Summary Report

Reduced L-Glutathione

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
Grant number: 2U01FD005946

Prepared by:

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REVIEW OF NOMINATIONS

Reduced L-glutathione (UNII code: GAN16C9B8O) was nominated for inclusion on the 503B Bulks List by McGuff Compounding Pharmacy Services, LLC, American Association of Naturopathic Physicians (AANP), Alliance for Natural Health (ANH), Integrative Medicine Consortium (IMC), American College for Advancement in Medicine (ACAM), and Fagron. McGuff Compounding Pharmacy Services, LLC, AANP, ANH, IMC, and ACAM nominated reduced L-glutathione as a 60-200mg/mL injection or inhalation for use in any conditions where there is a risk of oxidative stress or damage. Glutathione can prevent or reverse alcohol-induced fatty liver cirrhosis, hepatitis, and liver lesions; inhibit chemical induced carcinogenesis; improves prognosis of stroke victims; improve lung function and minimize oxygen-dependency in patients with COPD or chronic lung disease; autistic spectrum disorder (outside of the scope of this project). Fagron nominated reduced L-glutathione as a 3-100mg/mL injection to treat endometriosis.

Reasons provided for nomination to the 503B Bulks List include:

- Glutathione would be used in conjunction with FDA-approved treatment protocols to reduce the intensity of symptoms of the disease processes.
- When used in combination with FDA-approved treatment protocols, glutathione can reduce the severity of side effects.
- Since glutathione naturally occurs in the liver, a boost in glutathione can help preserve liver function in patients undergoing intense hepatic disease protocols.
- Side effects of FDA-approved medications to treat endometriosis.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of reduced L-glutathione 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 reduced L-glutathione; name variations of reduced L-glutathione 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 routes of administration 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

[name of substance]. 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 March 2, 2019. The search included a combination of ("reduced glutathione"[TIAB] OR "reduced L-glutathione"[TIAB] OR "l-glutathione reduced"[TIAB] OR "glutathione reduced"[TIAB] OR "reduced l-gsh"[TIAB] OR "reduced gsh"[TIAB]) AND (cirrhosis[TIAB] OR endometriosis[TIAB] OR "chronic obstructive pulmonary disease"[TIAB] OR copd[TIAB] OR hepatitis[TIAB] OR "lung disease"[TIAB] OR "liver disease"[TIAB] OR "stroke"[TIAB] OR radiation[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 reduced L-glutathione or the implementation of reduced L-glutathione 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.

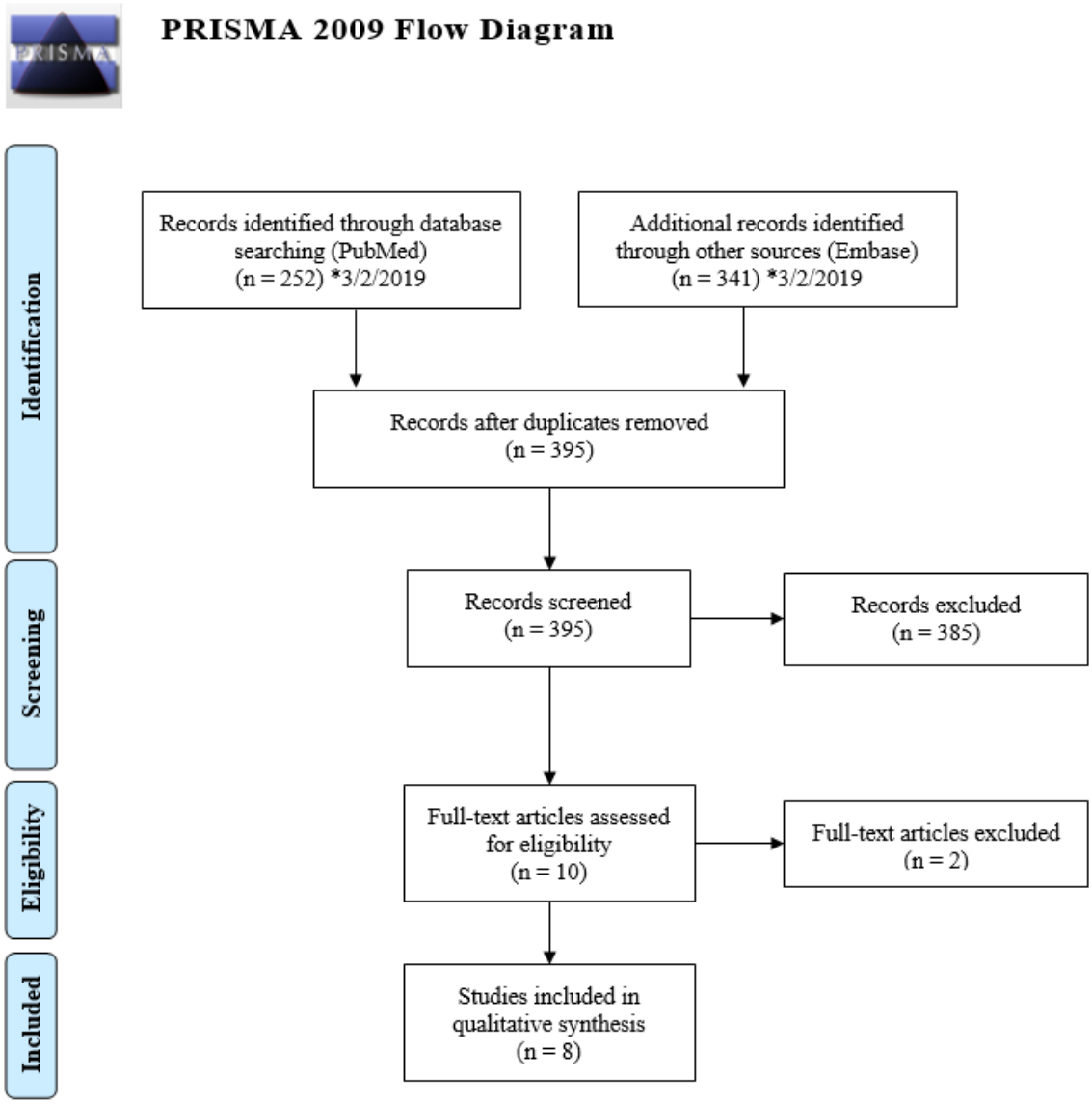
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for reduced L-glutathione 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 reduced L-glutathione 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 nominations and the results of the literature review, eight (8) medical specialties that would potentially use reduced L-glutathione were identified: dermatology, hepatology, naturopathy, neurology, obstetrics and gynecology, oncology, primary care, and pulmonology. 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. 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. Three (3) experts were contacted for an interview, of which zero (0) accepted and two (2) failed to respond to the interview request. One (1) expert stated "reduced L-glutathione is not used in liver disease," and therefore no additional follow-up was warranted.

Survey

General professional medical associations and specialty associations for dermatology, hepatology, naturopathy, neurology, obstetrics and gynecology, oncology, primary care, and pulmonology, identified from the nominations 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 thirteen 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)
Primary Care	American Academy of Environmental Medicine (AAEM)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Hepatology	American Association for the Study of Liver Diseases (AASLD)	Failed to respond
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Neurology	American Academy of Neurology (AAN)	Failed to respond
Obstetrics and Gynecology	American College of Obstetricians and Gynecology (ACOG)	Declined, survey not approved for distribution
Oncology	American Society for Clinical Oncology (ASCO)	Declined
Primary Care	American Academy of Family Physicians (AAFP)	Failed to respond
	American College of Physicians (ACP)	Failed to respond
Pulmonology	American Thoracic Society (ATS)	Declined

CURRENT AND HISTORIC USE

Summary of background information

- Reduced L-glutathione is not available as an FDA-approved product. There is a current United States Pharmacopeia (USP) dietary supplement monograph for reduced L-glutathione and reduced L-glutathione is available in various oral OTC formulations in the US.
- Reduced L-glutathione is not available in any of the select non-US countries.

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 select non-US countries and regions

Summary of literature review

Of the studies identified, five (5) were experimental and three (3) were descriptive. Only two (2) studies were conducted in the US, with five (5) in China, and one (1) in Italy. Cystic fibrosis and radiation induced dermatitis were the indications identified in the US-based studies and liver disease was the indication for all of the non-US studies. Only one (1) study identified a ROA, which was intravenous,

and three (3) studies identified a dose, with ranges from 300-2400mg/day. None of the studies discussed use as a compounded product.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[1–3]	3
Experimental[4–8]	5
Observational	0

Table 6. Number of studies by country

Country	Number of Studies
China[1,3,6–8]	5
Italy[4]	1
US[2,5]	2
	Total US: 2 Total non-US Countries: 6

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
Cystic fibrosis[2]	900-1350mg/day	–	Solution	Inhalation	14 days
	66mg/kg/day				6 weeks
Radiation dermatitis[5]	Apply 1-3 hours prior to radiation	–	Gel	Topical	2 months

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

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Drug induced liver injury[1,3]	–	–	–	–	–
Chronic alcoholic liver disease[4]	2400mg/day	–	–	–	15 days
Chronic hepatitis B[6]	1200mg/day	–	Solution	Intravenous	8 weeks
Decompensated hepatitis B cirrhosis[8]	–	–	–	–	–
Non-alcoholic fatty liver disease[7]	300mg/day	–	–	–	6 months

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

No interviews were conducted. A medical expert with a Medical Doctor (MD) specializing in oncology and an MD specializing in neurology failed to respond to the interview request. One medical expert with an MD specializing in hepatology replied via email that reduced L-glutathione is not used in liver disease.

Table 12. Overview of interviewees

No interviews were conducted

Summary of survey results

Table 13. Characteristics of survey respondents (16 people responded to the survey[a])

Board Certification	MD	ND	No Response
Dermatology	3	0	0
Naturopathic Doctor	0	6	0
Naturopathic Physician	0	5	0
No Board Certification	1	3	0
No Response	0	0	3

Abbreviations: MD, Doctor of Medicine; ND, Naturopathic Doctor.
[a]Some 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=8[a])
Compounded	4[b]
FDA-approved	0
Over-the-counter	1
Dietary	4
Unsure	0
No Response	2

[a]Out of 16 respondents, eight (8) reported using, prescribing, or recommending multiple types of reduced L-glutathione product.
[b]One (1) respondent reported using in combination as part of the Meyers cocktail.

Table 15. Compounded use of reduced L-glutathione in practice

Indication	Strength	Dosing Frequency	Dosage Form	ROA	Duration of Treatment	Patient Population
Anti-aging	–	–	–	–	–	–
Liver disease	200-1600mg	Weekly	–	Intravenous	6-12 months	Adults
Mood stabilizer	–	–	–	–	–	–
Multiple sclerosis	200-1600mg	Weekly	–	Intravenous	6-18 months	All patients
Neurological	–	–	–	–	–	–
Neuropathy	200-1600mg	Weekly	–	Intravenous	6-12 months	Adults
Parkinson's disease	200mg	TID	Spray	Nasal	2 months-indefinitely	All with condition
Potent antioxidant	–	–	–	–	–	–
Toxic chemical exposure	1000-2000mg	Weekly	–	Intravenous	3-6 months	Anyone with chemical exposure that damages liver, kidneys

Abbreviations: "–", not mentioned; ROA, route of administration; TID, three times a day.

Table 16. Indications for which reduced L-glutathione is considered standard therapy[a]

Indications	Standard Therapy		
	Compounded, n (N=4)	Non-compounded, n (N=4)	No response, n (N=2)
Asthma	0	1	0
Behavioral problems	0	1	0
Bronchiectasis	0	1	0
Cancer	1	0	0
Chemical toxicity	1	0	0
COPD	0	1	0
Detoxification	0	1	0
Environmental illness	1	0	0
Liver disease	3	1	0
Multiple sclerosis	1	0	0
Neurological conditions	1	0	0
Other[b]	1	0	0
No response	0	0	2

[a]Some respondents reported more than one indication.
[b]"soooooo many!!"

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

Theme	Reasons
Availability	• "Not available commercially"
Customizable	• "Because I can obtain it in a specific dose and form that I want for my patient"
Quality	• "Better, muuuuuuch better!!" • "Quality"

Table 18. Change in frequency of use of compounded reduced L-glutathione over the past 5 years

	Respondents, n (N=4)
No – use has remained consistent	1
Yes – I use it LESS often now	1
Yes – I use it MORE often now	2[a]
No response	0

[a]One respondent wrote "needed" and another wrote "more ill people in my practice"

Table 19. Do you stock non-patient specific compounded reduced L-glutathione in your practice?

	Respondents, n (N=4)
No	3
Yes[a]	1
No response	0

[a]Respondent reports stocking non-patient-specific compounded reduced-L-glutathione in physician office, and purchases from a compounding pharmacy for reasons of convenience.

Table 20. Questions related to stocking non-patient specific compounded reduced L-glutathione

One (1) respondent reports stocking non-patient specific compounded reduced L-glutathione in a physician office, purchases form a compounding pharmacy for convenience

CONCLUSION

Reduced L-glutathione was nominated for inclusion to the 503B Bulks List for use as a 60-200mg/mL injection or inhalation in any conditions where there is a risk of oxidative stress or damage and as a 3-100mg/mL injection to treat endometriosis.

Reduced L-glutathione is not a component of an FDA-approved product. There is a USP dietary monograph for the substance and it is available OTC in various dosage forms and strengths. It is not available in any of the select non-US countries searched,

From the literature review, cystic fibrosis and radiation-induced dermatitis were the indications identified in the US-based studies and liver disease was the indication for all of the non-US studies. Only one (1) study identified a ROA, which was intravenous, and three (3) studies identified a dose, with ranges from 300-2400mg/day. None of the studies discussed use as a compounded product.

No interviews were conducted. A medical expert with a MD specializing in oncology and an MD specializing in neurology failed to respond to the interview request. One (1) MD with a specialty in hepatology stated that reduced L-glutathione is not used to treat liver diseases.

From the survey, eight (8) of the sixteen (16) respondents use reduced L-glutathione, and of these eight (8), four (4) use a compounded product. Respondents stated that reduced L-glutathione is considered the standard of therapy for several conditions with doses ranging from 200-2000mg administered intravenously weekly and 200mg administered three times a day via a nasal spray.

APPENDICES

Appendix 1. References

1. Fang S, Qi L, Zhou N, Li C. Case report on alimentary tract hemorrhage and liver injury after therapy with oseltamivir: a case report. *Medicine (Baltimore)*. 2018;97(38):e12497.
2. Hudson VM. New insights into the pathogenesis of cystic fibrosis: pivotal role of glutathione system dysfunction and implications for therapy. *Treat Respir Med*. 2004;3(6):353-363.
3. Li X, Gao Y, Ji H, Guo X. Misdiagnosis of drug induced liver injury a case report. *Hepatol Int*. 2015;9(Suppl 1):S147.
4. Bardellini E, Bindi P, Borzone S, Caglieris F, Dagino F, Testa R. The effect of high doses of reduced glutathione on hepatic clearances and fibrogenetic activity in patients with chronic alcoholic liver disease. *Adv Ther*. 1992;9(2):116-122.
5. Enomoto TM, Johnson T, Peterson N, Homer L, Walts D, Johnson N. Combination glutathione and anthocyanins as an alternative for skin care during external-beam radiation. *Am J Surg*. 2005;189:627-631.
6. Qian L, Wang W, Zhou Y, Ma J. Effects of reduced glutathione therapy on chronic hepatitis B. *Cent Eur J Immunol*. 2017;42(1):97-100.
7. Wang Q, Lao J, Zou X, Huang Y. Clinical effect of metformin combined with reduced glutathione in non-alcoholic fatty liver disease. *J Gastroenterol Hepatol*. 2013;28(Suppl 3):186.
8. Zheng Y, Wu X. The clinical efficacy of adefovir dipvoxil combined with reduced glutathione therapy for decompensated hepatitis B cirrhosis. *J Dig Dis*. 2014;15(Suppl 1):73.

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 **reduced L-glutathione**. 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: Reduced L-glutathione

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **reduced L-glutathione**? 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: Q14 If What type(s) of product(s) do you use, prescribe, or recommend for reduced L-glutathione? Please check all th... != Compounded drug product

Skip To: Q3 If What type(s) of product(s) do you use, prescribe, or recommend for reduced L-glutathione? Please check all th... = Compounded drug product

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Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for reduced L-glutathione? Please check all th... = Compounded drug product

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

- ☐ Single
- ☐ Combination

Skip To: Q6 If Do you use compounded reduced L-glutathione as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded reduced L-glutathione as a single agent active ingredient, or as one active ingredient... = Combination

Q4. Please list all combination products in which you use compounded **reduced L-glutathione**.

_____

Q5. For which, if any, diseases or conditions do you consider compounded **reduced L-glutathione** standard therapy? _____

Q6. Does your specialty describe the use of compounded **reduced L-glutathione** in medical practice guidelines or other resources? _____

Q7. Over the past 5 years, has the frequency in which you have used compounded **reduced L-glutathione** 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 **reduced L-glutathione** instead of any FDA-approved drug product?
_____

Q9. Do you stock non-patient-specific compounded **reduced L-glutathione** in your practice location?

- Yes
- No

Skip To: End of Block If Do you stock non-patient-specific compounded reduced L-glutathione in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded reduced L-glutathione in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **reduced L-glutathione**? 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 **reduced L-glutathione**? 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 **reduced L-glutathione**? 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 reduced L-glutathione? Please check all that apply. = Convenience

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

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

Q13. For which, if any, diseases or conditions do you consider **reduced L-glutathione** standard therapy? _____

Q14. Does your specialty describe the use of **reduced L-glutathione** in medical practice guidelines or other resources? _____

End of Block: Reduced L-glutathione

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