

# Summary Report

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## Glycolic Acid

### Prepared for:

Food and Drug Administration

Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List

Grant number: 2U01FD005946

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January 2020

This report was supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award (U01FD005946) totaling \$2,342,364, with 100 percent funded by the FDA/HHS. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, the FDA/HHS or the U.S. Government.

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## REVIEW OF NOMINATION

Glycolic acid (UNII code: 0WT12SX38S) was nominated for inclusion on the 503B Bulks List by Sincerus Florida, LLC for treatment of hyperpigmentation disorders and photodamaged skin via topical creams, pads, and lotions from 0.08-70%. The reason provided for nomination to the 503B Bulks List is that the requested products are in greater strengths than the commercially available products.

## METHODOLOGY

### *Background information*

The national medicine registers of 13 countries and regions were searched to establish the availability of glycolic acid 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 glycolic acid; name variations of glycolic acid 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 glycolic acid. 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 27, 2018. The search included a combination of ("glycolic acid"[TIAB] OR "hydroxyacetic acid"[TIAB]) AND (therapy[TIAB] OR therapeutics[TIAB] OR clinical[TIAB] OR pigmentation[TIAB] OR pigment[TIAB] OR hyperpigmentation[TIAB] OR "photodamaged skin"[TIAB] OR skin[TIAB] OR photodamage[TIAB] OR warts[TIAB] OR keratosis[TIAB]) AND (humans[MeSH Terms] AND English[lang]). 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 glycolic acid or the implementation of glycolic acid 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.

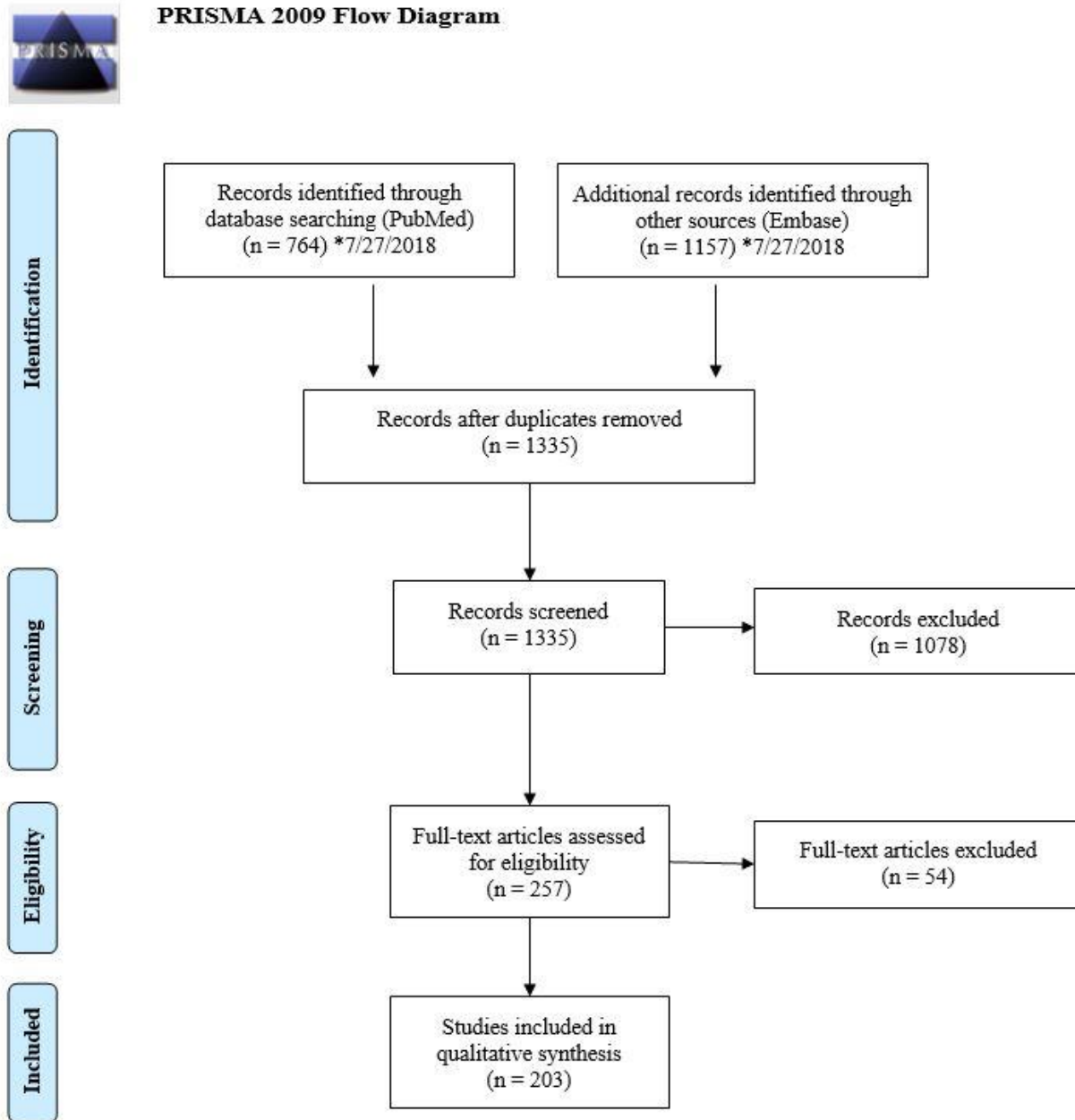
### Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for glycolic acid 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 glycolic acid 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

### *Outreach to medical specialists and specialty organizations*

Using the indications from the nomination and the results of the literature review, two (2) medical specialties that would potentially use glycolic acid were identified: dermatology and oncology. 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. Three (3) experts were contacted for interviews, of which two (2) accepted and one (1) failed to respond to the interview request. The 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 R1HSC 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 dermatology and oncology, identified from the nomination, literature review, and interviews, 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 five (5) 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

<b>Specialty</b>	<b>Association</b>
Dermatology	American Academy of Dermatology (AAD)
	American Society for Dermatologic Surgery (ASDS)

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”

## CURRENT AND HISTORIC USE

### *Summary of background information*

- Glycolic acid is not available as an FDA-approved product.
- Glycolic acid is available in various topical dosage forms as an OTC product in the US.
- There is no current United States Pharmacopeia (USP) monograph for glycolic acid. However, there is a current reagent monograph.
- Glycolic acid is not available in any of the foreign medicine registries searched.

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 region*

### *Summary of literature review*

- Total number of studies included: 203 studies (57 descriptive, 138 experimental, and 8 observational).
- Most of the studies were from the US (67).
- The most common indications for the use of glycolic acid in both the US and non-US countries were for skin rejuvenation, skin hyperpigmentation, and acne vulgaris/scarring.
- Compounded products were identified from both US (solution 12-70%) and non-US (10% cream, 7.15-20% gel, and 2% solution) studies.



Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive <sup>1-57</sup>	57
Experimental <sup>58-195</sup>	138
Observational <sup>196-203</sup>	8

Table 6. Number of studies by country

Country	Number of Studies
Australia <sup>187</sup>	1
Bangladesh <sup>75</sup>	1
Belgium <sup>101,153</sup>	2
Brazil <sup>8,15,29,134,156,175,190,196</sup>	8
Canada <sup>32,42</sup>	2
Chile <sup>44</sup>	1
China <sup>201</sup>	1
Colombia <sup>161</sup>	1
Egypt <sup>21,82,127,183,194</sup>	5
France <sup>68,88,171,172</sup>	4
Germany <sup>4,25,59,60</sup>	4
Greece <sup>41,57,116,117</sup>	4
Hong Kong <sup>9</sup>	1
India <sup>5,26,31,37-39,49,52,64,74,77,78,93,94,97,107,114,118,129,135,157-159,162,177-180,182,186,191</sup>	31
Iran <sup>86,145</sup>	2
Italy <sup>3,12,14,22,67,108,137,138,140-142,148,155,160,164,166-170,173</sup>	21
Japan <sup>24,33,35,36,91,103,110-113,130,188,197,200,203</sup>	15
Lebanon <sup>7</sup>	1
Malaysia <sup>2</sup>	1

The Netherlands <sup>16</sup>	1
Pakistan <sup>58,99,198</sup>	3
Poland <sup>128,195</sup>	2
Portugal <sup>11</sup>	1
Singapore <sup>34,132,133</sup>	3
South Korea <sup>106,119,120,149</sup>	4
Spain <sup>47,165</sup>	2
Switzerland <sup>1</sup>	1
Taiwan <sup>192</sup>	1
Thailand <sup>189</sup>	1
Turkey <sup>56,71,84,85,104,105,174,181</sup>	8
UK <sup>48</sup>	1
US <sup>6,10,13,17-20,23,27,28,30,40,43,45,46,50,51,53-55,61-63,65,66,69,70,72,73,76,79,81,83,87,89,90,92,95,96,98,100,102,109,115,121-126,131,136,139,143,144,146,147,150-152,163,176,184,185,193,199,202</sup>	67
Multiple Countries <ul style="list-style-type: none"> <li>• Belgium, France<sup>154</sup></li> <li>• France, Greece, Italy<sup>80</sup></li> </ul>	2
Total US: 67 Total non-US Countries: 136	

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
Skin rejuvenation <sup>6,10,20,27,30,43,45,46,54,61,62,65,70,73,81,83,87,89,95,96,100,121-123,125,139,143,144,146,147,152,176,185,199</sup>	–	2-15%	Cleanser, cream, lotion, serum	Topical	2-30 weeks
	–	20-70%	Peeling solution, gel		1-8 treatments
Skin hyperpigmentation <sup>10,20,30,45,50,70,72,76,79,92,98,102,109,115,131,147,150,163,193</sup>	–	5-20%	Cream, gel, lotion	Topical	2-24 weeks
	–	20-70%	Gel, peeling solution		1-12 treatments
Acne vulgaris and scarring <sup>20,23,30,45,53,54,66,69,70,184,202</sup>	–	5-10%	Foam, gel, lotion	Topical	6-12 weeks
	–	20-70%	Peel		–
Actinic keratosis <sup>13,17,18,28,136</sup>	–	20-70%	Gel, solution	Topical	Once-8 weeks
Rosacea <sup>20,54,70</sup>	–	70%	Peel	Topical	6 months
Abnormal keratinization <sup>40</sup>	–	8-70%	Lotion, solution	Topical	–
Impacted cerumen <sup>90</sup>	–	–	–	Otic	Once or twice
Laser skin resurfacing <sup>19</sup>	–	–	Cream	Topical	–
Lichen planus pigmentosus <sup>55</sup>	–	35-50%	Peel	Topical	16 weeks
Pseudofolliculitis barbae <sup>151</sup>	–	8%	Lotion, soap	Topical	8 weeks
Scalp psoriasis <sup>51,126</sup> and seborrheic psoriasis <sup>126</sup>	–	10%	Lotion, shampoo	Topical	8 weeks
Striae alba <sup>63</sup>	–	20%	Cream	Topical	12 weeks
Xerotic skin <sup>124</sup>	–	15%	Lotion	Topical	6 weeks

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

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Skin hyperpigmentation <sup>1,5,9,26,31,32,35-37,39,47,48,52,56-58,64,74,75,77,78,85,86,93,97,99,101,104,107,110,112,114,118,127,129,130,132-135,149,154,157-159,161,168,174,177-181,183,186,189,194,198,201</sup>	–	2-20%	Cream, gel, lotion, serum	Topical	4-26 weeks
	–	10-70%	Peeling solution		3-12 treatments
Acne vulgaris and scarring <sup>2-</sup> 4,8,9,12,14,16,24,31,34,38,39,41,52,57,59,60,71,80,82,84,94,103,105,106,108,113,116,117,119,120,130,137,142,162,170,182,188,192,197,200	–	1-15%	Cream, emulsion, gel, serum	Topical	1 week-24 weeks
	–	10-70%	Peeling solution		1-18 treatments
Skin rejuvenation <sup>4,12,15,21,22,25,29,44,67,68,88,91,111,128,140,141,148,153,156,164,167,169-173,187,190,191,203</sup>	–	3-50%	Cream, gel, lotion serum	Topical	2-12 weeks
	–	40-70%	Gel, peeling solution	Topical	2 days-6 weeks
	–	20-70%	Peeling solution	Topical	1-5 treatments
Warts <sup>33,49,165</sup>	–	15-50%	Gel	Topical	3 months
	–	35%	–		12 weeks
Actinic keratosis <sup>160,196</sup>	–	4%	Gel	Topical	3 months
	–	70%	Solution		–
Striae distensae <sup>138,145</sup>	–	10%	Cream	Topical	4 weeks
	–	70%	Cream		6 months
Plaque psoriasis <sup>12</sup> and scalp psoriasis <sup>166</sup>	–	–	Shampoo	Topical	12 weeks
	–	70%	Solution		–

Burn sequelae <sup>175</sup>	–	5-7%	Cream, gel	Topical	3 months
Congenital Hemidysplasia with Ichthyosiform nevus and Limb Defects (CHILD) syndrome <sup>7</sup>	–	12%	Cream	Topical	–
Dandruff <sup>155</sup>	–	–	Shampoo	Topical	Once
Keratosis pilaris <sup>9</sup>	–	20-70%	Solution	Topical	3-4 treatments
Minute digital hyperkeratosis <sup>11</sup>	–	15%	Lotion	Topical	–
Molluscum contagiosum <sup>42</sup>	–	–	–	Topical	–
Squamous cell carcinoma <sup>195</sup>	–	5%	Ointment	Topical	–

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

Table 10. Compounded products – US

Indication	Publication Year	Compounding Method	Dosage Form	Final Strength
Skin rejuvenation <sup>83</sup>	1993	<ul style="list-style-type: none"> <li>Medical grade 70% glycolic acid partially neutralized with ammonium hydroxide</li> </ul>	Peeling solution	12-70%

Table 11. Compounded products – non-US countries

Indication	Compounding Method	Dosage Form	Final Strength
Skin rejuvenation <sup>140,141,148</sup>	<ul style="list-style-type: none"> <li>Glycolic acid partially neutralized with sodium hydroxide or glycine and arginine</li> </ul>	Gel	20%
	<ul style="list-style-type: none"> <li>Glycolic acid partially neutralized with either glycine and arginine or glycine and lysine in a cream vehicle</li> </ul>	Cream	10%
	<ul style="list-style-type: none"> <li>Glycolic acid in a cream vehicle</li> </ul>	Cream	10%
	<ul style="list-style-type: none"> <li>Gelification of glycolic acid 70% in water</li> </ul>	Gel	7.15%
	<ul style="list-style-type: none"> <li>Glycolic acid with hydroxyethylcellulose, methylparaben, and glycerin</li> </ul>	Peel	70%
Acne vulgaris and scarring <sup>119,142</sup>	<ul style="list-style-type: none"> <li>Glycolic acid with lactic acid and carbonated water</li> </ul>	Peeling solution	2%
	<ul style="list-style-type: none"> <li>Glycolic acid buffered with chlorexidine digluconate and salicylic acid in a soybean liposome vehicle</li> </ul>	Cream	–

Abbreviation: “–”, not mentioned.

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

Two (2) interviews were conducted. One (1) medical expert specializing in oncology failed to respond to the interview request.

Table 12. Overview of interviewees

<b>Interviewee</b>	<b>Level of Training</b>	<b>Specialty</b>	<b>Current Practice Setting</b>	<b>Experience with Glycolic Acid</b>	<b>Interview Summary Response</b>
DER_01	MD	Dermatology	Academic medical institution Faculty at a School of Medicine	Yes	<ul style="list-style-type: none"> <li>• Currently buys different concentrations in big bottles and stocks it in the office</li> <li>• Commonly used for many indications – personally uses this every to every other week</li> </ul>
DER_03	MD	Dermatology Dermatology/Immunology	Independent consultant	Yes	<ul style="list-style-type: none"> <li>• There is a need for office stock for convenience and those who want to have tailored formulations.</li> <li>• Glycolic acid has been around for a long time and has a reasonable safety profile.</li> </ul>

Abbreviation: MD, Doctor of Medicine.

Indications:

- Disorders in which there is a need to exfoliate the skin
- Acne
- Post-inflammatory hyperpigmentation
- Wrinkles
- Melasma
- Treating lichenification

#### Administration and dosing considerations:

- The glycolic acid concentration depends on how deep of a peel the provider wants to induce.
  - Concentrations between 30-50% are very superficial peels.
    - One interviewee stated that glycolic acid is the most common superficial peel.
  - Concentrations that are greater than 70% are medium-depth peels.
    - Interviewee stated that most dermatologists are usually “at the 70% place. They’re not messing around with the lower concentrations, in general.” This is because they are using it for therapeutic reasons for diagnosis as opposed to the more superficial peeling.
- Glycolic acid is applied to the skin as a topical product and is almost always used with other agents.
- Duration of use
  - Very superficial peels are left applied for 1-2 minutes. Whereas deeper peels can be applied for up to 3-15 minutes.
- Frequency of use depends on the condition being treated
  - One interview reported they have a colleague that sees a patient every two weeks for repeated peels as treatment for acne.
  - Another interviewee says, “we have people on a regimen where they’re repeating it every two weeks.”
- Patient considerations
  - Some patients are more sensitive.
    - Fitzpatrick skin type – how dark somebody’s skin is can determine the concentration of glycolic acid and duration of use.
  - Pediatric acne patients are less likely to be treated with glycolic acid in adolescence.
  - There is a potential concern for higher exposure for patients with genetic disorders that relate to protein B6 in their skin. This would leave them susceptible to increased absorption of topical preparations. Examples include kids who have gotten salicylism and a disease called Netherton’s.

#### Need for office stock/bulk compounding

- NeoStrata are dermatologist-grade substances. They have varying concentrations but several people the interviewee has spoken to are “actually more used to ordering it in a bulk compounding space because they want to tailor that particular formulation, whether it’s buffered or non-buffered and what other excipients are in there.”
- Providers develop a familiarity and like the ability to order what they want to use.
  - “People who have a lot of experience and can manage them are gonna be using the liquids or the gel, will have a sort-of slower onset of action and maybe be used in a different context. So, they really like the ability to order up what they want to use. And, they’ve developed a familiarity with it and will use it.”
- For providers who use glycolic acid on a regular basis, office stock would be convenient to have. However, one interviewee also stated that there is another option on the market if they became unable to stock bulk compounded glycolic acid.
- An interviewee stated that many dermatologists like “controlling a lot more than just what percent glycolic acid they have.”
- Dermatologist do a lot of in-office detailing.



- One interviewee currently gets different concentrations (anywhere from 20 to 70%) in big bottles and stocks it in the office.

Other options

- Glycolic acid is viewed as a safer alternative to phenol and Jessner peels.
  - Jessner peels tend to be harder to control.
  - Phenol peels used in the old days, hard to control and could be devastating if left on for too long.
- Fraxel and related fractioned laser type therapy – the interviewee did not know as much about this but stated that these have taken over that space for the peels.

*Summary of survey results*

Table 13. Characteristics of survey respondents [1 person responded to the survey]

<b>Board Certification</b>	<b>No Response</b>
No Response	1

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

<b>Types of Products</b>	<b>Respondents, n (N=1<sup>a</sup>)</b>
Compounded	0
FDA-approved	1
Over-the-counter	1
Dietary	0
Unsure	0
No Response	0

<sup>a</sup>Out of one (1) respondent, one (1) reported using, prescribing, or recommending multiple types of glycolic acid product.

Table 15. Compounded use of glycolic acid in practice

*No survey respondents provided this information*

Table 16. Indications for which glycolic acid is considered a standard therapy

Indication	Standard Therapy	
	Compounded, n (N=0)	Non-compounded, n (N=2 <sup>a</sup> )
Acne	0	1
Anti-a ging	0	1
Sun damage	0	1
No response	0	0

<sup>a</sup>The respondent reported more than one indication.

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

*No survey respondents provided this information*

Table 18. Change in frequency of compounded glycolic acid usage over the past 5 years

*No survey respondents provided this information*

Table 19. Do you stock non-patient specific compounded glycolic acid in your practice?

*No survey respondents provided this information*

Table 20. Questions related to stocking non-patient specific compounded glycolic acid

*No survey respondents provided this information*

## CONCLUSION

Glycolic acid (UNII code: 0WT12SX38S) was nominated for inclusion on the 503B Bulks List by Sincerus Florida, LLC for treatment of hyperpigmentation disorders and photodamaged skin via topical creams, pads, and lotions from 0.08-70%. Glycolic acid is available in various topical dosage forms as an OTC product in the US; there is no current USP monograph. Glycolic acid is not approved in any of the foreign medicine registries searched.

From the literature review, the most common indication in the US in both the US and non-US countries were for skin rejuvenation, skin hyperpigmentation, and acne vulgaris/scarring. Compounded products were identified from both US (solution 12-70%) and non-US (10% cream, 7.15-20% gel, and 2% solution) studies.

From the interviews, one (1) interviewee expressed a need for office stock, and one (1) interviewee currently stocks glycolic acid in the office. Glycolic acid is commonly used for a variety of indications and has a reasonable safety profile.

From the survey, the one (1) respondent used glycolic acid as a FDA-approved and OTC product. This respondent reported that glycolic acid is standard therapy for acne, anti-aging, and sun damage.

## APPENDICES

### Appendix 1. References

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## 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 **glycolic acid**. 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](mailto: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](mailto:hrpo@umaryland.edu).

### End of Block: Welcome Page

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### Start of Block: Glycolic acid

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **glycolic acid**? 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 glycolic acid? Please check all th... != Compounded drug product*

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

Q2. Please list any conditions or diseases for which you use compounded **glycolic acid** 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 **glycolic acid** 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 glycolic acid as a single agent active ingredient, or as one active ingredient... != Combination*

*Display This Question:*

*If Loop current: Do you use compounded glycolic acid as a single agent active ingredient, or as one active ingredient... = Combination*

Q4. Please list all combination products in which you use compounded **glycolic acid**.

\_\_\_\_\_

Q5. For which, if any, diseases or conditions do you consider compounded **glycolic acid** standard therapy?

\_\_\_\_\_

Q6. Does your specialty describe the use of compounded **glycolic acid** in medical practice guidelines or other resources?

\_\_\_\_\_

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

\_\_\_\_\_

Q9. Do you stock non-patient-specific compounded **glycolic acid** in your practice location?

- Yes
- No

*Skip To: End of Block If Do you stock non-patient-specific compounded glycolic acid in your practice location? = No*

*Display This Question:*

*If Do you stock non-patient-specific compounded glycolic acid in your practice location? = Yes*

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

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

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

Q13. For which, if any, diseases or conditions do you consider **glycolic acid** standard therapy?

\_\_\_\_\_

Q14. Does your specialty describe the use of **glycolic acid** in medical practice guidelines or other resources?

\_\_\_\_\_

**End of Block: Glycolic acid**

**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