Summary Report

Vitamin A Acetate

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
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Prepared by:

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REVIEW OF NOMINATION

Vitamin A acetate (UNII code: 3LE3D9D6OY) was nominated for inclusion on the 503B Bulks List by the Specialty Sterile Pharmaceutical Society for treatment of vitamin A deficiency. Vitamin A acetate will be compounded as a 10,000-50,000 units/mL solution diluted into potential diluents such as sterile water, sodium chloride, and dextrose for intramuscular injection as well as in unspecified oral dosage forms.

The reasons provided for nomination to the 503B Bulks List include:

- Prescribers' preference or hospital formularies requiring varying concentrations, volumes, or final product containers for administration.
- It is relatively unsafe to expose the direct compounding area to hundreds of vials or ampules and hundreds of aseptic manipulations during the compounding of a typical batch size for an outsourcing facility; compounding from bulk is safer and more efficient.
- Commercially available finished products have an inherent variance in potency creating an uncertain final concentration for the new product.
- Use of state-of-the-art equipment, like the SKAN isolator technology, requires the use of bulk starting materials.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of vitamin A acetate products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA), and approval status, provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for vitamin A acetate; name variations of vitamin A acetate were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient; strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms, and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing vitamin A acetate. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through February 2, 2019. The search included a combination of ("retinol acetate"[TIAB] OR "vitamin a acetate"[TIAB] OR "retinyl acetate"[TIAB] OR "9-cis-retinyl acetate"[TIAB] OR qlt091001[TIAB] OR "all-trans-retinyl acetate"[TIAB]) AND ("vitamin deficiency"[TIAB] OR "retinol deficiency"[TIAB] OR "retinyl deficiency"[TIAB] OR "vitamin a deficiency"[TIAB] OR treat*[TIAB] OR therapy[TIAB] OR therapeutic*[TIAB] OR clinical[TIAB] OR indicat*[TIAB]) AND humans[MeSH Terms] AND English[lang] NOT autism. Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Articles were not excluded on the basis of study design. Articles were considered relevant based on the identification of a clinical use of vitamin A acetate or the implementation of vitamin A acetate in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

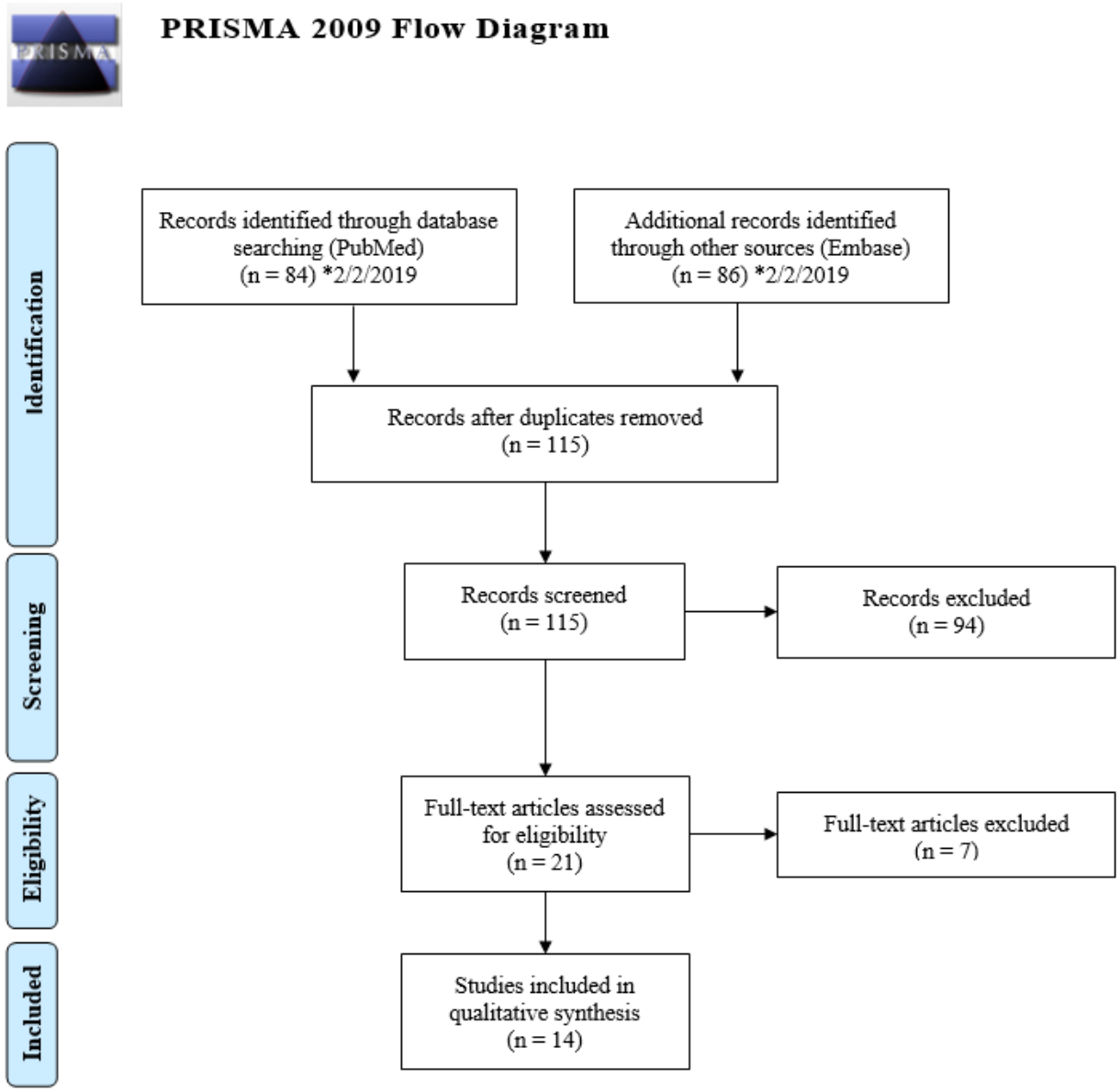
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for vitamin A acetate use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of vitamin A acetate compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indication from the nominations and the results of the literature review, five (5) medical specialties that would potentially use vitamin A acetate were identified: dermatology, naturopathy, oncology, ophthalmology, and primary care. Semi-structured interviews were conducted with subject matter experts within these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. One (1) expert was contacted for interviews, of which zero (0) accepted and zero (0) declined interviews. One (1) medical expert with a Doctor of Medicine (MD) specializing in oncology failed to respond to the interview request. No interviews were conducted.

Survey

General professional medical associations and specialty associations for dermatology, naturopathy, oncology, ophthalmology, and primary care, identified from the nomination and literature review were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to twelve (12) associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

Specialty	Association
Dermatology	American Academy of Dermatology (AAD)
	American Society for Dermatologic Surgery (ASDS)
Naturopathy	American Association of Naturopathic Physicians (AANP)
Ophthalmology	American Academy of Ophthalmology (AAO)
	American Society of Cataract and Refractive Surgery (ASCRS)
	American Society of Retina Specialist (ASRS)
Primary Care	American Academy of Environmental Medicine (AAEM)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Oncology	American Society of Clinical Oncology (ASCO)	Declined, "they are unable to share survey with members"
Primary Care	American Academy of Family Physicians (AAFP)	Failed to respond
	American College of Physicians (ACP)	Failed to respond

CURRENT AND HISTORIC USE

Summary of background information

- Vitamin A acetate is not available in any of the countries or regions searched. However, vitamin A palmitate is available as an FDA-approved 50,000 units/mL injection in the US.
- Vitamin A has a United States Pharmacopeia (USP) monograph.
- Vitamin A is available OTC in various oral dosage forms in the US and Canada.

Table 3. Currently approved products – US

No approved products in the US

Table 4. Currently approved products – select non-US countries and regions

No approved products in the selected non-US countries and regions

Summary of literature review

Fourteen 14 studies were included in the literature review, of which five (5) were in the US. There were no studies identified that utilized vitamin A acetate as an intramuscular injection or a compounded product.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive	0
Experimental[1–13]	13
Observational[14]	1

Table 6. Number of studies by country

Country	Number of Studies
Brazil[14]	1
India[1,7]	2
Indonesia[4,9]	2
Italy[2,11]	2
Nepal[6]	1
Spain[10]	1
United States (US)[3,5,8,12,13]	5
	Total US: 5 Total non-US Countries: 9

Table 7. Number of studies by combinations

No combination products were nominated

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Age-related macular degeneration[3]	10-40mg/m^2/week	–	–	Oral	4 doses
Antiaging[8]	Apply 2-3x/day	1%	Cream	Topical	2 weeks
Chemoprevention of cervical cancer[12]	3-18mg/day x 7 days	–	Gel	Vaginal	3 months
Chemoprevention of oral leukoplakia[13]	300,000 IU/week	–	Capsule	Oral	12 months
Vision impairment due to LCA or RP[5]	10-60mg/m^2/day x 7 days every 4 weeks	–	–	Oral	up to 3 courses

Abbreviations: "–", not mentioned; ROA, route of administration; LCA, Leber congenital amaurosis; RP, retinitis pigmentosa.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Retinitis pigmentosa[10]	15,000 IU/day	–	–	Oral	6-33 months
Breast cancer[2,11]	300,000 IU/day in 3 divided doses	50,000 IU	Capsule	Oral	1-26 months
Vitamin A deficiency[1]	200,000 IU x 1 q6 months	200,000 IU	Capsule	Oral	5 years
Vitamin A deficiency due to RYGB[14]	5,000 IU/day	5,000 IU	–	Oral	1 year
Supplementation during pregnancy[4,6]	1,000mcg/day-4,800mcg/week	–	Tablet	Oral	6 months-1 year
Supplementation in tuberculosis patients[7,9]	5,000 IU/day	5,000 IU	Capsule	Oral	6 months

Abbreviations: "–", not mentioned; ROA, route of administration; RYGB, Roux-en-Y gastric bypass.

Table 10. Compounded products – US

No compounded products from reported studies

Table 11. Compounded products – non-US countries

No compounded products from reported studies

Summary of focus groups/interviews of medical experts and specialty organizations

No interviews were conducted. One (1) medical expert specializing in oncology failed to respond to the interview request.

Table 12. Overview of interviewees

No interviews were conducted

Summary of survey results

Table 13. Characteristics of survey respondents [53 people responded to the survey[a]]

Board Certification	MD	ND	Other	No Response
Internal Medicine	1	0	0	0
Naturopathic Doctor	0	5	0	0
Naturopathic Physician	0	4	0	0
Ophthalmology	23	0	0	0
Other	0	0	1	0
No Response	0	0	0	22

[a]Multiple respondents reported more than one board certification.

Table 14. Types of products used, prescribed, or recommended

Types of Products	Respondents, n (N=13)
Compounded	4
FDA-approved	1
Over-the-counter	0
Dietary	1
Unsure	1
No Response	6

Table 15. Compounded use of vitamin A acetate in practice

Indication	Strength	Dosing Frequency	Dosage Form	ROA	Duration of Treatment	Patient Population
Bitot spots	–	–	–	–	–	–
Blepharitis	–	–	–	–	–	–
Eyelid margin keratinization after Stevens-Johnson syndrome	0.01%	BID	Ointment	Topical	As needed, sometimes ongoing	Post Stevens-Johnson syndrome
Ocular surface keratinization	0.05%	QID	Ointment	Topical	Ongoing	Severe dry eye, typically elderly women
Vitamin A deficiency	–	BID-TID	Ointment	Ointment	As needed	Adults

Abbreviations: ROA, route of administration; "–", not mentioned; BID, twice daily; TID, three times a day; QID, four times a day.

Table 16. Indications for which vitamin A acetate is considered standard therapy

Indication	Standard Therapy			
	Compounded, n (N=4)	Non-compounded, n (N=2[a])	Unsure, n (N=1)	No Response, n (N=6)
Dry eye	0	1	0	0
Keratosis pilaris	0	1	0	0
Mild eyelid margin keratinization	1	0	0	0
Non-healing defects	0	0	1	0
Part of AREDS	0	1	0	0
Viral infection	0	1	0	0
Vitamin A deficiency	2	0	0	0
None	1	0	0	0
No response	0	0	0	6

[a]Respondents reported more than one (1) indication.

Table 17. Reasons for using a compounded product instead of an FDA-approved product

Theme	Reasons
Availability	No FDA drop/ointment exists
	None available with FDA approval
Standard of care	There is no substitute
	Last option for severe dry eye

Table 18. Change in frequency of compounded vitamin A acetate usage over the past 5 years

	Respondents, n (N=4)
No–use has remained consistent	2
Yes–I use it LESS often now	2[a]
Yes–I use it MORE often now	0

[a]One (1) respondent reported use has decreased due to availability.

Table 19. Do you stock non-patient specific compounded vitamin A acetate in your practice?

	Respondents, n (N=4)
No	4
Yes	0

Table 20. Questions related to stocking non-patient specific compounded vitamin A acetate

No respondents reported stocking non-patient specific compounded vitamin A acetate

CONCLUSION

Vitamin A acetate was nominated for treatment of vitamin A deficiency as a 10,000-50,000 units/mL solution diluted into potential diluents such as sterile water, sodium chloride, and dextrose for intramuscular injection as well as in unspecified oral dosage forms. Vitamin A acetate is not available in any of the countries or regions searched. However, vitamin A palmitate is available as an FDA-approved 50,000 units/mL injection in the US. Vitamin A has a USP monograph and is available OTC in various oral dosage forms in the US and Canada.

From the literature review, no studies were identified that utilized vitamin A acetate as an intramuscular injection or a compounded product. No interviews were conducted.

From the survey, four (4) respondents reported using vitamin A acetate as a compounded product for treatment of bitot spots, blepharitis, eyelid margin keratinization after Stevens-Johnson syndrome, ocular surface keratinization, and vitamin A deficiency. Use of the compounded product is due to the unavailability of an FDA-approved drop/ointment. No respondents reported stocking non-patient specific compounded vitamin A acetate in their practice.

APPENDICES

Appendix 1. References

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en-Y gastric bypass: a 1-year follow up study. *Surg Obes Relat Dis*. 2017;13(2):227-233.

Appendix 2. Survey instrument

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **vitamin A acetate**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.
If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Vitamin A acetate

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **vitamin A acetate**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for vitamin A acetate? Please check all th... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for vitamin A acetate? Please check all th... = Compounded drug product

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for vitamin A acetate? Please check all th... = Compounded drug product

Q2. Please list any conditions or diseases for which you use compounded **vitamin A acetate** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

	Strength(s) (please include units)	Dosing frequency(ies)	Dosage form(s)	Route(s) of administration	Duration of therapy	Patient population
Condition 1 (please describe)						
Condition 2 (please describe)						
Condition 3 (please describe)						
Condition 4 (please describe)						
Condition 5 (please describe)						

Q3. Do you use compounded **vitamin A acetate** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

Skip To: Q5 If Do you use compounded vitamin A acetate as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded [substance] as a single agent active ingredient, or as one active ingredient... = Combination

Q4. Please list all combination products in which you use compounded **vitamin A acetate**.

_____

Q5. For which, if any, diseases or conditions do you consider compounded **vitamin A acetate** standard therapy? _____

Q6. Does your specialty describe the use of compounded **vitamin A acetate** in medical practice guidelines or other resources? _____

Q7. Over the past 5 years, has the frequency in which you have used compounded **vitamin A acetate** changed?

- Yes - I use it **MORE** often now (briefly describe why) _____
- Yes - I use it **LESS** often now (briefly describe why) _____
- No - use has remained consistent

Q8. Why do you use compounded **vitamin A acetate** instead of any FDA-approved drug product?

_____

Q9. Do you stock non-patient-specific compounded **vitamin A acetate** in your practice location?

- Yes
- No

Skip To: End of Block If Do you stock non-patient-specific compounded vitamin A acetate in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded vitamin A acetate in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **vitamin A acetate**? Please check all that apply.

- ☐ Physician office
- ☐ Outpatient clinic
- ☐ Emergency room
- ☐ Operating room
- ☐ Inpatient ward
- ☐ Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **vitamin A acetate**? Please check all that apply.

- ☐ Purchase from a compounding pharmacy
- ☐ Purchase from an outsourcing facility
- ☐ Compound the product yourself
- ☐ Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **vitamin A acetate**? Please check all that apply.

- ☐ Convenience
- ☐ Emergencies
- ☐ Other (please describe) _____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded vitamin A acetate? Please check all that apply. = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded vitamin A acetate? Please check all that apply. = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded vitamin A acetate? Please check all that apply. = Other (please describe)

Q13. For which, if any, diseases or conditions do you consider **vitamin A acetate** standard therapy?

_____

Q14. Does your specialty describe the use of **vitamin A acetate** in medical practice guidelines or other resources? _____

End of Block: Vitamin A acetate

Start of Block: Background Information

Q15. What is your terminal clinical degree? Please check all that apply.

- ▢ Doctor of Medicine (MD)
- ▢ Doctor of Osteopathic Medicine (DO)
- ▢ Doctor of Medicine in Dentistry (DMD/DDS)
- ▢ Naturopathic Doctor (ND)
- ▢ Nurse Practitioner (NP)
- ▢ Physician Assistant (PA)
- ▢ Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- ▢ No Board certification
- ▢ Allergy and Immunology
- ▢ Anesthesiology
- ▢ Cardiovascular Disease
- ▢ Critical Care Medicine
- ▢ Dermatology
- ▢ Emergency Medicine
- ▢ Endocrinology, Diabetes and Metabolism
- ▢ Family Medicine
- ▢ Gastroenterology
- ▢ Hematology
- ▢ Infectious Disease
- ▢ Internal Medicine
- ▢ Medical Toxicology
- ▢ Naturopathic Doctor
- ▢ Naturopathic Physician
- ▢ Nephrology
- ▢ Neurology
- ▢ Obstetrics and Gynecology
- ▢ Oncology
- ▢ Ophthalmology
- ▢ Otolaryngology
- ▢ Pain Medicine
- ▢ Pediatrics
- ▢ Psychiatry
- ▢ Rheumatology
- ▢ Sleep Medicine

- ☐ Surgery (please describe) _____
- ☐ Urology
- ☐ Other (please describe) _____

End of Block: Background Information