGENT GREEN	0	2	0	2
BYAGENT GREEN	0	1	0	1
SPY AGENT GREEN	15	3	16	50
SPY AGENT GREEN 2.5MG	0	0	1	1
SPY AGENT GREEN INPISE	0	0	2	2
SPY AGENT GREEN INVISE	0	0	1	1
SPY AGENT GREEN UNPISE	0	0	1	1
SPY AGENTGREEN	1	0	0	1
SPYAGENTGREEN	0	1	0	1
VIAGENT GREEN	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Spy Agent Green **Established name:** indocyanine green **Dosage form:** for injection **Strength(s):** 25 mg/vial **Usual Dose:** of 4 injections1.25 mg – 5 mg for single image, 3.75 mg – 10 mg for perfusion of extremities through skin with max of four doses, for biliary ducts 2.5 mg for max of 4 doses, for lymph nodes or lymphatic vessels 1.25 mg dose	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Spy Agent Green	100	Subject of review
2.	Pigment Green 7	76 (ortho = 80; phonetic = 72)	This name is not a drug. It is a coloring pigment used as a paint or additive for paint or printing ink. Its use is mainly in the paint industry, plastic industry, textile industry, ink industries, leather industries, coating industry, paper industries, and the rubber industry.
3.	Statuss Green	70 (ortho = 76)	Product discontinued per Redbook with no generic equivalents available.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
4.	Staycept	66
5.	Phenavent	65
6.	Pepsodent	64
7.	Senna-Gen	62 (ortho = 72)
8.	Stay Alert	62
9.	Striant	61
10.	Sylvant	61
11.	Serevent	60
12.	Nystavescent	60
13.	Phenavent D	60
14.	Rabies Antigen	59
15.	Spastrin	58

No.	Name	POCA Score (%)
16.	Gentran 40	58 (ortho = 72)
17.	Mentadent	58
18.	Sinuvent	57
19.	Sportscreme	57
20.	(b) (4) ***	56
21.	Sprayzoin	56
22.	Sudogest	56
23.	Mastic Dent	56
24.	Phenavent La	56
25.	(b) (4) ***	55
26.	Dupixent	55
27.	Prevident	55

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Spy Agent Green **Established name:** indocyanine green **Dosage form:** for injection **Strength(s):** 25 mg/vial **Usual Dose:** of 4 injections1.25 mg – 5 mg for single image, 3.75 mg – 10 mg for perfusion of extremities through skin with max of four doses, for biliary ducts 2.5 mg for max of 4 doses, for lymph nodes or lymphatic vessels 1.25 mg dose	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
28.	Superdent	68 (phonetic = 73)	This name pair has sufficient orthographic and phonetic differences.
29.	Respivent	66 (phonetic = 71)	This name pair has sufficient orthographic and phonetic differences.
30.	Pentagastrin	64 (ortho = 74)	This name pair has sufficient orthographic and phonetic differences.
31.	Imagent	62	This name pair has sufficient orthographic and phonetic differences.
32.	Stagesic	61	This name pair has sufficient orthographic and phonetic differences.
33.	Pavagen	60 (ortho = 70)	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Spy Agent Green **Established name:** indocyanine green **Dosage form:** for injection **Strength(s):** 25 mg/vial **Usual Dose:** of 4 injections1.25 mg – 5 mg for single image, 3.75 mg – 10 mg for perfusion of extremities through skin with max of four doses, for biliary ducts 2.5 mg for max of 4 doses, for lymph nodes or lymphatic vessels 1.25 mg dose	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
34.	Salagen	60 (ortho = 70)	This name pair has sufficient orthographic and phonetic differences.
35.	Ser-A-Gen	60 (ortho = 70)	This name pair has sufficient orthographic and phonetic differences.
36.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
37.	Betavent	60	This name pair has sufficient orthographic and phonetic differences.
38.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.
39.	Sutent	58	This name pair has sufficient orthographic and phonetic differences.
40.	Actagen	58	This name pair has sufficient orthographic and phonetic differences.
41.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
42.	Praluent	58	This name pair has sufficient orthographic and phonetic differences.
43.	Pseudovent	58	This name pair has sufficient orthographic and phonetic differences.
44.	Eprident	57	This name pair has sufficient orthographic and phonetic differences.
45.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences.
46.	Secretin-Ferring	56	This name pair has sufficient orthographic and phonetic differences.
47.	Spantuss Hd	56	This name pair has sufficient orthographic and phonetic differences.
48.	Sprintec	56	This name pair has sufficient orthographic and phonetic differences.
49.	(b) (4) ***	56 (phonetic = 70)	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Spy Agent Green **Established name:** indocyanine green **Dosage form:** for injection **Strength(s):** 25 mg/vial **Usual Dose:** of 4 injections1.25 mg – 5 mg for single image, 3.75 mg – 10 mg for perfusion of extremities through skin with max of four doses, for biliary ducts 2.5 mg for max of 4 doses, for lymph nodes or lymphatic vessels 1.25 mg dose	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
50.	Suprefact	56	This name pair has sufficient orthographic and phonetic differences.
51.	Sympazan***	56	This name pair has sufficient orthographic and phonetic differences.
52.	Synagis	56	This name pair has sufficient orthographic and phonetic differences.
53.	Articadent	56	This name pair has sufficient orthographic and phonetic differences.
54.	Baciguent	56	This name pair has sufficient orthographic and phonetic differences.
55.	Bristagen	56	This name pair has sufficient orthographic and phonetic differences.
56.	Estrogenic	56	This name pair has sufficient orthographic and phonetic differences.
57.	Indocyanine green	56	This name pair has sufficient orthographic and phonetic differences. This is the established name for the subject of this review.
58.	K-Vescent	56	This name pair has sufficient orthographic and phonetic differences.
59.	Mustargen	56	This name pair has sufficient orthographic and phonetic differences.
60.	Res-Q-Dent	55	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
61.	Avar-E Green	54 (ortho = 70)

No.	Name	POCA Score (%)
62.	Stiedex	54 (phonetic = 70)
63.	Aspiri -free	54
64.	Depotestogen	54
65.	Epogen/Procrit	54
66.	Gas-X-prevention	54
67.	Pacific Garden	54
68.	Palonosetron	54
69.	Pigment Gel	54
70.	Primestrin	54
71.	Sal-Plant Gel	54
72.	Sangre De Grado	54
73.	Sanomigran	54
74.	Sapropterin	54
75.	Spearmint Extract	54
76.	Vanex Grape	54
77.	Citanest Plain	53
78.	Genetron 12	53
79.	Genprin	53
80.	Salbuvent Rondo	53
81.	Pentacarinat	53
82.	Azo Gantrisin	52
83.	Pangestyme	52 (ortho =75)
84.	(b) (4) ***	52 (ortho = 70)
85.	Beta-Prograne	52
86.	Butesin Picrate	52
87.	Cyclodextrins	52
88.	Dep Gynogen	52
89.	Desenex Cream	52
90.	Diphenhist	52
91.	Duratestrin	52
92.	Dydrogesterone	52
93.	Estragyn La 5	52
94.	Gabapentin	52
95.	Metandren	52
96.	Mylanta Supreme	52
97.	Nitenpyram	52
98.	Penthrane	52
99.	Pitressin Tannate	52
100.	Potassium Estrone	52
101.	Procentra	52

No.	Name	POCA Score (%)
102.	Prodenrx Rinse	52
103.	Progestasert	52
104.	Promestriene	52
105.	Pyrethrins	52
106.	Sandrena	52
107.	Scarlet Red	52
108.	Salzentry	52
109.	Septra Grape	52
110.	Siberian Ginseng Root	52
111.	St. Joseph Aspirin	52
112.	Stainimax Gel	52
113.	Stannous Tartrate	52
114.	Stat Gel Fs Pro	52
115.	Sterapred	52
116.	Streptomycin	52
117.	Strychnine Nitrate	52
118.	Synapryn	52
119.	Tetradecene	52
120.	Therapentin-90	52
121.	Vagistat Cream	52
122.	Biogastrone	51
123.	Systane	51 (ortho = 70)
124.	Coated Aaspirin	51
125.	Deep Androgyn	51
126.	Gestrin	51
127.	Granisetron	51
128.	Ironspan Tablet	51
129.	Persantin Retard	51
130.	Phenetron	51
131.	Psedovent Ped	51
132.	Rastringent Ii	51
133.	Trppisetron	51
134.	Wasp Venom Protein	51
135.	Gentaspray	50 (ortho = 72)
136.	Asparagine	50 (ortho = 70)
137.	Ambrisentan	50
138.	Amnestrgen	50
139.	Aromadendrin	50
140.	Asparagine	50
141.	Aspergum Cherry	50

No.	Name	POCA Score (%)
142.	Aspir-Trin	50
143.	Aspirin Low Strength	50
144.	Aspirin-Antacid	50
145.	Asthmanefrin	50
146.	Astringyn	50
147.	Australian Dream	50
148.	Avar Green	50
149.	Bayer Aspirin	50
150.	Cayenne Extract	50
151.	Cogentin	50
152.	Cosyntrppin	50
153.	Cytadren	50
154.	D-Transallethrine	50
155.	Desogestrel	50
156.	Fast Green Fcf Stain	50
157.	First-Progesterone	50
158.	Flibanserin	50
159.	Gastrotsepin	50
160.	Hesperetin	50
161.	Isentress	50
162.	Isopentane	50
163.	Genotropin	50
164.	Iv Persantine	50
165.	Ketanserin	50
166.	Korean Ginseng Root	50
167.	Magnaprin	50
168.	Maltodextrin	50
169.	Novantrone	50
170.	Ondansetrone	50
171.	Opopanax Resin	50
172.	Pagitane	50
173.	Panheprin	50
174.	Papaya Seed Extract	50
175.	Parepectolin	50
176.	Peginesatide	50
177.	Perestan	50
178.	Pigment Blue 1	50
179.	Pipamperone	50
180.	Piperazine Citrate	50
181.	Potassium Nitrate	50
182.	Preventics Swab	50
183.	Prevident 5000 Plus	50
184.	Pro Vent Plus	50

No.	Name	POCA Score (%)
185.	Pyrantel	50
186.	Pyrilafen Tannate 12	50
187.	Respi-Tann Pd	50
188.	Saffron Extract	50
189.	Salazopyrin En	50
190.	Scandonest Plain	50
191.	Scar Zone Burn	50
192.	Septrin	50
193.	Sesame Extract	50
194.	Silver Nitrate	50
195.	Sitagliptin	50
196.	Snow Pea Extract	50
197.	Soap Sensations	50
198.	Soybean Germ Extract	50
199.	Spacol Tablet	50
200.	Spearmint Oil	50
201.	Spectinomycin	50
202.	Spelt Seed Extract	50
203.	Sprintec	50
204.	Sps Suspension	50
205.	Stearyl Stearate	50
206.	Streptozocin	50
207.	Superdent	50
208.	Surpass Extra Strength	50
209.	Sylatron	50
210.	Systane Nighttime	50
211.	Systane Ultra	50
212.	Tenuate Dospan	50
213.	Tepanil Ten-Tab	50
214.	Tetanus Toxin	50
215.	Trabectedin	50
216.	Triamterene	50
217.	Wheat Dextrin	50
218.	Ysp Aspirin	50
219.	Agenerase	47 (ortho = 70)
220.	Pentasa	46 (ortho = 70)
221.	IC-Green	43

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
222.	Brilliant green	65	This is not a drug, but a color additive
223.	Estrogens	64 (phonetic = 70)	Known as conjugated estrogens. Product discontinued with no generics available.
224.	Asperagenin	63 (ortho = 71)	This name is not a drug, but a biomaker for food product
225.	Saventrine	62	Foreign drug marketed in Hong Kong, South Africa, Greece, Singapore, United Kingdom, and Ireland
226.	Salbuvent	61	Foreign drug marketed in New Zealand, Finland, United Kingdom, Norway, Denmark, and Ireland
227.	Stagesic-10	61	Discontinued product with no available generics
228.	Pigment Brown 1	61	This is not a drug, but a color additive
229.	Pigment Red 1	61	This is not a drug, but a color additive
230.	Pigment Red 48	61	This is not a drug, but a color additive
231.	Pigment Red 5	61	This is not a drug, but a color additive
232.	Pigment Red 7	61	This is not a drug, but a color additive
233.	Topiragen	61	Discontinued name with no available generics per RedBook
234.	S Typhi (Ty-2 Strain)	60	This is not a drug, but a parasite Salmonella Typhi that causes Typhoid Fever
235.	Styramate	60	International drug marketed in South Korea
236.	Propagest	60	Discontinued name with no available generics per RedBook
237.	Stannate	59	This is not a drug, but a a compound formed by reaction of tin oxides (or hydroxides) with alkali
238.	Poly-Vent	59	Discontinued drug with no available generics per RedBook
239.	Respivent-D	59	Discontinued drug with no available generic per RedBook
240.	Gentran 70	58 (ortho = 72)	Discontinued product with no available generics
241.	(b) (4) ***	58 (ortho = 70)	Proposed Proprietary Name was found unacceptable (RCM # (b) (4)) and was withdrawn by Applicant. The Applicant submitted a new name on (b) (4), and was found acceptable on (b) (4)
242.	Segesterone	58	International drug marketed in Brazil
243.	Surgident	58	International drug, marketed in Switzeraland
244.	Pro-Vent	58	Foreign drug marketed in United Kingdom and Ireland
245.	Psorent	58	Discontinued name with no available generics per RedBook
246.	Pentran	56 (ortho = 70)	International drug marketed in United Kingdom

No.	Name	POCA Score (%)	Failure preventions
247.	Sage Extract	56	This is not a drug name, but a plant mostly used as flavoring spices for food
248.	Sepia Extract	56	This is not a drug. It is used in tooth powders & as a polishing agent
249.	Spectogard	56	Veterinary product
250.	Steareth-10	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as a surfactant/emulsifying agent in skin cosmetics
251.	Steareth-100	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as surfactant a in skin cosmetics
252.	Steareth-12	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
253.	Steareth-15	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
254.	Steareth-2	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
255.	Steareth-20	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
256.	Steareth-21	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
257.	Steareth-22	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
258.	Steareth-23	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
259.	Steareth-3	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
260.	Steareth-30	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as an ingredient in skin cosmetics
261.	Steareth-4	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as a surfactant/emulsilfying agent in skin cosmetics
262.	Steareth-7	56	This not a drug, but a polyethylene glycol ether of stearyl alcohol used as a surfactant/emulsilfying agent in skin cosmetics
263.	Stelujan	56	Name entered by Safety Evaluator. Unable to find product characteristics in Agency databases
264.	Strongid T	56	Veterinary product
265.	Malachite green	56	This is not a drug, but used as a green-coloured dye, as a counter-stain in histology, and for its anti-fungal properties in aquaculture.
266.	Myciguent	56	Discontinued name with available generics per RedBook
267.	Mylagen	56	Discontinued name with available generics per RedBook
268.	Pigment Orange 2	56	This is not a drug, but a color additive
269.	Pigment Orange 34	56	This is not a drug, but a color additive

No.	Name	POCA Score (%)	Failure preventions
270.	Teargen	56	Discontinued drug with no available generic per RedBook
271.	Solvent Brown 1	55	This is not a drug, but a synthetic dye/coloring agent used in inks and paints
272.	Solvent Red 27	55	This is not a drug, but a synthetic dye/coloring agent used in inks and paints
273.	Solvent Red 4	55	This is not a drug, but a synthetic dye/coloring agent used in inks and paints
274.	Styrene	55	This is not a drug name, but a synthetic chemical used in the manufacturing of plastics, rubber, and resins
275.	Loperagen	55	Foreign drug marketed in United Kingdom

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[6].

No.	Name	POCA Score (%)
276.	Estragyn 5	67
277.	Estra-Testrin	64
278.	Pegintron	63
279.	Estratest	62
280.	Physiotens	62
281.	Nystamont	60
282.	Cetazone T	58
283.	Dyspamet	58
284.	Estragyn La 5	58
285.	Hsp Anti	58
286.	Prascend	58
287.	Progest	58
288.	Progesterone	58
289.	Antatens	57
290.	Asparaginase	57
291.	Estro-Span C	57
292.	Pyrantel	57
293.	Pytest	57
294.	Alphagan P	56
295.	Asparagine	56
296.	Capzasin-P	56
297.	Citanest	56

[6] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
298.	Cyprodenate	56
299.	Pediatan D	56
300.	Pimavanserin	56
301.	Plantago Seed	56
302.	Respi-Tann G	56
303.	Respi-Tann Pd	56
304.	Tagamet	56
305.	Tagamet 100	56
306.	V Tan Dm Grape	56
307.	Cytamen	55
308.	Espotabs	55
309.	Lipo Gantrisin	55
310.	Netupitant	55
311.	Pangamate	55
312.	Protenate	55

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/s/

CASMIR I OGBONNA
11/15/2018

MISHALE P MISTRY on behalf of HINA S MEHTA
11/15/2018

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	August 7, 2018
Application Type and Number:	NDA 211580
Product Name and Strength:	Spy Agent Green (Indocyanine green) for injection
Total Product Strength:	25 mg/vial
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novadaq Technologies ULC.
Panorama #:	2018-24067287
DMEPA Safety Evaluator:	Idalia E. Rychlik, PharmD.
DMEPA Team Leader:	Hina Mehta, PharmD.
DMEPA Associate Director:	Mishale Mistry, PharmD., MPH

1 INTRODUCTION

This review evaluates the proposed proprietary name Spy Agent Green (Indocyanine green) for NDA 211580, from a misbranding perspective. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 26, 2018.

- Intended Pronunciation: [spahy] [ey-juh nt] [green]
- Active Ingredient: Indocyanine green
- Indication of Use:
    - Fluorescence imaging of blood flow and tissue perfusion during: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgeries, including general minimally invasive surgical procedures. (b) (4)
    - Fluorescence imaging of lymph nodes and delineation of lymphatic vessels in the cervix and uterus during lymphatic mapping in patients with solid tumors for which this procedure is a component of intraoperative management. (b) (4)
- Route of Administration: Intravenous, Interstitial
- Dosage Form: Powder for reconstitution
- Strength: 25 mg/vial
- Dose and Frequency:
    - Assessment of Blood Flow and Tissue Perfusion: The recommended dose for a single image sequence is 1.25 mg – 5 mg Spy AGENT Green (b) (4) For visualization of perfusion in extremities through the skin, the recommended dose is 3.75 - 10 mg (b) (4) (b) (4)
    - Imaging Extrahepatic Biliary Ducts: The recommended dose (b) (4)
    - Imaging of Lymph Nodes and Lymphatic Vessels During Lymphatic Mapping: The recommended dose is four 1.25 mg injections for a total dose of 5 mg.

- How Supplied: Spy AGENT™ Green (Indocyanine Green) is supplie [redacted]

  Spy Elite Kit containing [redacted] 25 mg Spy AGENT Green (Indocyanine Green) vial, one 10 mL Sterile Water for Injection, USP plastic vial, one sterile drape, [redacted]

  PINPOINT® Kit [redacted] one 25 mg Spy AGENT Green (Indocyanine Green) vial, one 10 mL Sterile Water for Injection, USP plastic vial, two x 3 ml syringes (sterile), 2 x 10 ml syringes (sterile), one 3-way stopcock (sterile), two 18G, 1 inch needles (sterile), [redacted]

  PINPOINT Lymphatics [redacted] Kit [redacted] one 25 mg Spy AGENT Green (Indocyanine Green for Injection, USP) vial, two 10 mL Sterile Water for Injection, USP plastic vials, [redacted] x 10 ml syringes (sterile), [redacted] luer-lock 10 ml syringes with controlled handle (sterile), four spinal needles 22G, 3.5 inch (sterile), [redacted]

- Storage: 20°C to 25°C (68°F to 77°F)

2 DISCUSSION

During the initial steps of the proprietary name review process, the Office of Prescription Drug Promotion (OPDP) did not recommend the use of the proposed proprietary name, Spy Agent Green, because it would misbrand the proposed product. OPDP provided the following statement:

OPDP objects to the proposed proprietary name, "SPY AGENT GREEN," because, as proposed, it is overly fanciful. As noted in your "REQUEST FOR PROPRIETARY NAME REVIEW" dated June 22, 2018 at page 2 of 10, indocyanine green "is a water soluble, tricarbocyanine dye that is commonly used as an intravascular imaging agent. ICG has a well-established safety profile, and it has been marketed in the United States (US) for almost 60 years." Thus, indocyanine green is a common substance, for which the limitations are readily recognized when "SPY AGENT GREEN" is listed by its established name [21 CFR 201.10(c)(3)]. The proposed proprietary name includes "SPY," which can be defined as "to search or look for intensively" (https://www.merriam-webster.com/dictionary/spy; accessed July 20, 2018), and "AGENT," which can be defined as "one that acts or exerts power" (https://www.merriam-webster.com/dictionary/agent; accessed July 20, 2018). The combination of terms creating the phrase "SPY AGENT" evokes the world of espionage, intrigue, stealth, and specialized skill to uncover secrets, as made popular by numerous fictional spy agents who have graced the covers of books and the scenes of movies for decades. Thus, the use of this phrase for a prescription drug product suggests it has the ability to silently and without notice display a specialized, intensive power to image, which would imply unique effectiveness or composition over other drugs with similar active ingredients. Given the imagery evoked by this name as described above, the proposed proprietary name "SPY AGENT GREEN" is overly fanciful and would therefore be misleading.

This concern was shared with the Division of Medical Imaging Products (DMIP). In email correspondence dated August 8, 2018, DMIP concurred with OPDP's assessment. DMEPA also concurs with this finding and will not perform a safety assessment of the proposed proprietary name.

3 CONCLUSION AND RECOMMENDATIONS

The proposed proprietary name, Spy Agent Green is unacceptable as it would misbrand the proposed product. Novadaq Technologies will be notified of FDA's decision to object to the name via letter.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Spy Agent Green, and have concluded that this name is unacceptable for the following reason:

We object to the proposed proprietary name, "SPY AGENT GREEN," because, as proposed, it is overly fanciful. As noted in your "REQUEST FOR PROPRIETARY NAME REVIEW" dated June 22, 2018 at page 2 of 10, indocyanine green "is a water soluble, tricarbocyanine dye that is commonly used as an intravascular imaging agent. ICG has a well-established safety profile, and it has been marketed in the United States (US) for almost 60 years." Thus, indocyanine green is a common substance, for which the limitations are readily recognized when "SPY AGENT GREEN" is listed by its established name [21 CFR 201.10(c)(3)]. The proposed proprietary name includes "SPY," which can be defined as "to search or look for intensively" (https://www.merriam-webster.com/dictionary/spy; accessed July 20, 2018), and "AGENT," which can be defined as "one that acts or exerts power" (https://www.merriam-webster.com/dictionary/agent; accessed July 20, 2018). The combination of terms creating the phrase "SPY AGENT" evokes the world of espionage, intrigue, stealth, and specialized skill to uncover secrets, as made popular by numerous fictional spy agents who have graced the covers of books and the scenes of movies for decades. Thus, the use of this phrase for a prescription drug product suggests it has the ability to silently and without notice display a specialized, intensive power to image, which would imply unique effectiveness or composition over other drugs with similar active ingredients. Given the imagery evoked by this name as described above, the proposed proprietary name "SPY AGENT GREEN" is overly fanciful and would therefore be misleading.

Please note that the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). The FD&C Act also provides that a drug is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading, such as by making misrepresentations with respect to safety or efficacy.

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/s/

IDALIA E RYCHLIK
08/07/2018

MISHALE P MISTRY on behalf of HINA S MEHTA
08/07/2018

MISHALE P MISTRY
08/07/2018