APPLICATION NUMBER:

020380Orig1s010

PROPRIETARY NAME REVIEW(S)
PROPRIETARY NAME REVIEW  
Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)  

*** This document contains proprietary information that cannot be released to the public***

Date of This Review: November 9, 2015  
Application Type and Number: NDA 020380/S-10  
Product Name and Strength: Differin Gel (adapalene) Gel, 0.1%  
Product Type: Single ingredient product  
Rx or OTC: OTC  
Applicant/Sponsor Name: Galderma  
Panorama #: 2015-1541586  
DMEPA Primary Reviewer: Tingting Gao, PharmD  
DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD  
DMEPA Deputy Director: Lubna Merchant, MS, PharmD  
DMEPA Director: Todd Bridges, RPh
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Reference ID: 3844505
1 INTRODUCTION
This review evaluates the proposed proprietary name, Differin Gel, for a Prescription (Rx) to Over-the-counter (OTC) switch of the Differin Gel 0.1%, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY
Adapalene has been marketed since May 31, 1996, as a prescription drug product under the proprietary name, Differin. Table 1 provides information on the approval of Differin (adapalene) products. Only the NDA 020380 Differin is being proposed for Rx to OTC switch at this time, the other dosage forms and strengths of Differin will remain Rx.

Table 1. Approval History of Differin Products (from Drugs@FDA)

<table>
<thead>
<tr>
<th>Drug Name/ Application #</th>
<th>Approval Date</th>
<th>Dosage Form/Route</th>
<th>Strength</th>
<th>Marketing Status</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Differin (NDA 020338)</td>
<td>May 31, 1996</td>
<td>Solution/Topical</td>
<td>0.1%</td>
<td>Discontinued</td>
<td>Galderma</td>
</tr>
<tr>
<td>Differin (NDA 020380)</td>
<td>May 31, 1996</td>
<td>Gel/Topical</td>
<td>0.1%</td>
<td>Prescription</td>
<td>Galderma</td>
</tr>
<tr>
<td>Differin (NDA 020748)</td>
<td>May 26, 2000</td>
<td>Cream/Topical</td>
<td>0.1%</td>
<td>Prescription</td>
<td>Galderma</td>
</tr>
<tr>
<td>Differin (NDA 021753)</td>
<td>June 19, 2007</td>
<td>Gel/Topical</td>
<td>0.3%</td>
<td>Prescription</td>
<td>Galderma</td>
</tr>
<tr>
<td>Differin (NDA 022502)</td>
<td>March 17, 2010</td>
<td>Lotion/Topical</td>
<td>0.1%</td>
<td>Prescription</td>
<td>Galderma</td>
</tr>
</tbody>
</table>

The Applicant previously submitted the proposed proprietary name, Differin *** on January 12, 2015. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, Differin *** unacceptable due to misbranding concerns in OSE Review #2015-47064, dated July 9, 2015 for IND 116864. 1

Galderma indicated that they would like to use the existing proprietary name for Rx product, Differin, as the proprietary name for the proposed OTC product. Since other prescription Differin products (NDA 020748, NDA 021753, and NDA 022502) will be marketed simultaneously with the proposed OTC product, DMEPA recommended Galderma to use a modifier to distinguish the proposed OTC product from existing Rx products to prevent product confusion during a teleconference on September 9, 2015. 2

Thus, the Applicant submitted the name, Differin Gel, for review on September 22, 2015.

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1 Gao T. Proprietary Name Review for Differin *** IND 116864. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 July 9. RCM No.: 2015-47064.

2 Memorandum of Teleconference Meeting Minutes for Differin (Adapalene) Gel, 0.1%. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 October 15. IND 116864.
1.2 PRODUCT INFORMATION

The following product information is provided in the September 22, 2015 proprietary name submission. The Applicant submitted a Prior Approval Supplement (NDA 020380/S-10) to switch the marketing status of NDA 020380 Differin (Adapalene) Gel, 0.1% from prescription (Rx) to over-the-counter (OTC).

Table 2: Comparison between Product Characteristics of the proposed OTC Differin Gel (NDA 020380) and approved Rx Differin Gel (NDA 020748), Cream (NDA 021753) and Lotion (NDA 022502)

<table>
<thead>
<tr>
<th>Product Characteristics</th>
<th>Proposed OTC Differin Gel (NDA 020380)</th>
<th>Approved Rx Differin Gel (NDA 020748)</th>
<th>Approved Rx Differin Cream (NDA 021753)</th>
<th>Approved Rx Differin Lotion (NDA 022502)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended pronunciation</td>
<td>Dif-er-in Gel</td>
<td>Dif-er-in</td>
<td>Dif-er-in</td>
<td>Dif-er-in</td>
</tr>
<tr>
<td>Active Ingredient</td>
<td>Adapalene</td>
<td>Adapalene</td>
<td>Adapalene</td>
<td>Adapalene</td>
</tr>
<tr>
<td>Indication of Use</td>
<td>topical treatment of acne in patients 12 years of age and older</td>
<td>topical treatment of acne vulgaris. [Pediatric Use: Safety and effectiveness in pediatric patients below the age of 12 have not been established.]</td>
<td>topical treatment of acne vulgaris. [Pediatric Use: Safety and effectiveness in pediatric patients below the age of 12 have not been established.]</td>
<td>topical treatment of acne vulgaris in patients 12 years of age and older</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Topical</td>
<td>Topical</td>
<td>Topical</td>
<td>Topical</td>
</tr>
<tr>
<td>Dosage Form</td>
<td>Gel</td>
<td>Gel</td>
<td>Cream</td>
<td>Gel</td>
</tr>
<tr>
<td>Strength</td>
<td>1 mg (0.1%)</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Dose and Frequency</td>
<td>Apply to affected area with a thin layer once daily. Clean skin thoroughly before applying the product.</td>
<td>Applied once a day to affected areas after washing in the evening before retiring. A thin film of the gel should be applied, avoiding eyes, lips, and mucous membranes.</td>
<td>Apply a thin film to affected areas of the skin, once daily at night time.</td>
<td>Apply a thin film to the entire face and any other affected areas of the skin once daily in the evening, after washing gently with a non-medicated soap</td>
</tr>
<tr>
<td>How Supplied</td>
<td>2 gram, 15 gram, and 45 gram tubes</td>
<td>45 g laminate tube</td>
<td>15 g tube</td>
<td>45 g tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>75 g laminate tube</td>
<td>45 g tube</td>
<td>45 g pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 oz (59mL) bottle pump</td>
</tr>
<tr>
<td>Storage</td>
<td>68° - 77°F (20° - 25°C). Keep out of reach of children.</td>
<td>68° - 77°F (20° - 25°C)</td>
<td>68° to 77°F (20° to 25°C)</td>
<td>68° to 77°F (20° to 25°C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2 RESULTS
The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT & INITIAL COMMENTS
The Division of Nonprescription Drug Products (DNDP) determined that the proposed name would not misbrand the proposed product. DMEPA concurred with the findings of DNDP’s assessment of the proposed name.

DNDP provided the following comments during the initial phase of the review:

There is another adapalene gel product with a 0.3% concentration that the applicant proposes will still be marketed as a prescription product which is also named “Differin Gel”. There is potential for confusion between a proposed OTC product and an RX product with the same name, though the concentrations will differ.

DMEPA notes that the existing Rx Adapalene Gel product in 0.3% is marketed under the proprietary name, Differin, not Differin Gel. However, we further evaluate the potential for confusion between the proposed OTC Differin Gel (Adapalene gel 0.1%) and the existing Rx Differin (Adapalene gel 0.3%) in section 2.2.5.

2.2 SAFETY ASSESSMENT
The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search
There is no USAN stem present in the proprietary name.³

2.2.2 Components of the Proposed Proprietary Name
Galderma indicated that the name “Differin Gel” is derived from the current proprietary name of Galderma with a modifier describing the dosage form for over-the-counter usage. Galderma further explained that although not currently marketed OTC, a dosage form descriptor will help differentiate this product from other 0.1% adapalene dosage forms (cream and lotion) that are currently marketed as prescribing drugs and could be switched to OTC status in the future.

This proprietary name is comprised of multiple words, the root name “Differin” and the modifier “Gel”. We further discuss our assessment of the modifier in Section 2.2.5 below.

2.2.3 FDA Name Simulation Studies
Sixty-eight practitioners participated in DMEPA’s prescription studies. Fifty-eight practitioners responded with the correct interpretation of the proposed name, “Differin Gel”. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

³ USAN stem search conducted on October 1, 2015.
2.2.4 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Differin that would be relevant for this review.

<table>
<thead>
<tr>
<th>Table 2. FAERS Search Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Search Date</strong></td>
</tr>
<tr>
<td><strong>Drug Name</strong></td>
</tr>
<tr>
<td><strong>Event (MedDRA Terms)</strong></td>
</tr>
<tr>
<td><strong>Search Terms Event List:</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Date Limits</strong></td>
</tr>
</tbody>
</table>
|                               | Last FAERS search was May 1, 2015 for OSE review 2015-47064 (IND 116864), dated July 9, 2015

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

The FAERS database gap search identified zero (0) cases.

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2.2.5 Evaluation of the modifier, “Gel”

Rx-to-OTC switches may be approved with the same indication(s), strength(s), and dosage form(s) (full switch), or one or more, but not all, of multiple indications, strengths, or dosage forms (partial switch) from its Rx equivalent. The proposed OTC Differin Gel product is identical with respect to indication, strength, dosage, formulation, manufacturing process, route and frequency of administration to the currently marketed prescription Differin (Adapalene gel 0.3%) product (approved under NDA 020380). Therefore, this would be a complete Rx to OTC switch for NDA 020380. However, we note that since other prescription Differin products (NDA 020748, NDA 021753, and NDA 022502) will be marketed simultaneously with the proposed OTC product, the addition of a modifier to the root name Differin is appropriate to differentiate between the Rx and OTC products.

Galderma proposed the modifier “Gel” to describe the dosage form for over-the-counter usage. Galderma further explained that a dosage form descriptor will help differentiate this product from other 0.1% adapalene dosage forms (cream and lotion) that are currently marketed as prescription drugs and could be switched to OTC status in the future.

Since Differin is also available as a gel (dosage form) with a 0.3% strength that will remain in prescription status, we were concerned with the possibility of wrong strength errors between Differin Gel (adapalene gel 0.1%) and Differin (adapalene gel 0.3%). In other words, we were concerned that a prescriber may write “Differin Gel” on a prescription pad for a consumer to obtain the OTC product Differin Gel (adapalene gel 0.1%), but a consumer may inadvertently receive the prescription Differin (adapalene gel 0.3%) instead because the 0.3% will be the only gel dosage form remaining Rx (strength of single strength products may be omitted on prescriptions). We sent an Information Request to Galderma on October 5, 2015, and Galderma provided the following response on October 12, 2015:

Galderma has evaluated the potential for prescribing errors due to the availability of Differin (adapalene) Gel, 0.3% as a prescription drug following the OTC-switch of Differin (adapalene) Gel, 0.1% and we do not believe that a risk exists based primarily on the fact that guidelines for writing prescriptions require that physicians include not only the name of the drug but also the strength. We believe that this practice is followed and will mitigate the risk of prescribing errors.

To further mitigate the chance for prescribing errors, Galderma will employ a broad series of communication strategies to ensure awareness of the change in status of adapalene 0.1% gel. These communication strategies include:

- Direct mail and e-mail communications to health care practitioners advising them of the switch of the 0.1% strength, along with identification of the adapalene products remaining prescription only, including Differin (adapalene) Gel, 0.3%
- Communications to pharmacies likewise advising them of the switch of the 0.1% strength, along with identification of the adapalene-containing products remaining prescription-only
- Advising all managed care organizations and other insurance providers of the switch and clearly identifying the strength and dosage form that is now OTC and which adapalene-containing products remain prescription-only
We evaluated Galderma’s response and noted that because Differin is currently available in two strengths, 0.1% and 0.3%, prescribers’ current practice is to indicate the strength on prescriptions to indicate the intended Differin product. Therefore, we believe that this practice of writing the strength on prescriptions will continue upon initial Rx to OTC switch for Differin (Adapalene gel 0.1%), which will help to differentiate Differin Gel 0.1% from the Differin (Adapalene gel 0.3%) product. During the initial switch period, Galderma also proposes to educate practitioners, pharmacists, and insurance providers of the 0.1% gel product’s switch to OTC status, which will also help to further mitigate the risk of confusion between Differin Gel 0.1% from Differin (Adapalene gel 0.3%) by increasing practitioners’ familiarity with the new Differin line of products.

We normally discourage the use of proprietary names that incorporate or suggest a particular dosage form as it may limit the use of the same proprietary name for future dosage forms of the product without making the proprietary name misleading. Although the proposed proprietary name contains the dosage form in the name, it is not incorporated within the root name but as a separate word/modifier and is limited to the gel dosage form. Since the dosage form for this formulation is indeed a gel, the proposed name is not misleading.

Therefore, the use of the modifier “Gel” for the proposed Adapalene Gel, 0.1%, does not present a safety concern and appears acceptable.

2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Nonprescription Drug Products (DNDP) via e-mail on October 22, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNDP on October 23, 2015, they stated no additional concerns with the proposed proprietary name, Differin Gel.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 Comments to the Applicant

We have completed our review of the proposed proprietary name, Differin Gel, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your September 22, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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4 REFERENCES


USAN Stems List contains all the recognized USAN stems.
APPENDICES

Appendix A

FDA’s Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.  

### Table 2- Prescreening Checklist for Proposed Proprietary Name

<table>
<thead>
<tr>
<th>Y/N</th>
<th>Question</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Is the proposed name obviously similar in spelling and pronunciation to other names?</td>
<td>Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.</td>
</tr>
<tr>
<td></td>
<td>Are there medical and/or coined abbreviations in the proprietary name?</td>
<td>Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.</td>
</tr>
<tr>
<td></td>
<td>Are there inert or inactive ingredients referenced in the proprietary name?</td>
<td>Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient’s value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).</td>
</tr>
<tr>
<td></td>
<td>Does the proprietary name include combinations of active ingredients?</td>
<td>Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).</td>
</tr>
<tr>
<td></td>
<td>Is there a United States Adopted Name (USAN) stem in the proprietary name?</td>
<td>Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.</td>
</tr>
<tr>
<td></td>
<td>Is this proprietary name used for another product that does not share at least one common active ingredient?</td>
<td>Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.</td>
</tr>
<tr>
<td></td>
<td>Is this a proprietary name of a discontinued product?</td>
<td>Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.</td>
</tr>
</tbody>
</table>
b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area of concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.
Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP’s decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator’s assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA’s final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.
Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA’s Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.
Appendix B: Prescription Simulation Samples and Results

Figure 1. Differin Gel Study (Conducted on October 2, 2015)

<table>
<thead>
<tr>
<th>Handwritten Requisition Medication Order</th>
<th>Verbal Prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication Order:</strong></td>
<td>Differin Gel</td>
</tr>
<tr>
<td>Differin Gel. Apply to affected areas once daily</td>
<td>Apply to affected areas once daily</td>
</tr>
<tr>
<td><strong>Outpatient Prescription:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

242 People Received Study
68 People Responded

<table>
<thead>
<tr>
<th>Total</th>
<th>24</th>
<th>21</th>
<th>23</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OUTPATIENT</td>
<td>VOICE</td>
<td>INPATIENT</td>
<td></td>
</tr>
<tr>
<td>DIFFERENGEL</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>DIFFERIN GEL</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<tr>
<td>DIFFEREN GEL</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<td>DIFFERENGEL</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>DIFFERIN GE</td>
<td>1</td>
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TINGTING N GAO
11/10/2015

CHI-MING TU
11/10/2015

LUBNA A MERCHANT
11/12/2015

TODD D BRIDGES
11/12/2015