Kyoku for Men™ - Claim Substantiation for DR-TV Campaign

SUMMARY: This document summarizes all claims made by Kyoku for Men™, which is a registered trademark of Kyoku Inc. (DBA: Kyoku Holdings LLC) located at 584 Broadway – Suite 506, New York, NY 10012, USA whose products are manufactured by RNA Corporation, an FDA approved & GMP (Good Manufacturing Practice) certified manufacturing facility located at 13570 Chatham Street, Blue Island, IL 60406, USA.

ABOUT KYOKU FOR MEN™

Kyoku for Men™ is the brand name under which Kyoku Inc. sells OTC acne & cosmetic products designed specifically for men's skin. These products are designed to help men cosmetically improve the appearance of their skin as well as help get rid of acne blemishes, blackheads, whiteheads, and protect against UV damage from the sun.

FDA COMPLIANCE

In particular, 2 products of Kyoku for Men™ are regulated FDA OTC (Over The Counter) drugs approved for Human Use:

- SKN-WS 333: Daily Facial Cleanser
    - Contains 0.5% Salicylic Acid (Acne Medication)
- SKN-FC 901: Facial Moisturizer (SPF 15)
    - Contains Ethylhexyl Methoxycinnamate 7.5%, (Sunscreen), Octocrylene 5.0% (Sunscreen), and Butyl Methoxydibenzoylmethane 2.5% (Sunscreen)

Both products labeling follows the FDA Final Monograph for Topical Anti-Microbial Drug Products for Over-the-Counter Human Use **21 CFR part 333 subpart D** & the FDA Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use **21 CFR part 352**. The product labels are attached in *Appendix 1 & Appendix 2* for reference & the appropriate monograph sections are attached in *Appendix 3 & Appendix 4*.

ABOUT DR. ASIM M. AKHTAR

Dr. Asim Munir Akhtar is a medical sciences researcher, not a licensed medical professional, and holds a PhD (also known as a Doctor of Philosophy or "DPhil") from the University of Oxford located in Oxford, United Kingdom. Dr. Akhtar began his PhD studies immediately following graduation from the University of Illinois (Urbana, Champaign) in July of 2007. He completed his PhD studies at the University of Oxford by submitting his thesis, entitled "Molecular Magnetic Resonance Imaging of Vascular Inflammation using Microparticles of Iron Oxide" in 2010, which was met with critical acclaim from the University of Oxford for it's insights into vascular inflammation in disease states such as Ischemia Reperfusion Injury, Atherosclerosis, and Multiple Sclerosis. Dr. Akhtar was awarded his doctorate by the Medical

Sciences Division – Cardiovascular Medicine at the University of Oxford – Hertford College in the Michelmas term of 2010.

Dr. Akhtar's qualifications & thesis are available for public viewing via the following hyperlink: http://ora.ox.ac.uk/objects/uuid:12bf8e4f-2909-4715-a6fe-bf42d9d8355a and his CV is attached in *Appendix 5.*

In addition to being awarded the distinguished degree of "Doctor of Philosophy" by the Medical Sciences Division at the University of Oxford, Dr. Akhtar has published several peer-reviewed research articles within the field of vascular inflammation, as follows:

- ***Akhtar AM**, Schneider JE, Chapman SJ, Jefferson A, Digby JE, et al. (2010) In Vivo Quantification of VCAM-1 Expression in Renal Ischemia Reperfusion Injury Using Non-Invasive Magnetic Resonance Molecular Imaging. PLoS ONE **5**(9): e12800. doi:10.1371/journal.pone.0012800*

- *McAteer MA, **Akhtar AM**, Von Zur Muhlen C, Choudhury RP. (2009) An Approach to Molecular Imaging of Atherosclerosis, Thrombosis, and Vascular Inflammation Using Microparticles of Iron Oxide. Atherosclerosis **209**(1): 18-27.*

- *Hoyte LC, Brooks KJ, Nagel S, **Akhtar AM**, Chen R, et al. (2010) Molecular Magnetic Resonance Imaging of Acute Vascular Cell Adhesion Molecule-1 Expression in a Mouse Model of Cerebral Ischemia. J Cereb Blood Flow Metab **30**(6): 1178-87*

- ***Akhtar AM**, Chen Y, Schneider JE, Digby JM, McAteer MA, Wood KJ, Choudhury RP. Magnetic Resonance Imaging of Renal Ischemia Reperfusion Injury using Microparticles of Iron-Oxide targeting VCAM-1. American Heart Association 2008, New Orleans (oral presentation)*

- ***Akhtar AM**, Schneider JE, McAteer MA, Chapman SJ, Barnes H, Digby JM, Wood KJ, Choudhury RP. In-Vivo Magnetic Resonance Imaging of Renal Ischemia Reperfusion Injury using Microparticles of Iron-Oxide targeting VCAM-1. British Cardiovascular Society 2009, London (oral presentation)*

It should be duly understood that while Dr. Akhtar does possess an expertise in the field of vascular inflammation & disease states, he is not a licensed medical professional nor does he claim to be and his advice should not be taken as a substitute for professional advice or recommendations from a licensed doctor or dermatologist.

IMPORTANT LEGAL DISCLAIMER FOR TESTIMONIALS, RISK, AND TYPICAL RESULTS FOR CUSTOMERS

As with any treatment program, you assume certain risks to your health and safety by using Kyoku for Men™ products. Any form of acne treatment carries risks if used incorrectly, and Kyoku for Men™ is no exception. It is possible that you may make

your acne worse if instructions are not followed correctly or you overuse products in an attempt to make them work quicker or more effectively. Although thorough instruction is included with each product, realize that Kyoku for Men™ does involve some risk of a negative reaction to your skin. Kyoku for Men™ offers a 100% money-back guarantee — you can return the products for any reason if you are not satisfied with the results. However, we cannot guarantee your specific results in getting clear skin. It is possible that you will not see any results with these products – everybody's skin and body is in fact different. Unique genetic and/or hereditary factors may play a role in your treatment. It is also possible that your acne may get worse. The stories and testimonials of the clients you see on this page are real and were taken from e-mails we receive to our customer service e-mail address. However, it must be disclaimed that these testimonials are not claimed to represent typical results with the products. They are meant as a showcase of what the most motivated and dedicated clients can do with these products. Your results may vary, and you may not get the same results when using the products due to differences in your individual history, genetics, and personal motivation. Dr. Asim Akhtar is not a medical doctor or dermatologist; however, he does hold a PhD from the University of Oxford in Clinical Medicine & Research, specifically in the field of vascular inflammation. His advice is not meant as a substitute for medical advice. Please consult your doctor before beginning use of this product if necessary and do consult a dermatologist if you have any negative reactions or your acne becomes worse. Results will vary, and you should not use this information as a substitute for help from a licensed professional.

HOW IS KYOKU FOR MEN™ SCIENTIFICALLY DESIGNED TO HELP ELIMINATE ACNE IN MEN'S SKIN?

Acne Vulgaris is a disorder of the pilosebaceous unit. The pathogenic factors of acne are, as follows: increased sebum secretion, follicular epidermal hypercornification, Propionibacterium acnes colonization and inflammation, which leads to a lowered oxygen environment where P. Acnes bacteria can colonize in the skin, leading to acne lesions. This is the clinically accepted pathogenesis of acne vulgaris[1]

In a double blind, peer reviewed clinical trial involving 914 acne patients (278 male and 636 female), male acne patients were found to have more inflammatory acne lesions as well as more acne lesions on their entire face than women. The proportion of inflammatory lesions over the total number of acne lesions was higher in male patients than in female patients. Similarly, sebum levels on the forehead were higher in male patients. In male acne patients, the sebum of the T-zone showed positive correlation with both the number of inflammatory lesions and the proportion of inflammatory lesions over the total number of acne lesions. All findings were statistically significant. With regard to sexual differences, male acne patients had more inflammatory lesions. Male acne patients also showed higher proportions of the inflammatory lesions.[2]

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[1] Shaheen, B., Gonzalez, M. (2012). "Acne sans *P. acnes*." JEADV. **27**: 1-10.

[2] Choi., C.W., Choi., J.W., et al. (2011). "Facial Sebum affects the development of acne, especially the distribution of

[2] Choi., C.W., Choi., J.W., et al. (2011). "Facial Sebum affects the development of acne, especially the distribution of
inflammatory acne." JEADV. **27**: 301-306

These results are in agreement with several other studies on the topic that have concluded that male patients experience more severe, longer lasting acne than their female counterparts due to inherent increased androgen / testosterone production and increased sebum (oil) levels on the skin. Therefore, one may surmise that inflammation and excessive oil production on the skin is higher in male patients, resulting in significantly greater acne lesions as well as acne severity.[3,4,5]

In another double-blind, peer reviewed clinical trial involving 242 acne patients and 188 control patients, researchers discovered that higher testosterone in men is a significant risk factor in the occurrence of adolescent acne. A higher 17-OHP level aggravates the severity of male adolescent acne, while a higher estradiol level protects females against the onset of adolescent acne. All findings were statistically significant.[6]

Therefore, Kyoku for Men™ has used this research to create products for men's unique skincare needs & acne profile. From data, we can see that reducing inflammation & oily skin is key to the reducing of acne in men. As it's main acne fighting ingredient, Kyoku for Men's™ product **SKN-WS 333: Daily Facial Cleanser** contains 0.5% Salicylic Acid, which is an FDA-approved OTC drug approved for human use to treat acne. Salicylic acid is the primary ingredient in aspirin; therefore, it is highly effective at reducing inflammation and treating acne by penetrating the follicle. It encourages the shedding of dead skin cells from within the follicle, helping keep the pores clear of cellular debris. This is how Kyoku for Men™ 'penetrates men's skin to help treat acne at its source,' which the aforementioned research has shown is inflammation within the sebaceous glands. In this way, it reduces the number of pore blockages and breakouts on the skin. Therefore, Kyoku for Men™ sells this product primarily for men to reduce inflammation and treat their acne and includes it in every single acne treatment kit that it makes.

Our acne treatment kits also contain other, complimentary products that aid in the effectiveness of the main OTC acne treatment product, which is the Daily Facial Cleanser. The reason we have designed it this way is due to low acne patient adherence from irritation common in OTC acne treatments. Dryness or skin irritation may cause barrier disruption of the stratum corneum leading to increased transepidermal water loss (TEWL) and production of inflammation. Physicians recommend patients use moisturizers as adjunctive treatment of acne, especially when topical benzoyl peroxide, a topical retinoid, or salicylic acid is used.[7] Moisturizers contain three main properties, which are occlusive, humectant, and emollient effects (Janamontri et al.). In Kyoku for Men's™ **SKN-FC 901: Facial Moisturizer (SPF 15)**, we have included 'Soline,' (INCI: Sunflower Oil Unsaponifiables) which is a cosmetic ingredient containing 90% unsaturated fatty acids (including 20% oleic acid and 60% linoleic aci) and 1% natural Vitamin E that aids in the reduction of TEWL

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[3] Adityan B., Thappa D.M. (2009). "Profile of acne vulgaris – a hospital-based study from South India. Indian J Dermatol Venereol, **75**: 272-278

[4] Amado J.M., Matos M.E., Abreu A.M. et al. (2006). "The prevelance of acne in the north of Portugal." J Eur Acad Dermatol Venereol. **20**: 1287-1295

[5] Kilkenny M., Merlin K., Plunkett A., et al. (1998). " The prevalence of common skin conditions in Australian school students: 3. Acne vulgaris." Br J Dermatol. **139**: 840-845.

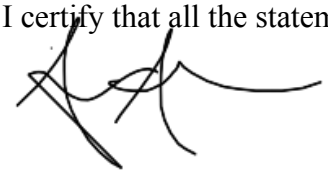
[6] Wei, B., Qu L., Zhu H., et al. (2014). "Higher 17-alpha-Hydroxoyprogesterone levels aggravated the severity of male adolescent acne in northeast China." Dermatology. **1018-8665**: 1-4.

[7] Chularojanamontri. L., Tuchinda., P., Kulthanan., K. et al. (2014). "Moisturizers for acne: what are their constituents?" J Clin Aesthet Dermatol. **7**(5): 36-44.

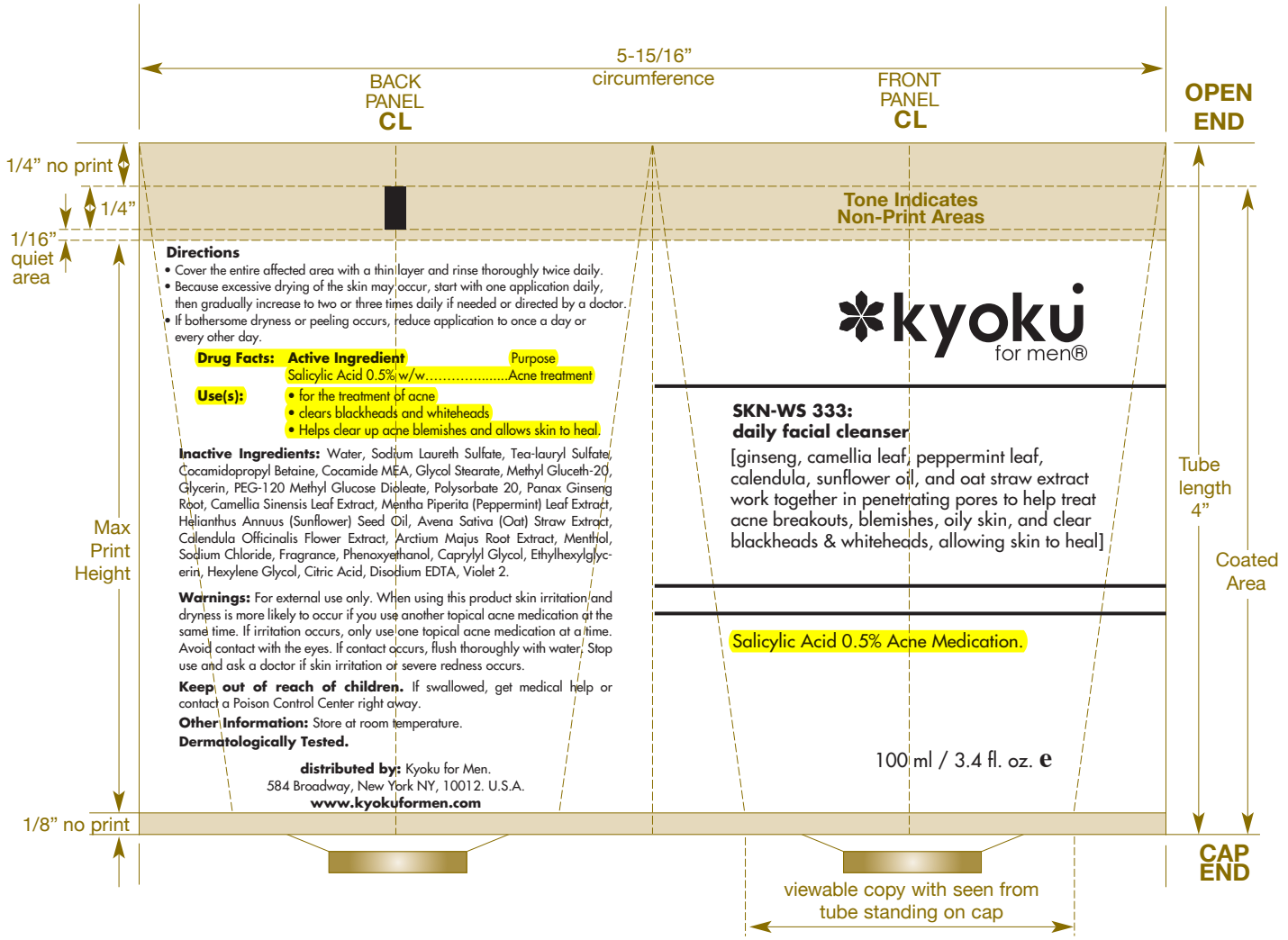
and ‘soothes’ the skin. Our Facial Moisturizer SPF 15 is an OTC drug in it’s own right as a sunscreen. We had done this to protect the skin against mild sunburn, which often leads to inflammation and helps neutralize it. Similarly, our Facial Moisturizer contains Green Tea Leaf & Aloe Vera, which are herbal (non-medicated) oil-soluble anti-inflammatories. Furthermore, our Facial Moisturizer contains Advanced Delivery Technology, which we have called our ‘Microparticle Technology’ we acquired from Barnet Products Corporation called ‘Lecinol S-10.’ Lecinol S-10 is a hydrogenated phospholipid that can be used to create encapsulation or Liposomes of water-soluble or oil-soluble actives. This aids in the penetration of oil-soluble anti-inflammatories into the skin. Since men’s skin is thicker than women’s skin, we used this technology to help the anti-inflammatories absorb into the skin. The data for this ingredient is included in *Appendix 6*. This product is not meant to be an OTC Acne Treatment; however, it is sold in combination with our Daily Facial Cleanser as a cosmetic product to help skin recover from the drying effects of Salicylic Acid. We do not wish nor have we intended for this product to be any sort of NDA (New Drug Application) and all claims for this particular product are cosmetic and it is meant to be used alongside our Daily Facial Cleanser as combination therapy and help protect the skin against UV damage, which can in some cases lead to inflammation that is associated with acne.

Lastly, our kits also contain another cosmetic product **SKN-MSQ 273: Lava Masque**. This is a purely cosmetic product that contains several natural ingredients to help purify pores and detoxify skin through the use of a mineral-rich mud mask. This product is mean to be used as combination therapy alongside the Daily Facial Cleanser to help the appearance of the skin without further irritating it or causing additional inflammation, which can lead to even more acne. This product contains Phyko-AC, a complex of oligosachharide (OGS) or marine origin and zinc (INCI name: Water & Hydrolized Algin & Zinc sulfate). Phyko-AC has been shown in studies sponsored by Barnet Corporation to reduce skin sebum levels (Data in *Appendix 7*). Also, this masque contains Atoligomer, a balanced cocktail of micro and macro minerals, which increases strength of the epidermis as per ex-vivo tests sponsored by Barnet Corporation (Data in *Appendix 8*). Finally, this product contains Volcanic Black Sand, which is a natural exfoliants that allows the removal of dead skin cells, oil, and ‘toxins’ to help improve overall appearance of the skin. This product is not meant to be an OTC Acne Treatment; however, it is sold in combination with our Daily Facial Cleanser as a cosmetic product to help skin recover from the drying effects of Salicylic Acid. We do not wish nor have we intended for this product to be any sort of NDA (New Drug Application) and all claims for this particular product are cosmetic. It is meant to be used alongside our Daily Facial Cleanser as combination therapy to help cosmetically improve the appearance of the skin.

I certify that all the statements made above are true to the best of my knowledge,



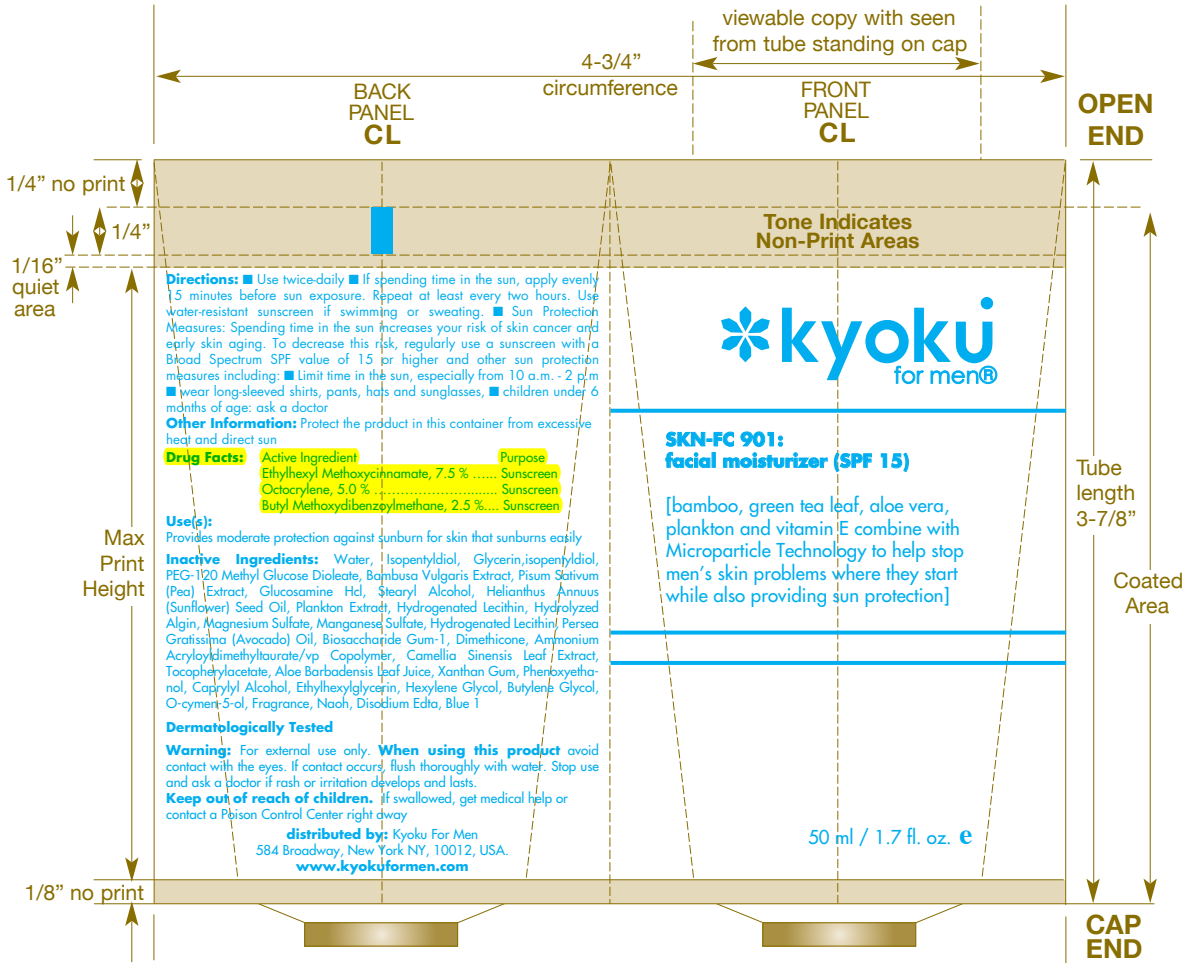
Dr. Asim M. Akhtar, PhD
Founder & CEO – Kyoku, Inc.



JOB TITLE:	**RNA CORPORATION** 3.4oz Daily Facial Cleanser		PART NO. kyoku-TB-WS333 (ART REV 11-14)	NO. OF COLORS: 1	NO. OF PLATES: 1	DATES: Dec. 2, 2014
PLATE NUMBER:	**19976-01** A		PRINT COLORS: A-Black silkscreen B- C- D- E- F-			TUBE COLORS: A98 WHITE
TUBE SIZE:	2" x 4"	REPEAT: 5-15/16" / REVISION: 0				JSN PACKAGING PRODUCTS

Please review this Proof carefully for proper placement, punctuation, and color separation. Please note this Proof is used to verify the location of each print color, with each print color indicated in the info block to confirm the actual print color. Changes can easily be made at the pre-approval stage, but once this proof is approved, artwork changes will result in additional artwork charges and possible production liability at the customer's expense. Once this Proof is approved, JSN will proceed directly to plates and production.

Signature_____Date _____



JOB TITLE: **RNA CORPORATION** 1.7oz Facial Moisturizer SPF 15			PART NO. kyoku-TB-FC901 (Art Rev 11-14)	NO. OF COLORS: 1	NO. OF PLATES: 1	DATES: Dec. 2, 2014
PLATE NUMBER: **19977-01** A			PRINT COLORS:			TUBE COLORS: BLACK
TUBE SIZE: 1-1/2" x 3-7/8"	REPEAT: 4-3/4"	REVISION: 0	A-White silkscreen	D-		JSN PACKAGING PRODUCTS
			B-	E-		
			C-	F-		

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Signature_____Date _____

subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.303 Definitions.

As used in this subpart:

(a) *Acne.* A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes.

(b) *Acne blemish.* A flaw in the skin resulting from acne.

(c) *Acne drug product.* A drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads.

(d) *Acne pimple.* A small, prominent, inflamed elevation of the skin resulting from acne.

(e) *Blackhead.* A condition of the skin that occurs in acne and is characterized by a black tip.

(f) *Whitehead.* A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin.

§ 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following when labeled according to § 333.350.

(a) Resorcinol 2 percent when combined in accordance with § 333.320(a).

(b) Resorcinol monoacetate 3 percent when combined in accordance with § 333.320(b).

(c) Salicylic acid 0.5 to 2 percent.

(d) Sulfur 3 to 10 percent.

(e) Sulfur 3 to 8 percent when combined in accordance with § 333.320.

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(a) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

(b) Resorcinol monoacetate identified in § 333.310(b) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350

§ 333.350 Labeling of acne drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "acne medication," "acne treatment," "acne medication" (insert dosage form, e.g., "cream," "gel," "lotion," or "ointment"), or "acne treatment" (insert dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(b) *Indications.* The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section and may contain any of the additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the" (select one of the following: "management" or "treatment") "of acne."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any one or more of the following statements:

(i) (Select one of the following: "Clears," "Clears up," "Clears up most," "Dries," "Dries up," "Dries and clears," "Helps clear," "Helps clear up," "Reduces the number of," or "Reduces the severity of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "and allows skin to heal."

(ii) "Penetrates pores to" (select one of the following: "eliminate most," "control," "clear most," or "reduce the number of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iii) "Helps keep skin clear of new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iv) "Helps prevent new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "from forming."

(v) "Helps prevent the development of new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 333.310.* (i) "For external use only."

(ii) "Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor."

(2) *For products containing sulfur identified in §§ 333.310 (d) and (e).* "Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor."

(3) *For products containing any combination identified in § 333.320.* "Apply to affected areas only. Do not use on broken skin or apply to large areas of the body."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) "Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to *once* a day or every other day."

(2) The directions described in paragraph (d)(1) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks, may be applied and removed and should have appropriate directions.

(3) *Optional directions.* In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: "*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated: (select one of the following: 'elsewhere on this label,' 'above,' or 'below.')"

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

Dated: June 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-19304 Filed 8-15-91; 8:45 am]

BILLING CODE 4160-01-M

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 5]
[Revised as of April 1, 2014]
[CITE: 21CFR352.10]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER D--DRUGS FOR HUMAN USE

PART 352 -- SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE [STAYED INDEFINITELY]

Subpart B--Active Ingredients

Sec. 352.10 Sunscreen active ingredients.

The active ingredient of the product consists of any of the following, within the concentration specified for each ingredient, and the finished product provides a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part:

(a) Aminobenzoic acid (PABA) up to 15 percent.

(b) Avobenzone up to 3 percent.

(c) Cinoxate up to 3 percent.

(d) [Reserved]

(e) Dioxybenzone up to 3 percent.

(f) Homosalate up to 15 percent.

(g) [Reserved]

(h) Menthyl anthranilate up to 5 percent.

(i) Octocrylene up to 10 percent.

(j) Octyl methoxycinnamate up to 7.5 percent.

(k) Octyl salicylate up to 5 percent.

(l) Oxybenzone up to 6 percent.

(m) Padimate O up to 8 percent.

(n) Phenylbenzimidazole sulfonic acid up to 4 percent.

(o) Sulisobenzone up to 10 percent.

(p) Titanium dioxide up to 25 percent.

(q) Trolamine salicylate up to 12 percent.

(r) Zinc oxide up to 25 percent.

[64 FR 27687, May 21, 1999] Effective Date Note:

At 67 FR 41823, June 20, 2002, § 352.10 was amended by revising paragraphs (f) through (n), effective Sept. 1, 2002. This amendment could not be incorporated because at 66 FR 67485, Dec. 31, 2001 the

effective date was stayed until further notice. For the convenience of the user, the revised text is set forth as follows:

(f) Ensulizole up to 4 percent.

(g) Homosalate up to 15 percent.

(h) [Reserved]

(i) Meradimate up to 5 percent.

(j) Octinoxate up to 7.5 percent.

(k) Octisalate up to 5 percent.

(l) Octocrylene up to 10 percent.

(m) Oxybenzone up to 6 percent.

(n) Padimate O up to 8 percent.

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Page Last Updated: 09/01/2014

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Asim Akhtar

Founder & CEO - Kyoku Holdings LLC

akhtar.asim@gmail.com

Summary

Currently, I'm the CEO & President of Kyoku for Men. I have a history in medical research, personal care product manufacturing, applied laboratory science, and direct marketing. I'm a passionate entrepreneur with a thirst for knowledge, thinking outside the box, meeting great people, building teams, innovating in the marketplace, never ending growth, and working with the people in our company so we all achieve our individual and collective goals.

Experience

Founder & CEO at Kyoku Holdings LLC

August 2010 - Present (4 years 5 months)

Started in 2010 by Dr. Asim Akhtar, Kyoku for Men is a men's grooming & acne treatment brand that encompasses a variety of skincare products that help young men eliminate acne, breakouts, and oily skin that seem to come up especially during a specific time in a young man's life. There are no other brands in the market today that address men's acne in quite the way Kyoku for Men does – we literally invented the 'male acne' category. Here at Kyoku, we take skincare, acne, and our customer's results very seriously – in fact, it's all that we do. We want to make sure very single one of our clients goes on to become the best man he can be, from the inside out. Kyoku for Men has been featured in over 300+ pieces of press including GQ, Esquire, Men's Health and has won several industry awards including 'Best Face Wash' by Men's Health in 2012 and 'Best in Shaving' by GQ in 2011, to name a few. Kyoku products sell in 18 different countries in over 500 retail locations, including Barney's, Macy's, Boots UK, Shoppers Drug Mart Canada, and Douglas Pharmacies in Europe, to name a few. It's been quite the journey and we hope to help even more men eliminate their acne and become the men they have always wanted to be in the future.

Partner at RNA Corporation

January 2003 - Present (12 years)

RNA Corporation, based out of Blue Island, IL is involved in the business of private label manufacturing of consumer goods, namely haircare and skincare.

1 recommendation available upon request

Publications

In Vivo Quantification of Vcam-1 Expression in Renal Ischemia Reperfusion Injury Using Non-Invasive Magnetic Resonance Molecular Imaging

PLOS One September 21, 2010

Authors: Asim Akhtar

Vascular cell adhesion molecule-1 (VCAM-1) is upregulated in ischemia reperfusion injury (IRI), persisting after restoration of blood flow. We hypothesized that microparticles of iron oxide targeting VCAM-1 (VCAM-MPIO) would depict “ischemic memory” and enable in vivo assessment of VCAM-1 expression.

An approach to molecular imaging of atherosclerosis, thrombosis, and vascular inflammation using microparticles of iron oxide.

Atherosclerosis March 2010

Authors: Asim Akhtar

The rapidly evolving field of molecular imaging promises important advances in the diagnosis, characterization and pharmacological treatment of vascular disease. Magnetic resonance imaging (MRI) provides a modality that is well suited to vascular imaging as it can provide anatomical, structural and functional data on the arterial wall. Its capabilities are further enhanced by the use of a range of increasingly sophisticated contrast agents that target specific molecules, cells and biological processes. This article will discuss one such approach, using microparticles of iron oxide (MPIO). MPIO have been shown to create highly conspicuous contrast effects on T2*-weighted MR images. We have developed a range of novel ligand-conjugated MPIO for molecular MRI of endothelial adhesion molecules, such as vascular cell adhesion molecule-1 (VCAM-1) and P-selectin expressed in vascular inflammation, as well as activated platelet thrombosis. This review discusses the application of ligand-targeted MPIO for in vivo molecular MRI in a diverse range of vascular disease models including acute vascular inflammation, atherosclerosis, thrombosis, ischemia-reperfusion injury and ischemic stroke. The exceptionally conspicuous contrast effects of ligand-conjugated MPIO provide a versatile and sensitive tool for quantitative vascular molecular imaging that could refine diagnosis and measure response to treatment. The potential for clinical translation of this new class of molecular contrast agent for clinical imaging of vascular syndromes is discussed.

CCR2-mediated antiinflammatory effects of endothelial tetrahydrobiopterin inhibit vascular injury-induced accelerated atherosclerosis.

Circulation September 30, 2008

Authors: Asim Akhtar

Vascular injury results in loss of endothelial nitric oxide (NO), production of reactive oxygen species (ROS), and the initiation of an inflammatory response. Both NO and ROS modulate inflammation through redox-sensitive pathways. Tetrahydrobiopterin (BH4) is an essential cofactor for endothelial nitric oxide synthase (eNOS) that regulates enzymatic synthesis of either nitric oxide or ROS. We hypothesized that endothelial BH4 is an important regulator of inflammation and vascular remodeling.

VCAM-1-targeted magnetic resonance imaging reveals subclinical disease in a mouse model of multiple sclerosis

Journal for the Federation of American Societies for Experimental Biology September 9, 2011

Authors: Asim Akhtar

Diagnosis of multiple sclerosis (MS) currently requires lesion identification by gadolinium (Gd)-enhanced or T2-weighted magnetic resonance imaging (MRI). However, these methods only identify late-stage pathology associated with blood-brain barrier breakdown. There is a growing belief that more widespread, but currently

undetectable, pathology is present in the MS brain. We have previously demonstrated that an anti-VCAM-1 antibody conjugated to microparticles of iron oxide (VCAM-MPIO) enables in vivo detection of VCAM-1 by MRI. Here, in an experimental autoimmune encephalomyelitis (EAE) mouse model of MS, we have shown that presymptomatic lesions can be quantified using VCAM-MPIO when they are undetectable by Gd-enhancing MRI. Moreover, in symptomatic animals VCAM-MPIO binding was present in all regions showing Gd-DTPA enhancement and also in areas of no Gd-DTPA enhancement, which were confirmed histologically to be regions of leukocyte infiltration. VCAM-MPIO binding correlated significantly with increasing disability. Negligible MPIO-induced contrast was found in either EAE animals injected with an equivalent nontargeted contrast agent (IgG-MPIO) or in control animals injected with the VCAM-MPIO. These findings describe a highly sensitive molecular imaging tool that may enable detection of currently invisible pathology in MS, thus accelerating diagnosis, guiding treatment, and enabling quantitative disease assessment.—Serres, S., Mardiguian, S., Campbell, S. J., McAteer, M. A., Akhtar, A., Krapitchev, A., Choudhury, R. P., Anthony, D. C., Sibson, N. R. VCAM-1-targeted magnetic resonance imaging reveals subclinical disease in a mouse model of multiple sclerosis.

Skills & Expertise

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Social Media Marketing
Strategic Planning

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Thesis

Reference: **Asim M. Akhtar, (2010). Molecular magnetic resonance imaging of vascular inflammation using microparticles of iron oxide. DPhil. University of Oxford.**

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Title: Molecular magnetic resonance imaging of vascular inflammation using microparticles of iron oxide

Abstract:
One approach that has demonstrated success in the field of molecular imaging utilizes microparticles of iron oxide (MPIO) conjugated to specific antibodies and/or peptides to provide contrast effects on MRI in relation to the molecular expression of a specified target. The experimental aims of this thesis were 1) to investigate the ability of VCAM-1 and P-selectin targeted MPIO to detect the expression of VCAM-1 and P-selectin on the activated endothelium in-vitro and in-vivo in mouse models of renal and cerebral ischemia reperfusion injury, and 2) develop a novel contrast agent for imaging αvβ3-integrin expression in angiogenesis using

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