CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215985Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	June 27, 2022
Requesting Office or Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	NDA 215985
Product Name and Strength:	Zoryve (roflumilast) cream, 0.3%
Applicant/Sponsor Name:	Arcutis Biotherapeutics, Inc.
OSE RCM #:	2021-1931
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container labels and carton labeling received on June 22, 2022 for Zoryve. The Division of Dermatology and Dentistry (DDD) requested that we review the revised container labels and carton labeling for Zoryve (Appendix A) to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a] We also note the statement on the 60-g sample carton was changed from (b) (4) to "Zoryve Experience Sample" and we find the proposed statement acceptable.

2 CONCLUSION

The Applicant implemented all of our recommendations and we have no additional recommendations at this time.

[a] Patel, M. Label and Labeling Review for Zoryve (NDA 215985). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 JUN 21. RCM No.: 2022-971.

6 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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Clinical Inspection Summary

Date	21 June 2022
From	Elena Boley, M.D., M.B.A. Good Clinical Practice Assessment Branch Division of Clinical Compliance Evaluation Office of Scientific Investigations
To	Qianyiren (Cicy) Song, RPM Hamid Tabatabai, M.D., Medical Reviewer Dave Kettl, M.D., Medical Team Leader Kendall Marcus, M.D., Division Director Dermatology and Dentistry
NDA #	215985
Applicant	Arcutis Biotherapeutics, Inc.
Drug	Roflumilast cream (ARQ-151), 0.3%
NME	No
Proposed Indication	Treatment of mild to severe plaque psoriasis
Consultation Request Date	03 Nov 2021
Summary Goal Date	22 Jun 2022
Action Goal Date	10 Jul 2022
PDUFA Date	22 Jul 2022

I. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

Drs. Stewart and Alonso-Llamazares were inspected in support of NDA 215985, covering Protocols ARQ-151-301 and ARQ-151-302. Despite some protocol deviations at the two sites, the study overall appears to have been conducted adequately, and the data generated by these sites appear acceptable in support of the respective indication.

During the clinical investigator inspections, the records related to the primary efficacy endpoint of "Investigator Global Assessment (IGA) success," defined as an IGA score of 'Clear' or 'Almost Clear' plus a 2-grade improvement from Baseline to Week 8, were reviewed and verified against the sponsor's data line listings for all 44 subjects randomized at these 2 sites. No discrepancies were noted. There was no evidence of under-reporting of adverse events.

II. BACKGROUND

NDA 215985 was submitted in support of the use of roflumilast cream (ARQ-151), 0.3%, for the treatment of chronic plaque psoriasis in adolescents (12 to 17 years of age, inclusive) and adults (≥18 years of age). The two pivotal studies supporting the application were the following:

- ARQ-151-301: A Phase 3, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled

Study of the Safety and Efficacy of ARQ-151 Cream 0.3% Administered QD in Subjects with Chronic Plaque Psoriasis

- ARQ-151-302: A Phase 3, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-151 Cream 0.3% Administered QD in Subjects with Chronic Plaque Psoriasis

These two studies were identically designed, randomized, parallel-group, double-blind, vehicle-controlled, multicenter studies in subjects with chronic plaque psoriasis. Eligible subjects included male and female children (2 to 11 years old), adolescents (12 to 17 years old), and adults (≥8 years old) who had a clinical diagnosis of psoriasis vulgaris of at least 6 months duration (3 months for children) as determined by the investigator. Subjects had to have an IGA score of at least Mild (2) at Baseline and a Psoriasis Area and Severity Index (PASI) score of at least 2 (excluding the scalp, palms, and soles) at Baseline. Subjects had to have stable disease for the past 4 weeks, with 2% to 20% Body Surface Area (BSA) involvement. For a complete list of inclusion and exclusion criteria, please see the protocol.

The study course consisted of a screening phase (maximum duration of 35 days) and a treatment phase (maximum duration of 8 weeks). Upon completion of this study at 8 weeks, subjects had the opportunity to participate in an open-label extension (OLE) study (ARQ-151-306) of up to 6 months in duration. For those subjects who entered the OLE study, the Week 8 visit of the present study was the Day 1 visit for ARQ-151-306, and there was no Week 9 follow-up visit. Subjects who did not enter ARQ-151-306 were to have a minimum of 7 clinic visits, including Screening, Baseline, Week 2, Week 4, Week 6, and Week 8 (final week of treatment), as well as a Week 9 follow-up visit (1 week after last dose). The anticipated maximum duration of subject participation for either Study 301 or Study 302 was 14 weeks.

After the screening period, subjects were randomized in a 2:1 ratio to roflumilast cream 0.3% once daily or to vehicle cream once daily. Randomization was stratified by site of involvement, baseline IGA score (IGA=2 vs. IGA≥3), and intertriginous involvement at baseline (Intertriginous-IGA [I-IGA] ≥2, yes vs no).

The IGA for chronic plaque psoriasis is a five-point scale that provides a global clinical assessment of psoriasis severity (based on plaque thickening, scaling, and erythema) ranging from 0 to 4, where 0 indicates ‘Clear,’1 indicates ‘Almost Clear,’ 2 indicates ‘Mild,’ 3 indicates ‘Moderate,’ and 4 indicates ‘Severe’ findings. A decrease in score relates to an improvement in signs and symptoms.

Roflumilast cream 0.3% or vehicle cream was applied daily to all lesions of plaque psoriasis. Areas of application were all areas affected, including the face, trunk, genitals/skin folds, or limbs (excluding the scalp). Although palms and soles were treated, these did not count toward any measure of efficacy.

A follow-up visit occurred approximately 1 week after treatment was completed for subjects who did not enter the OLE study.

The ***primary efficacy endpoint***, achievement of "IGA success," was defined as an IGA score of 'Clear' or 'Almost Clear' plus a 2-grade improvement from Baseline to Week 8. (b) (4) performed subject randomization and provided the tablet for the clinical investigator to record the IGA data at each visit.

Details relevant to Study ARQ-151-301

Study 301 was conducted at 43 centers that randomized subjects in the United States and Canada. The first subject was screened on December 9, 2019, and the last subject completed their final visit on November 16, 2020. Of the 439 subjects that were enrolled, 388 completed the study. The original protocol was dated October 31, 2019, with the final protocol and amendment dated February 21, 2020.

Details relevant to Study ARQ-151-302

Study 302 was conducted at 43 centers that randomized subjects in the United States and Canada. The first subject was screened on December 9, 2019, and the last subject completed their final visit on November 23, 2020. Of the 442 subjects that were enrolled, 395 subjects completed the study. The original protocol was dated October 31, 2019, with a final protocol and amendment dated February 21, 2020.

Rationale for Site Selection

The clinical sites were chosen primarily based on numbers of enrolled subjects, site-specific efficacy results, low protocol deviations, and financial interest >25K.

III. RESULTS (by site):

1. **Daniel M. Stewart, D.O.**
   Site #116
   43900 Garfield Rd Suite 106
   Clinton Township, MI 48038
   PDUFA Inspection Dates: 04 to 08 Apr 2022

At this site for Protocol ARQ-151-301, 26 subjects were screened, 19 were randomized, and 15 subjects completed the study. Of the 4 subjects who terminated early, 3 withdrew consent and 1 was terminated at the request of the physician (subject # (b) (6), due to elevated liver enzymes). All subjects who terminated early had been assigned to the vehicle treatment group.

The inspection evaluated the study records for the 19 randomized subjects was conducted. Records reviewed during the inspection included, but were not limited to, the study protocol and amendments; institutional review board (IRB) submissions, approvals, and correspondence; subject eligibility criteria; informed consent process and forms; source records, including medical records and other regulatory documentation (e.g., Form FDA 1572s); primary efficacy endpoint data; adverse event reporting; protocol deviations; drug accountability logs; and monitor logs and follow-up letters.

There was no evidence of under-reporting of adverse events. The primary source for the efficacy data was the eCOA (electronic Clinical Outcome Assessment) tablet. After the data was entered into the eCOA tablet by the clinical investigator (CI), it was synced/uploaded to the electronic case report form (eCRF). A PDF version of the eCRF was ultimately sent to the CI via a USB. During the inspection, the data on the USB was reviewed, and the IGA scores at the Baseline and Week 8 visits were verified against the data line listings or all 19 randomized subjects. No discrepancies were noted.

For 3 out of 15 subjects (20%), the performance of the primary and secondary efficacy endpoints assessments was attributed to the clinical research coordinator (CRC). According to the protocol, the clinical investigator was supposed to assess the primary and secondary efficacy endpoints. These protocol deviations were submitted to the NDA, and a note to file was created to explain these occurrences. Dr. Stewart confirmed that he did perform these specific assessments that were incorrectly attributed to the CRC.

Reviewer's comments: For these three subjects, the attributability of the primary and several secondary endpoints was incorrect. The endpoint data was attributed to the CRC rather than the CI because the CRC failed to sign out of the tablet and the CI subsequently failed to sign in before the CI performed his assessments. This issue would not affect the overall efficacy analysis. This issue was discussed with Dr. Stewart during the inspection closeout meeting. Dr. Stewart acknowledged these items and ensured preventative measures would be in place for future trials to avoid repeating these mistakes.

2. **Javier Alonso-Llamazares, M.D.**
   Site #244 [also called site 7]
   201 Madeira Ave
   Coral Gables, FL 33134
   PDUFA Inspection Dates: 29 March 2022 to 07 April 2022

At this site for Protocol ARQ-151-301, 26 subjects were screened, 25 were randomized, 1 was lost to follow-up (subject (b) (6)), and 24 subjects completed the study.

The inspection evaluated the study records for the 25 randomized subjects was conducted. Records reviewed during the inspection included, but were not limited to, the study protocol and amendments; signed investigator agreements; financial disclosure statements; IRB submissions and correspondence; subject eligibility criteria; informed consent process and forms; source records, including medical records and other regulatory documentation (e.g., Form FDA 1572s); primary efficacy endpoint data; adverse event reporting; protocol deviations; concomitant medications; vital sign entries; drug accountability logs; and monitor logs and follow-up letters.

The IGA scores were entered into the tablet at each visit. In a clarification email dated 02 June 2022, the field investigator confirmed that she reviewed certified copies of the IGA data which were provided to the site via a CD-ROM. This IGA data was compared to the data line listings provided by the sponsor for baseline and Week 8 for all 25 randomized subjects. No

discrepancies were noted.

There was no evidence of under-reporting of adverse events with the exception of an elevated potassium of 5.9 mmol/L (collected on Week 8/Visit 6 in subject # (b) (6)), which was not reported to the sponsor. Additionally, there was no indication that the clinical investigator took any actions to follow up on the value.

Reviewer's comment: To ensure patient safety, the CI should have followed up on the elevated potassium by rechecking the potassium level and possibly performing an ECG. Without additional information to show clinical meaningfulness of this lab abnormality, this single unreported elevated potassium is unlikely to change the safety evaluation of the drug.

For four of the 25 subjects (16%), documentation of Investigator and Subject Local Tolerability Assessments at their Baseline visits occurred 1-1.5 months after the Baseline visit. For each of these subjects (b) (6) the Baseline tolerability assessments indicated no reaction to the product. As a preventative measure, the site used a second coordinator to review the form with the CI to ensure it is always completed at the time of the visit.

Reviewer's comment: The delayed recording of Baseline Investigator and Subject Local Tolerability Assessments for the four subjects identified above is a protocol violation and affects data reliability. However, the overall drug safety profile is unlikely to be affected because these same subjects received subsequent doses, with no reactions noted on the associated tolerability assessments. The possibility of a clinically meaningful reaction to the first administration without reactions to subsequent IP administrations is very low.

{See appended electronic signature page}

Elena Boley, M.D., M.B.A.
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

CONCURRENCE:

{See appended electronic signature page}

Phillip Kronstein, M.D.
Team Leader
Good Clinical Practice Assessment Branch
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CONCURRENCE:

{See appended electronic signature page}

Kassa Ayalew, M.D., M.P.H
Division Director
Acting Branch Chief
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

cc:
Central Doc. Rm. NDA 215985
DDD/Project Manager/ Qianyiren Song
DDD/Medical Reviewer/ Hamid Tabatabai
DDD/Medical Team Leader/ Dave Kettl
DDD/Division Director/ Kendall Marcus
OSI/DCCE/Division Director and (Acting) Branch Chief/Kassa Ayalew
OSI/DCCE/GCPAB/Team Leader/Phillip Kronstein
OSI/DCCE/GCPAB/Reviewer/Elena Boley
OSI/ GCPAB/Program Analyst/Yolanda Patague

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/s/

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	June 1, 2022
To:	Qianyiren Song, PharmD Regulatory Project Manager **Division of Dermatology and Dentistry (DDD)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Ruth Mayrosh PharmD Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Laurie Buonaccorsi, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	ZORYVE (roflumilast) cream
Dosage Form and Route:	for topical use
Application Type/Number:	NDA 215985
Applicant:	Arcutis Biotherapeutics, Inc.

1 INTRODUCTION

On September 29, 2021, Arcutis Biotherapeutics, Inc. submitted for the Agency's review an original New Drug Application (NDA) 215985 for ZORVYE (roflumilast) cream. The proposed indication for ZORVYE (roflumilast) cream is for the topical treatment of plaque psoriasis, including in the intertriginous areas, in patients 12 years of age and older.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Dermatology and Dentistry (DDD) on March 1, 2022 for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for ZORYVE (roflumilast) cream.

2 MATERIAL REVIEWED

- Draft ZORYVE (roflumilast) cream PPI received on September 29, 2021, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on May 20, 2022.
- Draft ZORYVE (roflumilast) cream Prescribing Information (PI) received on September 29, 2021, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on May 20, 2022.
- Approved DALIRESP (roflumilast) tablets comparator labeling dated January 23, 2018.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the PPI document using the Arial font, size 10.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language

- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)
- ensured that the PPI is consistent with the approved comparator labeling where applicable.

4 CONCLUSIONS

The PPI is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the PPI is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI.

Please let us know if you have any questions.

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06/01/2022 10:57:19 AM

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: May 27, 2022

To: Hamid Tabatabai, MD, Clinical Reviewer,
Division of Dermatology and Dentistry (DDD)
Qianyiren Song, Regulatory Project Manager, DDD

From: Laurie Buonaccorsi, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: James Dvorsky, Team Leader, OPDP

Subject: OPDP Labeling Comments ZORYVE™ (roflumilast) cream, for topical use.

NDA: 215985

In response to DDD's consult request dated February 28, 2022, OPDP has reviewed the proposed product labeling (PI), patient package insert (PPI), and carton and container labeling for the original NDA submission for ZORYVE™ (roflumilast) cream, for topical use (Zoryve).

Labeling

OPDP's comments on the proposed labeling are based on the draft PI and PPI received by electronic mail from DDD on May 20, 2022, and the proposed carton and container labeling received by electronic mail from DDD on May 23, 2022.

PI and carton and container labeling: Our comments on the proposed PI and carton and container labeling are provided below.

PPI: A combined OPDP and Division of Medical Policy Programs (DMPP) review will be completed, and comments on the proposed PPI will be sent under separate cover.

Thank you for your consult. If you have any questions, please contact Laurie Buonaccorsi at (240) 402-6297 or laurie.buonaccorsi@fda.hhs.gov.

1. For all proposed carton and container labeling, the established name should be at least half as large as the letters comprising the proprietary name and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features, according to 21 CFR 201.10 (g)(2). The proprietary name is more than twice the size of the established name and the bright bolded font is more prominent than the font used for established name. We recommend the established name on all proposed carton and container labeling be revised to have prominence commensurate with the proprietary name.

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LAURIE J BUONACCORSI
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LABEL AND LABELING REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	February 28, 2022
Requesting Office or Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	NDA 215985
Product Name, Dosage Form, and Strength:	Zoryve (roflumilast) cream, 0.3%
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Arcutis Biotherapeutics, Inc.
FDA Received Date:	September 29, 2021
OSE RCM #:	2021-1931
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

1 REASON FOR REVIEW

As part of the approval process for Zoryve (roflumilast) cream, the Division of Dermatology and Dentistry (DDD) requested that we review the proposed Zoryve prescribing information (PI), Patient Package Insert (PPI), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B – N/A
Human Factors Study	C – N/A
ISMP Newsletters*	D – N/A
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F – N/A
Labels and Labeling	G

N/A=not applicable for this review

*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We reviewed the Prescribing Information (PI), Patient Package Insert (PPI), interim container labels, container labels, and carton labeling. We note that the applicant has proposed interim container labels to be used until pre-printed empty aluminum tubes are available.

We find the labels and labeling can be improved to prevent wrong dose and wrong route of administration errors.

4 CONCLUSION & RECOMMENDATIONS

We conclude that the proposed label and labeling can be improved and we provided recommendations below in Section 4.1 for the Division and Section 4.2 for the Applicant to address our concerns.

4.1 RECOMMENDATIONS FOR DIVISION OF DERMATOLOGY AND DENTISTRY (DDD)

A. Prescribing Information

1. Dosage and Administration Section

a. We note the PPI states [redacted] (b) (4) However, in the Dosage and Administration of the Highlights and Full Prescribing Information [redacted] (b) (4) is not mentioned. We recommend revising for consistency.

4.2 RECOMMENDATIONS FOR ARCUTIS BIOTHERAPEUTICS, INC.

We recommend the following be implemented prior to approval of this NDA:

A. General Comments (Container labels & Carton Labeling)

1. To ensure consistency with the Prescribing Information, revise the statement, [redacted] (b) (4) to read "Recommended Dosage: See prescribing information."

B. Container Labels

1. For the interim 5 g professional sample size label, decrease the prominence of the statements "For Topical Use Only", "[redacted] (b) (4), "Not for oral, ophthalmic, or intravaginal use", "Rx Only" as this information appears more prominent than the established name on the principal display panel. Additionally, relocate "Professional Sample – Not for Sale" below the "Not for oral, ophthalmic, or intravaginal use" statement.

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Zoryve received on September 29, 2021 from Arcutis Biotherapeutics, Inc..

Table 2. Relevant Product Information for Zoryve	
Initial Approval Date	N/A
Active Ingredient	roflumilast
Indication	topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older
Route of Administration	topical
Dosage Form	cream
Strength	0.3%
Dose and Frequency	Apply to affected areas once daily and rub in completely.
How Supplied	white to off white cream containing 0.3% roflumilast and is supplied in 60 g aluminum tubes. 60 g tube: NDC 80610 130 60
Storage	Store at room temperature between 68°F and 77°F (20°C to 25°C).
Container Closure	aluminum tube

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[a] along with postmarket medication error data, we reviewed the following Zoryve labels and labeling submitted by Arcutis Biotherapeutics, Inc..

- Container Label received on September 29, 2021
- Carton Labeling received on September 29, 2021
- Professional Sample Container Label received on September 29, 2021
- Professional Sample Carton Labeling received on September 29, 2021
- Prescribing Information and Patient Package Insert (Images not shown) received on September 29, 2021, available from \\CDSESUB1\evsprod\nda215985\0001\m1\us\draft-clean-labeling-text.docx

G.2 Label and Labeling Images

Container Labels

Interim

(b) (4)

[redacted]

[a] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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