

Summary Report

Pyridoxal 5-Phosphate

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Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks
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REVIEW OF NOMINATION

Pyridoxal 5-phosphate (UNII code: 5V5IOJ8338) was nominated for inclusion on the 503B Bulks List by Fagron to treat pyridoxal 5-phosphate deficiency and improve immune response via injection at strengths ranging from 25-100mg/day.

Reasons provided for nomination to the 503B Bulks list include that pyridoxal 5-phosphate is the active form of FDA-approved substance pyridoxine hydrochloride and therefore is beneficial for patients with reduced ability to convert between forms naturally. Also, pyridoxal 5-phosphate is not available as an FDA-approved product.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of pyridoxal 5-phosphate 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 pyridoxal 5-phosphate; name variations of pyridoxal 5-phosphate 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(s); 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 pyridoxal 5-phosphate. 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 July 11, 2018. The search included a combination of ("pyridoxal phosphate"[TIAB] OR "vitamin b6"[TIAB] OR "pyridoxal 5 phosphate"[TIAB]) AND ("therapy"[TIAB] OR "therapeutics"[TIAB] OR "seizures"[TIAB] OR "epilepsy"[TIAB] OR "pyridoxine deficiency" [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 pyridoxal 5-phosphate or the implementation of pyridoxal 5-phosphate 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.

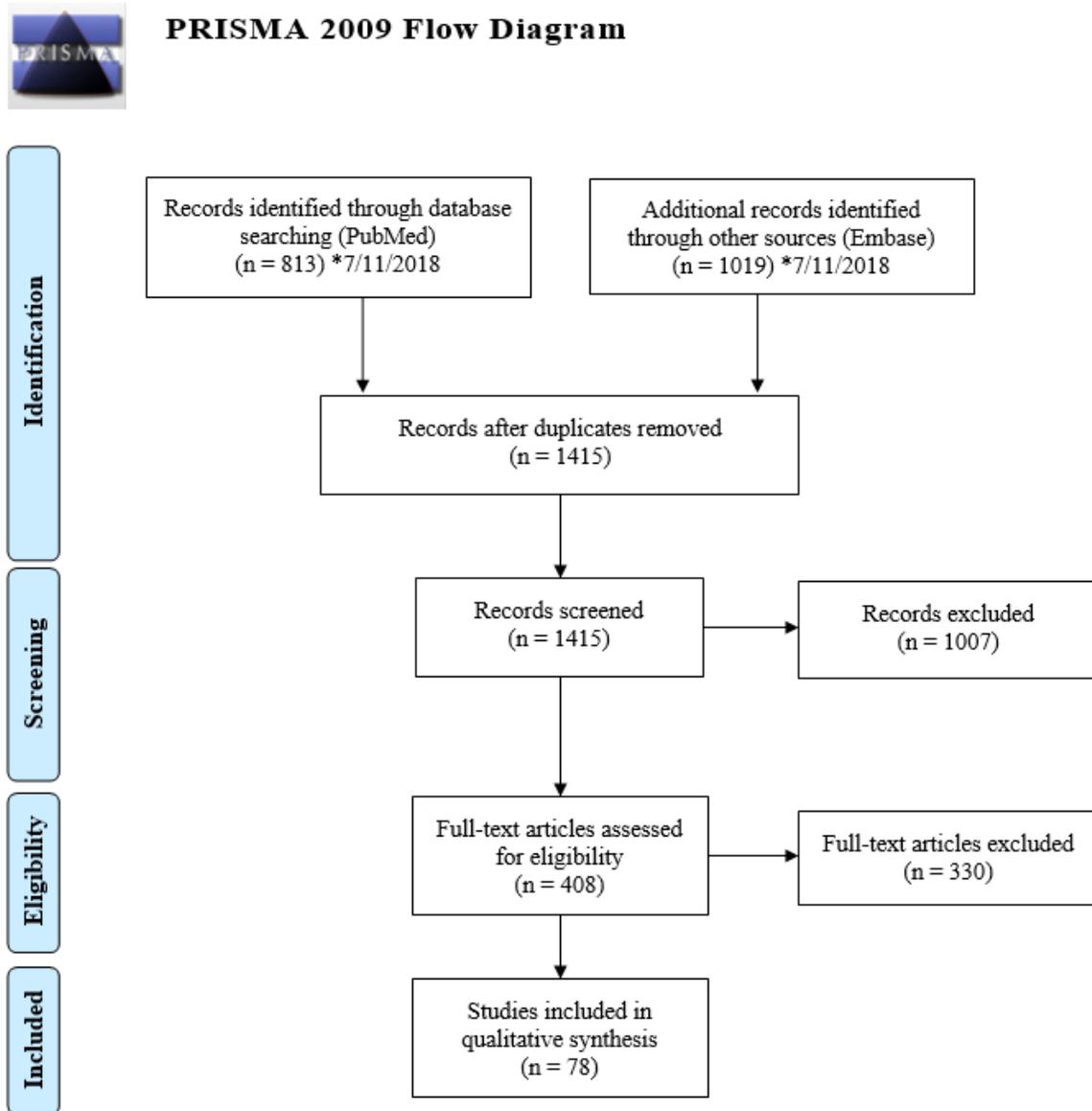
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for pyridoxal 5-phosphate 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 pyridoxal 5-phosphate 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). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: 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 indications from the nomination and the results of the literature review, six (6) medical specialties that would potentially use pyridoxal 5-phosphate were identified: endocrinology, naturopathy, neurology, pediatrics, primary care, and toxicology. 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. Eight (8) experts were contacted for interviews, of which eight (8) accepted and zero (0) declined interviews. All interviews were recorded and transcribed via ©Rev.com. QSR International's Nvivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for endocrinology, naturopathy, neurology, and primary care, identified from the nominations, literature review, and interviews, were contacted to facilitate distribution of an online survey. Based on interview response, pyridoxal 5-phosphate was not sent to pediatrics or toxicology associations. For pediatrics, interviews focused on use in neurology. For toxicology, poisonings that are treatable with this substance are uncommon in the US and therefore is not used in this space. 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 eight (8) 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.

Due to the identification of additional substances relevant to these associations, pyridoxal 5-phosphate was included on surveys with ascorbyl palmitate, cupric sulfate, hydroxocobalamin HCl, methylcobalamin/mecobalamin, riboflavin-5'-phosphate sodium, sodium selenite pentahydrate, vitamin A acetate, and zinc sulfate.

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
Naturopathy	American Association of Naturopathic Physicians (AANP)
Primary Care	American Association of Environmental Medicine (AAEM)

Table 2. Associations that declined participation

Specialty	Association	Reasons for declining
Endocrinology	American Association of Clinical Endocrinologists (AACE)	Declined, “Endocrinologists are not generally in the compounding space.”
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Neurology	American Academy of Neurology (AAN)	Failed to respond
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

- Pyridoxal 5-phosphate is not available as an FDA-approved product.
- Pyridoxal 5-phosphate is not available as an OTC product in the US.
- There is no current United States Pharmacopeia (USP) monograph for pyridoxal 5-phosphate.
- Pyridoxal 5-phosphate is approved in the EU as an orphan medication for pyridoxamine 5-phosphate oxidase deficiency (see Table 4).

Table 3. Currently approved products – US

No approved products in the US

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

Active Ingredient	Concentration	Dosage Form	ROA	Approved For Use		
				Country	Status	Approval Date ^b
Pyridoxal5-phosphate	–	–	Intra venous	EU	Orphan Medicine	10/15/2014

Abbreviations: “–”, not mentioned; ROA, route of administration

^aMedicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, ROA and approval status) provided in a useable format. Information was recorded only for products with strengths, forms and/or ROAs similar to those requested in the nominations. See Methodology for full explanation.

^bIf multiple approval dates and/or multiple strengths, then earliest date provided.

Summary of literature review

- Total number of studies included: 78 studies (63 descriptive, 8 experimental, and 7 observational studies).
- Most of the studies were from Japan (22), followed by the US (15), and the UK (11).
- The most prevalent indications for pyridoxal 5-phosphate were seizures and infantile spasms.
- Dosing ranges by ROA:
 - Oral (7-100mg/kg/day, 5-210mg/day)
 - Intravenous (10-50mg/kg/day, 100-500mg/day)
 - Intramuscular (20-400mg/day)
 - Subcutaneous (30mg/day)
- No compounded products were identified from any studies.

Table 5. Types of studies

Types of Articles	Number of Studies
Descriptive ¹⁻⁶³	63
Experimental ⁶⁴⁻⁷¹	8
Observational ⁷²⁻⁷⁸	7

Table 6. Number of studies by country

Country	Number of Studies
Australia ^{54,65}	2
Canada ^{14,15,48,49}	4
China ⁵⁵	1
Egypt ⁶⁴	1
Finland ^{45,68}	2
Germany ^{13,18,29}	3
India ²³	1
Italy ^{35,46,74}	3
Japan ^{2,5,17,25,26,28,33,37-39,50,56,58-60,67,69,72,75-78}	22
Korea ²⁰	1
Saudi Arabia ³²	1
Spain ^{51,62,73}	3
Switzerland ^{3,42,43,47}	4
Taiwan ^{31,53,71}	3
Thailand ⁵²	1
UK ^{1,4,61,7,8,12,22,30,36,44,57}	11
US ^{6,9,40,41,63,66,70,10,11,16,19,21,24,27,34}	15
Total US: 15 Total non-US Countries: 63	

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
Seizures/infantile spasms ^{6,10,11,16,27,34,40,41}	7-50mg/kg/day	–	–	Oral	–
	10mg/kg/day			Intra venous	
Sideroblastic anemia ^{24,66}	50mg/day	–	–	Intramuscular	14 days
	100-200mg/day			Intra venous	8-10 days
Acute intermittent porphyria ⁹	–	–	–	–	–
Amyotrophic lateral sclerosis ⁷⁰	160mg/day	40mg	Tablet	Oral	6 months
Aromatic L-amino acid decarboxylase (AADC) deficiency ¹⁹	–	–	–	–	–
Proline synthetase co-transcribed bacterial homolog (PROSC) mutation ²¹	–	–	–	–	–
Thrombocytopenia in severe alcoholism ⁶³	20mg/day	–	–	Intramuscular	–

Abbreviations: “–”, not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Seizures/infantile spasms/Ohtahara syndrome ^{1,3,18,20,22,28-32,35,36,4,37,39,42-49,5,50-57,60,61,7,62,67,69,71,72,75-78,12-15,17}	8.5-100mg/kg/day	–	–	Oral	–
	30-400mg/day			Intramuscular	
	10-50mg/kg/day			Intra venous	
Anemia ^{2,33,38,68}	5-210mg/day	–	–	Oral	–
	300-500mg/day			Intra venous	6 days
	250mg twice weekly-250mg/day			Intramuscular	2-16 weeks
Aromatic L-amino acid decarboxylase (AADC) deficiency ^{1,8}	–	–	–	–	–
Schizophrenia ^{25,59}	30-60mg/day	30mg	Tablet	Oral	2-12 weeks
Congenital erythropoietic porphyria ⁵⁸	30mg/day	–	–	Subcutaneous	–
Ginkgo seed poisoning ²⁶	2mg/kg	–	–	Intra venous	–
Hodgkin’s disease ⁷⁴	–	–	–	Intra venous	2-76 days
Inborn errors of metabolism ²³	–	–	–	–	–
Neuropediatric disorders ⁷³	10-30mg/kg/day	–	–	Oral	–
Violent a ggressive behavior ⁶⁵	–	–	Capsule	Oral	16 weeks
Vitamin B6 deficiency ⁶⁴	50mg/day	–	–	Oral	5-7 days

Abbreviations: “–”, not mentioned; ROA, route of administration.

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

Seven (7) interviews were conducted.

Table 12. Overview of interviewees

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Pyridoxal 5-phosphate	Interview Summary Response
END_02	MD	Endocrinology, Diabetes, and Metabolism	Academic medical institution	No	<ul style="list-style-type: none"> • Does not use pyridoxal 5-phosphate • Does not know of anyone who uses it
NAT_01 A-B	ND	None	Private practice	Yes	<ul style="list-style-type: none"> • Does use pyridoxal 5-phosphate regularly • Keeps office stock of compounded intravenous pyridoxal 5-phosphate
NEU_01	MD	Neurology	Academic medical institution	No	<ul style="list-style-type: none"> • Does not see in practice for a dult epilepsy
NEU_02	MD	Pediatrics Child and Adolescent Neurology Neurodevelopmental Disabilities Clinical Neurophysiology	Academic medical institution	Yes	<ul style="list-style-type: none"> • Does use pyridoxal 5-phosphate • Wants intravenous pyridoxal 5-phosphate office stock; does not stock, no access to dosage form.

PED_01	MD	Internal Medicine Pediatrics HIV Medicine	Academic medical institution	Yes	<ul style="list-style-type: none"> • Has given pyridoxal 5-phosphate • Does not see much need for compounded product
TOX_04	MD	Medical Toxicology Addiction Medicine Emergency Medicine	Tertiary referral center	No	<ul style="list-style-type: none"> • Uses pyridoxine • Does not use pyridoxal 5-phosphate
TOX_05	MD	Medical Toxicology	Tertiary referral center	No	<ul style="list-style-type: none"> • Uses pyridoxine • Does not use pyridoxal 5-phosphate
TOX_06	MD	Medical Toxicology Occupational Medicine Internal Medicine	Independent Consultant Faculty at a School of Medicine	No	<ul style="list-style-type: none"> • Has no information on pyridoxal 5-phosphate

Abbreviations: MD, Doctor of Medicine; ND, Naturopathic Doctor.

Use of pyridoxal

- Three interviewees reported use of pyridoxal 5-phosphate
 - Two reported use for vitamin supplementation and nerve issues (such as carpal tunnel and neuropathies).
 - One interviewee stated that they use it for adult patients who have low energy, “problems detoxing”, Lyme disease, autism, bipolar disorder, and antiaging. Also used intravenously for cancer, depression, and inflammatory diseases.
 - Oral dosage 0.5-1g, once or twice a day. Intravenous dose 25-50mg, once or twice per week.
 - One had seen parents add pyridoxal 5-phosphate to “resistant epileptics, or they had headache variance or different things”, but interviewee had never given it for seizures or without consulting a neurologist.
 - Dosage forms reported included oral (pill, capsule), intravenous, subcutaneous, and topical (cream).

Pyridoxal 5-phosphate compared to pyridoxine

- Two responded that the reason for giving pyridoxal 5-phosphate over pyridoxine is that pyridoxal is the active form and therefore ready to go if a patient has poor absorption or needs fast supplementation.

- One said that considering the number of enzyme systems that convert pyridoxine to the active forms, there would not be many patients who would see a clinical difference in receiving pyridoxal 5-phosphate over pyridoxine.
- Did comment that the problem with giving a pyridoxine complex is that a higher dose would be needed to get desired effect, which would increase the risk of pyridoxine-related side effects.

Pyridoxal 5-phosphate for specific indications

- Pyridoxine-dependent epilepsy
 - Four interviewees discussed pyridoxine-dependent epilepsy, though only one of the interviewees actively reported using it for this in their patients.
 - One interviewee said “P5P dependent epilepsy” would be the only condition they would consider pyridoxal 5-phosphate to be standard therapy for but had never seen it in practice.
 - One interviewee stated that there is a group of patients who do not respond to pyridoxine due to deficiency in pyridoxine/pyridoxamine phosphate oxidase; therefore, the active form (pyridoxal 5-phosphate) is often necessary.
 - One interviewee stated that they would give pyridoxal 5-phosphate as 10mg/kg every 6 hours as an IV solute-set over 20 minutes. Admitted that for maintenance dosing they would need to use the oral form and said that most kids end up taking 50mg four times per day. The oral form requires crushing so that the family can put it into formula (interviewee commented that it would be great if there was an oral liquid dosage form).
 - The test dose is one to two doses of 50mg; maintenance dose is 40-50mg every four to six hours.
- Toxicity
 - One interviewee discussed use of pyridoxine for prophylaxis and treatment of isoniazid related toxicity.
 - Pyridoxal 5-phosphate is not typically used.
 - Two interviewees were asked about use of pyridoxal 5-phosphate in treatment of poisoning from ginkgo biloba seeds and mushrooms
 - Neither had heard about B6 as a possibility for ginkgo. Very few cases of ginkgo seed poisonings in the US.
 - Gyromitra mushrooms are not very common in the areas of the United States where the interviewees practiced. One said they would administer pyridoxine if patient was seizing, but not common.
- Pyroluria
 - One interviewee brought up pyroluria. Their thoughts were that there are numerous non-specific symptoms that make it difficult to diagnose and difficult to rationalize treatment.

Need for compounded pyridoxal 5-phosphate

- One reported that the only reason they would want a compounded formulation over an over-the-counter B6 supplement would be if the patient was unable to take large capsules or if “whatever was on the shelf wasn’t palatable”.
- One reported that parenteral pyridoxal 5-phosphate is useful for patients with PNPO deficiency who do not respond to pyridoxine. Not available in the US and not on hospital formularies,
- therefore must go to vitamin shops for enteral products.

Need for “office stock”

- Four interviewees did not think there are situations where pyridoxal 5-phosphate would be used in an emergency situation where they would need to have it already prepared as “office stock.”
 - Two said, “It wouldn’t even make it into the aircraft emergency kits”.
- One expressed interest in having intravenous pyridoxal 5-phosphate available in the hospital pharmacy, since it is a common product to trial, even if pyridoxine-dependent epilepsy is uncommon. Reported that many neonatal seizures cannot be trialed on pyridoxal 5-phosphate because the hospital does not have the intravenous dosage form.
- One interviewee stated they keep office stock of oral supplements and compounded IV vials (3mg/mL).
 - If needs an oral supplement, either recommends an OTC product or writes a prescription for a compounding pharmacy.
 - Reported keeping five vials of compounded intravenous pyridoxal 5-phosphate in office.

Summary of survey results

Table 13. Characteristics of survey respondents [7 people responded to survey.^a]

Board Certification	ND	No Response
Naturopathic Doctor	5	0
Naturopathic Physician	4	0
No Response	0	1

Abbreviation: ND, Naturopathic Doctor.

^aSome respondents reported more than one terminal clinical degree or board certification.

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

Types of products	Respondents, n (N=5^a)
Compounded	1
FDA-approved	0
Over-the-counter	0
Dietary	3
Unsure	0
No response	1

^aOut of seven (7) respondents, five (5) reported using, prescribing, or recommending pyridoxal 5-phosphate product.

Table 15. Compounded use of pyridoxal 5-phosphate in practice^a

Indication	Strength	Dosing frequency	Dosage Form	ROA	Duration of treatment	Patient population
“many!!”	–	–	–	–	–	–

Abbreviations: “–”, not mentioned; ROA, route of administration.

^aOne (1) respondent

Table 16. Indications for which pyridoxal 5-phosphate is considered a standard therapy^a

Indication	Standard Therapy			
	Compounded, n (N=1)	Non-Compounded, n (N=3)	Unsure, n (N=0)	No Response, n (N= 1)
Anxiety	0	1	0	0
Carpal tunnel syndrome	0	1	0	0
Depression	0	1	0	0
Insomnia	0	1	0	0
Menstrual irregularities	0	1	0	0
Neuropathy	0	1	0	0
Nutrient deficiency	0	3	0	0
Other ^b	1	0	0	0
Skin concerns	0	1	0	0
No Response	0	0	0	1

^aSome respondents reported more than one indication.

^b“soooooo many !!”

Table 17. Reasons for using compounded product instead of the FDA-approved products

Reasons
<ul style="list-style-type: none"> • “better”

Table 18. Change in frequency of compounded pyridoxal 5-phosphate usage over the past 5 years

	Respondents, n (N=1)
No - use has remained consistent	0
Yes - I use it LESS often now	0
Yes - I use it MORE often now ^a	1

^aOne (1) respondent wrote “needed”.

Table 19. Do you stock non-patient specific compounded pyridoxal 5-phosphate in your practice?

	Respondents, n (N=1)
No	0
Yes ^a	1

^aRespondent reports stocking non-patient-specific compounded pyridoxal 5-phosphate in physician office and purchases the product from a compounding pharmacy for convenience.

Table 20. Questions related to stocking non-patient specific compounded pyridoxal 5-phosphate

No additional survey respondents provided information for this section

CONCLUSION

Pyridoxal 5-phosphate was nominated for inclusion on the 503B Bulks list to treat pyridoxal 5-phosphate deficiency and improve immune response via injectable administration. Out of the national medical registers that were reviewed, pyridoxal 5-phosphate is only available in the EU as an orphan medication for pyridoxamine 5'-phosphate oxidase deficiency.

From the literature review conducted, the most prevalent indication for pyridoxal 5-phosphate was seizures/infantile spasms. Studies were found to support use of pyridoxal 5-phosphate in cases of deficiency, as nominated.

Interviewees were divided on the use of pyridoxal 5-phosphate. Three of seven people interviewed had experience with this substance; two out of these three reported a need for having the compounded product since it is not commercially available. Only one kept office stock, but another interviewee said they would keep office stock if they had access to the dosage form.

Out of specialty organizations that were approached for survey participation, only the AANP and AAEM agreed to participate. Out of seven survey respondents, five reported using pyridoxal 5-phosphate in practice. One respondent reported using compounded pyridoxal 5-phosphate for unspecified indications and kept office stock for convenience.

APPENDICES

Appendix 1. References

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Appendix 2. Survey instrument

Pyridoxal 5-phosphate monohydrate

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 **pyridoxal 5-phosphate**. 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: Pyridoxal 5-phosphate monohydrate

Q1 What type(s) of product(s) do you use, prescribe, or recommend for **pyridoxal 5-phosphate**? 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 pyridoxal 5-phosphate? Please... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for pyridoxal 5-phosphate? Please... = Compounded drug product

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for pyridoxal 5-phosphate? Please... = Compounded drug product

Q2 Please list any conditions or diseases for which you use compounded **pyridoxal 5-phosphate** 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 **pyridoxal 5-phosphate** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

Single

Combination

Skip To: Q519 If Do you use compounded pyridoxal 5-phosphate as a single agent active ingredient, or as one active... != Combination

Display This Question:

If Loop current: Do you use compounded pyridoxal 5-phosphate as a single agent active ingredient, or as one active... = Combination

Q4 Please list all combination products in which you use compounded **pyridoxal 5-phosphate**.

Page Break

Q5 For which, if any, diseases or conditions do you consider compounded **pyridoxal 5-phosphate** standard therapy?

Q6 Does your specialty describe the use of compounded **pyridoxal 5-phosphate** in medical practice guidelines or other resources?

Q7 Over the past 5 years, has the frequency in which you have used compounded **pyridoxal 5-phosphate** 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 **pyridoxal 5-phosphate** instead of any FDA-approved drug product?

Q9 Do you stock non-patient-specific compounded **pyridoxal 5-phosphate** in your practice location?

- Yes
- No

Skip To: End of Block If Do you stock non-patient-specific compounded pyridoxal 5-phosphate in your practice location? = No

Page Break

Display This Question:

If Do you stock non-patient-specific compounded pyridoxal 5-phosphate in your practice location? = Yes

Q10 In what practice location(s) do you stock non-patient-specific compounded **pyridoxal 5-phosphate**? 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 **pyridoxal 5-phosphate**? 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 pyridoxal 5-phosphate? 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 pyridoxal 5-phosphate? Please check al... = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded pyridoxal 5-phosphate? Please check al... = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded pyridoxal 5-phosphate? Please check al... = Other (please describe)

Page Break _____

Q13 For which, if any, diseases or conditions do you consider **pyridoxal 5-phosphate** standard therapy?

Q14 Does your specialty describe the use of **pyridoxal 5-phosphate** in medical practice guidelines or other resources?

End of Block: Pyridoxal 5-phosphate monohydrate

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