

STATE OF FLORIDA  
BOARD OF MEDICINE

Final Order No. DOH-15-0854-**DS** -MQA

FILED DATE JUN 15 2015  
Department of Health

By: *Carol Sudeus*  
Deputy Agency Clerk

IN RE: PETITION FOR DECLARATORY  
STATEMENT OF LAWRENCE S. HALPERIN, M.D.  
AND COVALENT MEDICAL, LLC.

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**FINAL ORDER ON PETITIONS FOR DECLARATORY STATEMENT**

This matter came before the Board of Medicine (hereinafter the "Board") on April 10, 2015, in Deerfield Beach, Florida, for consideration of the *Petition for Declaratory Statement Lawrence S. Halperin, M.D. and Covalent Medical, LLC* (attached hereto as exhibit A). The Notice of Petition for Declaratory Statement was published on August 29, 2014, in Volume 40, No. 169, in the Florida Administrative Register.

The Petition filed by Dr. Halperin and Covalent Medical, LLC, (hereinafter the "Petitioners" or "Covalent") inquires as to whether Dr. Halperin and other Florida physician members of Covalent Medical LLC may recommend and sell "Focus" vitamins and supplements to patients from their Florida medical offices without running afoul of the Patient Self-Referral Act of 1992.<sup>1</sup>

**FINDINGS OF FACTS**

The facts set forth in the Petition (exhibit A) and attachments are hereby adopted and incorporated herein by reference as the findings of fact by the Board.

**CONCLUSIONS OF LAW**

1. The Board of Medicine has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

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<sup>1</sup> Section 456.053, Florida Statutes (2014).

2. The Petition filed in this cause is in substantial compliance with the provisions of 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code.

3. For purposes of determining standing in this matter, the Petitioners, allopathic physicians licensed pursuant to Chapter 458, Florida Statutes, are substantially affected persons due to the fact that their failure to comply with Section 456.053, Florida Statutes, may result in disciplinary action by the Board.

4. As set forth in their Petition, Dr. Halperin and other member physicians of Covalent intend to recommend and sell "Focus" vitamins and supplements to patients who may benefit from their use from their Florida medical offices. For purposes of this proceeding, as to whether such activity is permissible under Section 458.053, Florida Statutes, turns on the sole question of whether these vitamins and supplements constitute "health care items" under Section 456.053, Florida Statutes.

5. The Board finds that the record establishes that the "Focus" vitamins and supplements in question are over the counter products regulated by the FDA and by Florida law under the umbrella of foods and not regulated as a drug. Furthermore, they are categorized as general groceries by the Florida Department of Revenue for taxing purposes and are not reimbursable under various Florida and Federal health plans. Therefore, based on the foregoing, the Board concludes that Petitioners' "Focus" vitamins and supplements do not constitute "health care items" under Section 456.053, Florida Statutes, and accordingly the Petitioners may recommend and sell such items to patients from their Florida medical offices without running afoul of the Patient Self-Referral Act of 1992.

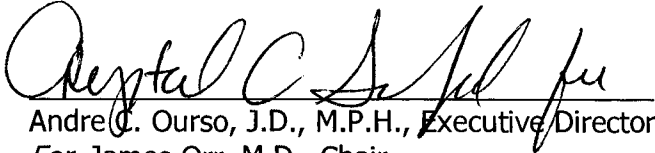
6. The Board's response to this Petition addresses solely the question propounded by the Petitioner and only addresses issues regarding the practice of medicine and not any other profession. The Board's conclusion is based solely on the Board's application of the

factual circumstances outlined in the Petition and presented to the Board to the pertinent statutory and rule provisions set forth above.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

**DONE AND ORDERED** this 15<sup>th</sup> day of June, 2015.

**BOARD OF MEDICINE**

  
Andre C. Ourso, J.D., M.P.H., Executive Director  
For James Orr, M.D., Chair

**NOTICE OF APPEAL RIGHTS**

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail and email transmission to: Emily S. Waugh, Esq., Ausley & McMullen, P.A., 123 South Calhoun Street, Tallahassee, Florida 32301, ewaugh@ausley.com; and by email transmission to Edward A. Tellechea, Chief Assistant Attorney General, at [ed.tellechea@myfloridalegal.com](mailto:ed.tellechea@myfloridalegal.com); and Daniel Hernandez, Interim General Counsel, at [Daniel.Hernandez@flhealth.gov](mailto:Daniel.Hernandez@flhealth.gov) , on this 15<sup>th</sup> day of June , 2015.

Brygel Saunders

**Deputy Agency Clerk**

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Rick Scott**  
Governor

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the Healthiest State in the Nation

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**TO:** Adrienne Rodgers, J.D., Bureau Chief  
Health Care Practitioner Regulation

**FROM:** André Ourso, J.D., MPH, Executive Director  
Board of Medicine

**SUBJECT:** Delegation of Authority

**DATE:** June 15, 2015

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This is to advise you that while I am out of the office, June 15, 2015 to June 26, 2015 Crystal Sanford is delegated to serve as Executive Director for the Board of Medicine. Mrs. Sanford can be reached at (850) 245-4132. I will return to the office on Monday, June 29, 2015.

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**Florida Department of Health**

Division of Medical Quality Assurance • Bureau of Health Care Practitioner Regulation  
4052 Bald Cypress Way, Bin C-03 • Tallahassee, FL 32399-3256  
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STATE OF FLORIDA  
BOARD OF MEDICINE

**FILED**  
DEPARTMENT OF HEALTH  
DEPUTY CLERK  
CLERK: *Amy L. Conway*  
DATE: 8-27-14

IN RE: Petition for Declaratory Statement of  
Lawrence S. Halperin, M.D. and  
Covalent Medical, LLC,

Petitioners

Case No. \_\_\_\_\_

**PETITION FOR DECLARATORY STATEMENT  
BEFORE THE BOARD OF MEDICINE**

Pursuant to Section 120.565, Florida Statutes, and Rule Chapter 28-105, Florida Administrative Code, Petitioners Covalent Medical, LLC and Lawrence S. Halperin, M.D., individually and as a representative of Covalent Medical, LLC, petition the Board of Medicine for a Final Order setting forth a Declaratory Statement on the facts and law presented herein.

**Background Information**

1. Petitioner, Lawrence S. Halperin, M.D., is a physician licensed pursuant to Chapter 458, Florida Statutes, and is an owner in Covalent Medical, LLC ("Covalent"). Dr. Halperin is Board certified by the American Board of Ophthalmology. For over 20 years he has practiced retinal surgery with The Retinal Group of Florida, with offices in Boynton Beach, Boca Raton, and Fort Lauderdale, Florida.
2. Petitioner, Covalent is a limited liability company organized under the laws of Delaware. Covalent is owned predominately by physicians from across the United States, including physicians licensed to practice medicine in the State of Florida.
3. For purposes of this Petition, Petitioners' authorized representative is Emily S. Waugh with the law firm of Ausley & McMullen, P.A., 123 South Calhoun Street, Tallahassee, Florida

32301; telephone number 850-425-5428; facsimile 850-895-3122; and email address [ewaugh@ausley.com](mailto:ewaugh@ausley.com). For purposes of this Petition, Petitioners' contact information is the same as that of its undersigned counsel.

4. The agency affected by this Petition is the Board of Medicine of the State of Florida (the "**Board**").

5. This Declaratory Statement is based on Section 456.053, Florida Statutes, which is known as the Patient Self-Referral Act of 1992 ("**Florida Act**"). The Florida Act encourages Florida physicians to use the declaratory statement procedure to determine the applicability of the Act as it applies to licensees. Fla. Stat. § 456.053(5)(b)(4).

6. Covalent produces and sells various types of "Focus" vitamins and mineral supplements in Florida and throughout the United States. The products are designed to support ocular health.

7. One of Covalent's products, named "Focus Select," consists of vitamins and mineral supplements which were the subject of the Age-Related Eye Disease Study sponsored by the National Eye Institute ("**Supplement**").

8. The Florida investors in Covalent include: (a) Petitioner Halperin, (b) other physicians who are licensed to practice medicine in Florida, and (c) entities which are owned by physicians licensed to practice medicine in Florida ("**Florida Physician Investors**"). No individual Florida Physician Investor owns more than one (1) unit. No entity owns more than one (1) unit per Florida physician. Each Florida Physician Investor paid Two Thousand Dollars (\$2,000.00) per unit.

9. With one known exception, the Covalent investors who reside outside Florida are either: (a) physicians licensed to practice in other states or (b) entities which are owned by such physicians. The exception is that one unit was distributed to the chief executive officer of a retinal surgery group in Washington, D.C., in exchange for administrative services which he performed on Covalent's behalf. The other non-Florida investors own one unit per physician and paid \$2,000.00 per unit, except: (a) a minimal number of additional units were distributed to the Board Members in exchange for their service on the Board and (b) five (5) units were distributed to each of Covalent's two (2) managing partners in exchange for services performed for Covalent. With respect to the units owned by the two (2) managing partners: (i) each managing partner is a physician licensed in a another state, (ii) the five (5) units owned by each managing partner represent five percent (5%) of the total units and are valued at Ten Thousand Dollars (\$10,000.00), and (iii) the value of the services performed for Covalent by each of the managing partners exceeds \$10,000.00.

10. The terms under which an investment interest in Covalent is offered to an investor who is in a position to make referrals to Covalent are no different than the terms offered to an investor who is not in a position to make such referrals.

11. The terms under which an investment interest is offered to an investor who is in a position to make referrals to Covalent are not related to the previous or expected volume or value of referrals from that investor to Covalent.

12. There is no requirement that an investor makes referrals or is in a position to make referrals to Covalent as a condition for becoming or remaining an investor in Covalent.

13. Covalent does not loan funds to, or guarantee a loan for, any investment if the investor uses any part of such loan to obtain the investment interest.



14. To date, Covalent has not made any distributions to its investors. When and if Covalent becomes profitable, the distributions to its investors will not be made directly or indirectly based on the value of volume of an investor's referrals to Covalent. The amount to be distributed to an investor will represent a return on the investment interest which is directly proportionate to the amount of the capital investment (including the fair market value of any preoperational services rendered) invested in Covalent.

15. The Florida Physician Investors desire to recommend the Supplement to their patients and sell the Supplement from their Florida medical offices. The Florida Physician Investors will only recommend the Supplement to their patients who might benefit from the Supplement.

16. The Florida Physician Investors will comply with the disclosure requirements of Section 456.052, Florida Statutes. Specifically, before recommending the Supplement, the Florida Physician Investors will provide each patient with a written disclosure form informing the patient of: (a) the existence of the investment interest in Covalent, (b) Covalent's name and address, (c) the patient's right to obtain the Supplement at the location or from the supplier of the patient's choice, including Covalent, and (d) the names and addresses of at least two alternative sources for the Supplement. Each Florida Physician Investor will post a copy of the disclosure form in a conspicuous public place in his or her office.

17. The issue involved in this request for Declaratory Statement affects the substantial interests of Petitioners and the Florida Physician Investors who desire to refer patients to, and sell, the Supplement and other similar products which Covalent may produce in the future.

#### **Requested Declarations**

18. Petitioners respectfully request that the Board of Medicine make the following declarations:

(a) The Supplement does not constitute a "health care item" under the Florida Act.

(b) The Florida Physician Investors may refer patients to, and sell, the Supplement, and such will not subject the Florida Physician Investors to disciplinary action by the Florida Board of Medicine under the Florida Act.

### The Supplement

19. The Supplement contains various vitamins and minerals based on the Age-Related Eye Disease Study sponsored by the National Eye Institute. The primary ingredients are Vitamin C, Vitamin E, zinc, copper, Lutein, and Zeaxanthin.

20. The Supplement is available to the general public, is sold over the counter, and does not require a prescription.

21. The Supplement is regulated by the U.S. Food and Drug Administration as a "food product", not as a drug.

22. The advertising states the Supplement is a "dietary supplement designed to provide a daily source of essential vitamins and minerals to support macular health." The advertising states:

Though there are no known cures for AMD [age-related macular degeneration], a recent study by the National Eye Institute (NEI) found that taking high doses of certain antioxidant vitamins and minerals could promote macular health.

23. The advertising cautions these statements have not been evaluated by the FDA. The advertising further cautions:

This product is not intended to diagnose, treat, cure or prevent any disease.

24. The Supplement is currently sold in vitamin stores in Florida and throughout the United States and in medical offices by physicians who are not investors.

25. Additional information about the Supplement is attached as Exhibit A.

**Issue: Whether Vitamins and Supplement Are "Health Care Items"**

26. In general terms, the Florida Act prohibits health care providers from referring patients for the provision of "designated health services" and other "health care items or services" to an entity in which the health care provider is an investor, unless certain exceptions are met. Fla. Stat. § 456.053(5). None of those exceptions applies to Petitioners.

27. The term "health care item" is not defined by the Florida Act.

28. To Petitioners' knowledge, the term "health care item" has not been defined by a Florida court or by the Board of Medicine.

29. The term "health care item" is not used under the federal patient self-referral law (commonly known as the "Stark Act"). The Stark Act applies to certain "designated health services." If the health care item or service at issue is not a "designated health service," then the Stark Act does not apply. The Stark Act defines "designated health services" to include out-patient prescription drugs. 42 U.S.C. § 1395 nn(6). However, the Stark Act does not apply to over-the-counter drugs, vitamins, or minerals.

30. Petitioners respectfully submit the Supplement should not be considered a "health care item" under the Florida Act. The Supplement is not marketed or recommended as a drug to prevent, diagnose, or treat disease. As explained below, both the U.S. Food and Drug Administration ("FDA") and Florida law regulate the Supplement as "foods." As also explained below, the Supplement is not reimbursable by various Florida and federal health plans.

### FDA Regulations

31. The federal Food, Drug, and Cosmetic Act (“FDA Act”) creates important distinctions in the treatment of foods (including dietary supplements), drugs, and other items regulated by the FDA. 21 U.S.C. § 321 et seq. The FDA regulates the following categories:

- (a) Prescription and non-prescription (over-the-counter) drugs.
- (b) Foods, including dietary supplements.
- (c) Vaccines, blood products, and other biologics.
- (d) Medical devices.
- (e) Electronic products.
- (f) Cosmetics.
- (g) Veterinary products.
- (h) Tobacco products.

<http://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm>

32. The FDA regulates the Supplement as a “food,” and not in the category of a non-prescription or over-the-counter drug. The FDA’s website indicates “foods” include dietary supplements, bottled water, food additives, infant formulas, and other food products. <http://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm>. A “dietary supplement” is a product taken by mouth that contains a “dietary ingredient” intended to supplement the diet. 21 U.S.C. § 321(ff). The “dietary ingredients” in such products may include vitamins and minerals. Id.

33. In 1994, the U.S. Congress amended the FDA Act to establish standards with respect to dietary supplements. Public Law 103-417. The 1994 Congressional findings included:

(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

...

(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

...

(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least \$4,000,000,000;

...

(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

Public Law 103-417, § 2.

#### **Florida Regulation**

34. "Medicine/drugs" or "drugs" are regulated in Florida by the Florida Board of Pharmacy under the "Florida Pharmacy Act." Fla. Stat. Ch. 465. "Medicinal drugs" or "drugs" are defined as "substances or preparations commonly known as 'prescription' or 'legend' drugs which are required by federal or state law to be dispensed only on a prescription... ." Fla. Stat. § 465.003(8). The Supplement is sold over-the-counter and does not require a prescription.

Consequently, the Supplement is not considered a “medicinal drug” or “drug” regulated by the Florida Pharmacy Act.

35. Drugs, devices, and cosmetics are regulated by the Florida Department of Business and Professional Regulation under the “Florida Drug and Cosmetic Act.” Fla. Stat. Ch. 499, Pt. I. The definition of “drug” in the Florida Drug and Cosmetic Act is similar to the definition of “drug” in the federal FDA Act. The Supplement does not meet the definition of “drug” under the Florida Drug and Cosmetic Act. Fla. Stat. § 499.003(19).

36. “Food” is regulated in Florida by the Florida Department of Agriculture and Consumer Services under the “Florida Food Safety Act.” Fla. Stat. Ch. 500. “Food” is defined to include various articles, including “articles for which health claims are made... and which are not considered drugs solely because their labels or labeling contain health claims.” Fla. Stat. § 500.03(1)(n). The Supplement falls within the definition of “food” under the Florida Food Safety Act.

37. Accordingly, the Supplement is regulated in Florida as “food” by the Florida Department of Agriculture and Consumer Services. The Supplement is not regulated as a “medicinal drug” or “drug” by the Florida Board of Pharmacy or by the Florida Department of Business and Professional Regulation.

#### **Reimbursement Under Florida and Federal Health Plans**

38. Vitamins and dietary supplements are not reimbursed under Florida’s workers’ compensation. The Florida Workers’ Compensation Health Care Provider Reimbursement Manual, 2008 Edition, provides:

Reimbursement shall not be made for oral vitamins, nutrient preparations and dietary supplements.

Manual, Section V(B)(2)(c). This Manual is adopted by reference as part of Florida's rules which govern workers' compensation. Fla. Admin. Code Rule 69L-7.020.

39. Vitamins are not reimbursed by the Florida Medicaid-Prescribed Drug Services Program, except for a few exceptions which do not apply to this Supplement. Florida Medicaid-Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook, updated June 2012, pages 2-7, 2-14. This Handbook is incorporated into the Florida Administrative Code rules governing the Medicaid program. Fla. Admin. Code Rule 59G-4.250.

40. Vitamins and minerals, including prescription vitamins and minerals, are not included in basic Part D Medicare coverage, except prenatal vitamins and fluoride preparation products. CMS Product #11315-P ("Medicare Drug Coverage Under Medicare Part A, Part B, Part C, and Part D") (revised January 2014).

#### Conclusion

41. In summary, the Supplement is an over-the-counter product regulated by the FDA and by Florida under the umbrella of foods, is not regulated as a drug, and is not reimbursable by various Florida and federal health plans.

WHEREFORE, Petitioners respectfully request that the Board of Medicine issue a Final Order declaring:

(a) The Supplement does not constitute a "health care item" under the Florida Act; and

(b) The Florida Physician Investors may refer patients for the Supplement and sell the Supplement in Florida without violating the prohibitions of Section 456.053, Florida Statutes.

Respectfully submitted this 27<sup>th</sup> day of August, 2014.

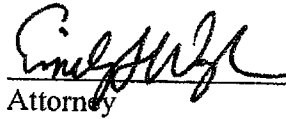


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Attorney for Petitioners,  
Lawrence S. Halperin, M.D.  
and Covalent Medical, LLC


**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished, by Hand Delivery, to Edward A. Tellechea, Chief Assistant Attorney General, Administrative Law Bureau, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; and Crystal A. Sanford, CPM, Program Operations Administrator, Department of Health (DOH) / Division of Medical Quality Assurance (MQA), Board of Medicine, 4052 Bald Cypress Way, # C03, Tallahassee, Florida 32399-3256, this 27<sup>th</sup> day of August, 2014.

  
Attorney



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# FOCUS SELECT

PREMIUM MACULA FORMULA

**WITH LUTEIN**

**Eye Vitamin & Mineral Supplement**

Based on AREDS 2 Formula\*

180 SOFTGELS (90 DAY SUPPLY)

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**DIRECTIONS**  
As a dietary supplement, place 2 softgels (1 provided in the inner sachet) in the eye Focus Select Softgel Dispenser 2, once daily with meals. Do not use if the inner sachet is empty. Do not use if the inner sachet is damaged or if the softgel is broken.

**WARNING:**  
Not intended for pregnant, nursing, or expectant women. Use only as directed. Do not use if you are allergic to any of the ingredients. Contains 100% natural ingredients. No artificial colors, flavors, or preservatives. Contains 100% natural ingredients. No artificial colors, flavors, or preservatives. Contains 100% natural ingredients. No artificial colors, flavors, or preservatives.

**STOP IN A 90-DAY PLACE**  
DO NOT USE IF SOFTGEL SEALS ARE DAMAGED OR BROKEN.  
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- 90 Day Supply
- Based on AREDS 2 Formula
- 10mg Lutein Per Day


**Supplement Facts**

Serving Size: 1 softgel  
Servings Per Container: 180

Amount Per Serving	% DV
Vitamin C (Ascorbic Acid).....	250 mg 417%
Vitamin E.....	200 IU 677%
(dl-alpha-tocopheryl Acetate)	
Zinc (Oxide).....	12.5 mg 88%
Copper (Oxide).....	0.7 mg 55%
Lutein.....	5 mg
Zeaxanthin.....	1 mg

\*Daily value not established

Contains 100% natural ingredients. No artificial colors, flavors, or preservatives. Contains 100% natural ingredients. No artificial colors, flavors, or preservatives.



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**In the Quality of  
Your Vision at Risk?**

Sight is one of our most valued senses, allowing us to experience and enjoy the imagery of life. The most routine activities—walking, reading, driving—are dependent upon the quality of our vision. When visual quality is lost, our lives are dramatically impacted. You may be facing this risk if you've been diagnosed with macular degeneration, the leading cause of vision loss among people over the age of 60.

Age-related macular degeneration (AMD or ARMD) is a disease of the retina affecting a small area at the center called the macula, which enables you to see fine details. Progressively damaging the macula, AMD can result in the blurring, distorting or distortion of your central vision. In some cases, it can lead to permanent vision loss.

Though there are no known cures for AMD, a recent study by the National Eye Institute (NEI) found that taking high doses of certain antioxidant vitamins and minerals could promote macular health.<sup>1</sup>

Providing daily care to thousands of patients, a group of over 400 retina specialists joined together to develop a line of high-quality and affordable vitamins—Focus Vision Supplements.

<sup>1</sup>Journal of Age-Related Eye Disease (JAREDS) Study. National Eye Institute. Retrieved October 28, 2009. <http://www.nei.nih.gov/rd/rdresearch/rdresearch.htm>

**Focus Select**

Focus Select is a premium eye supplement designed to provide a daily source of essential vitamins and minerals to promote macular health.

Based on the AREDS-2 study, sponsored by the National Eye Institute, Focus Select contains high levels of antioxidants and zinc. The study found these vital nutrients to be effective in supporting and promoting macular health.

Manufactured in an FDA-registered facility in the United States, Focus Select is produced with high-quality ingredients and undergoes extensive testing to ensure a premium product.

Developed by retina specialists, representing some of the most prestigious retina institutions in the country, Focus Select is a trusted formula developed through scientific research and industry expertise.

**The Benefits of Focus Select**

- Daily source of essential vitamins and minerals to promote macular health
- Scientific formula developed by retina specialists
- Free of gluten and artificial preservatives
- Safe for smokers and non-smokers



**Is it Right for You?**

Speak with your eye doctor today to determine if Focus Select is the best choice for supporting your vision health. To order Focus Select, or view our complete line of eye supplements, visit [www.focusvitamins.com](http://www.focusvitamins.com) or call toll-free at (855) 652-6287.

**Developed Through Science**

In 1992, the National Eye Institute launched the Age-Related Eye Disease Study (AREDS) to determine whether high doses of antioxidant vitamins and minerals could support vision health. Published in 2001, the results clearly demonstrated that the tested ingredients provided ocular health benefits. Based on the findings of this landmark study, we developed our first product for macular health—Focus Macular<sup>®</sup>.

A follow-up study (AREDS-2) was conducted between 2006-2012, testing modifications to improve the original formula. The results found that beta-carotene, an ingredient which may increase the risk of developing lung cancer among smokers, could be replaced with lutein and zeaxanthin. Focus Select is based on the formula utilized in AREDS-2, providing a premium supplement which promotes macular health and is safe for smokers and non-smokers.

**Focus Vision Supplements**



**High-Quality Ingredients**  
Formulated with high-quality ingredients and extensively tested



**Based on Science**  
Created through scientific research and proven to promote eye health



**Physician Recommended**  
Developed by retina specialists and trusted by doctors across the nation

Order online at [www.focusvitamins.com](http://www.focusvitamins.com)

**EXHIBIT A  
TO**

**PETITION FOR DECLARATORY STATEMENT**