CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213593Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

IND 126863

MEETING MINUTES

RxM™ Therapeutics, LLC
Attention: Elizabeth N. Dupras, RAC
Senior Director, Regulatory Affairs
B&H Consulting Services, Inc
50 Division Street, Suite 206
Somerville, NJ 08876

Dear Ms. Dupras:[1]

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Omeprazole Powder for Oral Suspension Kit.

We also refer to the meeting between representatives of your firm and the FDA on September 4, 2019. The purpose of the meeting was to discuss the nonclinical and clinical data, as well as general regulatory topics to support a 505(b)(2) NDA for Omeprazole Powder for Oral Suspension Kit.

A copy of the official minutes of the meeting/telecon is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call me at (301) 796-5408.

Sincerely,

{See appended electronic signature page}

CAPT Mimi Phan, Pharm.D.
U.S. Public Health Service, RPM
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Enclosure:

- Meeting Minutes

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM OF MEETING MINUTES

Meeting Type: B
Meeting Category: Pre-NDA

Meeting Date and Time: September 4, 2019, 10:00AM-11:00AM (EST)
Meeting Location: 10903 New Hampshire Avenue
White Oak Building 21, Conference Room: 1539
Silver Spring, Maryland 20903

Application Number: IND 126863
Product Name: Omeprazole Powder for Oral Suspension Kit

Proposed Indication: For the treatment of frequent gastroesophageal reflux
Sponsor Name: RxM™ Therapeutics, LLC [Insert meeting date and time]

Meeting Chair: Erica Lyons, MD
Meeting Recorder: Mimi Phan, PharmD

FDA ATTENDEES

Division of Gastroenterology and Inborn Errors Products (DGIEP)
Jessica J. Lee, M.D., Associate Division Director
Erica Lyons, M.D., Medical Officer Team Leader
Marjorie Dannis, M.D., Medical Officer
Sushanta Chakder, Ph.D., Pharmacology/Toxicology Team Leader
CAPT Mimi Phan, Pharm.D., Regulatory Project Manager

Office of Clinical Pharmacology (OCP) / Division of Clinical Pharmacology III (DCPIII)
Jie Wang Ph.D., Clinical Pharmacology Team Leader
Anand Balakrishnan, Ph.D., Clinical Pharmacology Reviewer

Office of Pharmaceutical Quality (OPQ) / Office of New Drug Products / Division of Biopharmaceutics
Bryan Ericksen, Ph.D., Biopharmaceutics Reviewer

Office of New Drugs Policy
Richard Ishihara, Senior Policy Advisor

SPONSOR ATTENDEES

Neal I. Muni, M.D., MSPH, President and CEO; CutisPharma, Inc.
Zeus Pendon, Ph.D., Senior Director, Formulation Development; CutisPharma, Inc.
Se-Se Yennes, Vice President, Corporate Strategy & New Product Planning; CutisPharma, Inc.

Michael Beckloff, Chief Development Officer; Silvergate Pharmaceuticals Inc.
Susan Prather, Director Regulatory Affairs; Silvergate Pharmaceuticals Inc.
Elizabeth N. Dupras, RAC, Senior Director, Regulatory Agent; B&H Consulting Services, Inc.
Wei Miao, Regulatory Affairs Project Manager, Regulatory Consultant; B&H Consulting Services, Inc.

1.0 BACKGROUND

Omeprazole Powder for Oral Suspension is an immediate-release formulation that contains sodium bicarbonate which raises the gastric pH and thereby, protects omeprazole from acid degradation. The proposed product formulation is for (b) (4) , for reduction of risk of upper GI bleeding in critically ill patients, (b) (4) According to RxM™ Therapeutics, LLC, the kit is targeted to fulfill an unmet need for an omeprazole product that provides a palatable option for those individuals unable or unwilling to swallow capsules and tablets, and accommodates flexibility in dosing. The purpose of the requested meeting is to discuss the collected data and development plan to support a 505(b)(2) NDA for Omeprazole Powder for Oral Suspension Kit.

FDA sent Preliminary Comments to Sponsor on August 28, 2019.

2. DISCUSSION

Question 1: Does the Agency agree with the organization of the eCTD?

FDA Response to Question 1:
From technical perspective (and not content-related) the proposed approach is acceptable for all modules **except for 2.7 and 3.2.R**.
You should not create additional nodes beyond what is in the specifications. Instead, the submission needs to comply with ICH and FDA specifications. Ensure your approach fits the DTD and the "Granularity Annex", located here: https://www.fda.gov/media/71551/download. Please see below additional comments regarding modules 2.7 and 3.2.R.

Modules		Comment
Module 2	2.7.1	One document may be submitted at this level.
	2.7.2	One document may be submitted at this level.
	2.7.3	One document for each indication should be submitted, although closely related indications can be within a single document.
	2.7.4	One document may be submitted at this level.
	2.7.5	One document may be submitted at this level.
	2.7.6	One document may be submitted at this level.
Module 3	3.2.R	This folder should be included where regional information is appropriate. Reference should be made to regional guidance for the types of information to be included in this section. Refer to https://www.fda.gov/media/71551/download

Question 2: Does the Agency agree that the action on the NDA for Omeprazole Powder for Oral Suspension Kit will meet the criteria for categorical exclusion defined in 21 CFR 25.31(a) and that no environmental assessment is required?

FDA Response to Question 2:
Your proposal appears reasonable. However, the final determination will be made at the time of NDA review.

For further information, refer to the following Guidance on environmental assessment: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/environmental-assessment-human-drug-and-biologics-applications

Question 3: Does the Agency agree with the proposed approach to draft the PLR-format labeling for Omeprazole Powder for Oral Suspension Kit?

FDA Response to Question 3:
In principle, your proposal to include information from the FDA-approved labeling from both Zegerid and Prilosec delayed-release capsules would be reasonable provided you establish an adequate scientific bridge to each listed drug (LD).

Question 4: Does the Agency agree that the draft labeling for Omeprazole Powder for Oral Suspension Kit is adequate for submission in the planned 505(b)(2) NDA?

FDA Response to Question 4:
No, we do not agree. We consider sodium bicarbonate to be an active ingredient in your product, and this should be reflected in the proposed labeling. Ultimately, review and negotiations of labeling format and content will be addressed during the NDA review.

Meeting Discussion:
The Sponsor acknowledged sodium bicarbonate as an active ingredient in their product and agreed to update the draft labeling accordingly and as consistent with the labeling for the LD, Zegerid.

Question 5: Does the Agency agree that no additional nonclinical studies are needed to support the 505(b)(2) NDA application?

FDA Response to Question 5:
Yes, we agree that no additional nonclinical studies are necessary provided you establish an adequate scientific bridge between your product and each LD. You will also need to justify the safety of all inactive ingredients present in your product.

Question 6: Does the Agency agree that the data demonstrating the scientific bridge between the proposed Omeprazole Powder for Oral Suspension Kit and the Agency's findings of safety and efficacy for Zegerid® and PRILOSEC® DR are adequate to support a 505(b)(2) NDA?

FDA Response to Question 6:
No, we cannot agree at this time. You have conducted a relative BA study (OME-RM02-001) in healthy subjects comparing the pharmacokinetics of your product (omeprazole powder for oral suspension kit, RM-02, 40 mg) with the referenced products Zegerid (omeprazole/sodium bicarbonate powder for oral suspension, 40 mg) and omeprazole delayed-release capsules USP (40 mg). The adequacy of the relative BA results to establish a scientific bridge between your product and each LD will be determined after we have completed our formal review of the full study report and assessment of other factors including validation of the bioanalytical methods used in the PK study.

Question 7: Does the Agency agree that (b) (4)

FDA Response to Question 7:

(b) (4)

Meeting Discussion:

(b) (4)

Question 8: Does the Agency agree that submission of CRFs is not needed in the planned 505(b)(2) NDA?

FDA Response to Question 8:

Given the lack of deaths, SAEs, and discontinuations due to study drug related adverse events observed in your relative BA study, we agree with your proposal to not include CRFs with the NDA submission.

Question 9: Does the Agency agree that no specific Risk Evaluation and Mitigation Strategy or other risk minimization activities are needed for Omeprazole Powder for Oral Suspension Kit and that a routine pharmacovigilance approach can be applied once Omeprazole Powder for Oral Suspension Kit is marketed?

FDA Response to Question 9:

At this time, it does not appear that such activities in addition to routine pharmacovigilance are indicated; however, should the general scientific knowledge regarding the use and safety of PPIs evolve this may be revisited during the application review.

FDA Additional Comment:

We note the inclusion of language describing (b) (4)

(b) (4)

Meeting Discussion:

(b) (4)

Post Meeting Comment:
Regarding your overall development plan, we remind you that an agreed iPSP will be required prior to the submission of your planned NDA. As stated below in **Section 3.0 ADMINISTRATIVE COMMENTS, PREA REQUIREMENTS**, failure to include an Agreed iPSP with a marketing application could result in a refuse to file action.

3.0 ADMINISTRATIVE COMMENTS

PREA REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Please be advised that under the Food and Drug Administration Safety and Innovation Act (FDASIA), you must submit an Initial Pediatric Study Plan (iPSP) within 60 days of an End-of-Phase-2 (EOP2) meeting. In the absence of an EOP2 meeting, refer to the draft guidance below. The iPSP must contain an outline of the pediatric study or studies that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation, and any previously negotiated pediatric plans with other regulatory authorities. The iPSP should be submitted in PDF and Word format. Failure to include an Agreed iPSP with a marketing application could result in a refuse to file action.

For additional guidance on the timing, content, and submission of the iPSP, including an iPSP Template, please refer to the draft guidance for industry *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans*.[2] In addition, you may contact the Division of Pediatric and Maternal Health at 301-796-2200 or email Pedsdrugs@fda.hhs.gov. For further guidance on pediatric product development, please refer to FDA.gov.[3]

DATA STANDARDS FOR STUDIES

Under section 745A(a) of the FD&C Act, electronic submissions "shall be submitted in such electronic format as specified by [FDA]." FDA has determined that study data

[2] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[3] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm

contained in electronic submissions (i.e., NDAs, BLAs, ANDAs and INDs) must be in a format that the Agency can process, review, and archive. Currently, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data that use the standards specified in the Data Standards Catalog.[4]

On December 17, 2014, FDA issued the guidance for industry *Providing Electronic Submissions in Electronic Format--- Standardized Study Data.* This guidance describes the submission types, the standardized study data requirements, and when standardized study data will be required. Further, it describes the availability of implementation support in the form of a technical specifications document, Study Data Technical Conformance Guide,[5] as well as email access to the eData Team (cder-edata@fda.hhs.gov) for specific questions related to study data standards. Standardized study data will be required in marketing application submissions for clinical and nonclinical studies that started after December 17, 2016. Standardized study data will be required in commercial IND application submissions for clinical and nonclinical studies that started after December 17, 2017. CDER has produced a Study Data Standards Resources web page[6] that provides specifications for sponsors regarding implementation and submission of clinical and nonclinical study data in a standardized format. This web page will be updated regularly to reflect CDER's growing experience in order to meet the needs of its reviewers.

Although the submission of study data in conformance to the standards listed in the FDA Data Standards Catalog will not be required in studies that started on or before December 17, 2016, CDER strongly encourages IND sponsors to use the FDA supported data standards for the submission of IND applications and marketing applications. The implementation of data standards should occur as early as possible in the product development lifecycle, so that data standards are accounted for in the design, conduct, and analysis of clinical and nonclinical studies. For clinical and nonclinical studies, IND sponsors should include a plan (e.g., in the IND) describing the submission of standardized study data to FDA. This study data standardization plan (see the Conformance Guide) will assist FDA in identifying potential data standardization issues early in the development program.

If you have not previously submitted an eCTD submission or standardized study data, we encourage you to send us samples for validation following the instructions at FDA.gov.[7] For general toxicology, supporting nonclinical toxicokinetic, and

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[4] http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm

[5] http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf

[6] http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

[7] https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/Electro nicSubmissions/ucm174459.htm

carcinogenicity studies, submit data in the Standards for the Exchange of Nonclinical Data (SEND) format. The validation of sample submissions tests conformance to FDA supported electronic submission and data standards; there is no scientific review of content.

The Agency encourages submission of sample data for review before submission of the marketing application. These datasets will be reviewed only for conformance to standards, structure, and format. They will not be reviewed as a part of an application review. These datasets should represent datasets used for the phase 3 trials. The FDA Study Data Technical Conformance Guide[8] (Section 7.2 eCTD Sample Submission pg. 30) includes the link to the instructions for submitting eCTD and sample data to the Agency. The Agency strongly encourages Sponsors to submit standardized sample data using the standards listed in the Data Standards Catalog referenced on the FDA Study Data Standards Resources web site.[9] When submitting sample data sets, clearly identify them as such with **SAMPLE STANDARDIZED DATASETS** on the cover letter of your submission.

Additional information can be found at FDA.gov.[10]

LABORATORY TEST UNITS FOR CLINICAL TRIALS

CDER strongly encourages IND sponsors to identify the laboratory test units that will be reported in clinical trials that support applications for investigational new drugs and product registration. Although Système International (SI) units may be the standard reporting mechanism globally, dual reporting of a reasonable subset of laboratory tests in U.S. conventional units and SI units might be necessary to minimize conversion needs during review. Identification of units to be used for laboratory tests in clinical trials and solicitation of input from the review divisions should occur as early as possible in the development process. For more information, please see the FDA website entitled Study Data Standards Resources[11] and the CDER/CBER Position on Use of SI Units for Lab Tests website.[12]

SUBMISSION FORMAT REQUIREMENTS

[8] https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf
[9] https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
[10] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm
[11] http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
[12] https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM587505.pdf

The Electronic Common Technical Document (eCTD) is CDER and CBER's standard format for electronic regulatory submissions. The following submission types: **NDA, ANDA, BLA, Master File** (except Type III) and **Commercial INDs** must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit FDA.gov.[13]

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to the FDA and enables the secure submission of regulatory information for review. Submissions less than 10 GB must be submitted via the ESG. For submissions that are greater than 10 GB, refer to the FDA technical specification *Specification for Transmitting Electronic Submissions using eCTD Specifications*. For additional information, see FDA.gov.[14]

SECURE EMAIL COMMUNICATIONS

Secure email is required for all email communications from FDA when confidential information (e.g., trade secrets, manufacturing, or patient information) is included in the message. To receive email communications from FDA that include confidential information (e.g., information requests, labeling revisions, courtesy copies of letters), you must establish secure email. To establish secure email with FDA, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications (except for 7-day safety reports for INDs not in eCTD format).

PATIENT-FOCUSED ENDPOINTS

An important component of patient-focused drug development is describing the patient's perspective of treatment benefit in labeling based on data from patient-focused outcome measures [e.g., patient-reported outcome (PRO) measures]. Therefore, early in product development, we encourage sponsors to consider incorporating well-defined and reliable patient-focused outcome measures as key efficacy endpoints in clinical trials, when appropriate, and to discuss those measures with the Agency in advance of confirmatory trials. For additional information, refer to FDA's guidance for industry *Patient-Reported Outcome Measures: Use in Medical Product Development to Support Claims.*

505(b)(2) REGULATORY PATHWAY

The Division recommends that sponsors considering the submission of an application through the 505(b)(2) pathway consult the Agency's regulations at 21 CFR 314.54, and the draft guidance for industry *Applications Covered by Section 505(b)(2)* (October

[13] http://www.fda.gov/ectd
[14] http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway

1999).[15] In addition, FDA has explained the background and applicability of section 505(b)(2) in its October 14, 2003, response to a number of citizen petitions that had challenged the Agency's interpretation of this statutory provision (see Docket FDA-2003-P-0274-0015, available at Regulations.gov.[16]

If you intend to submit a 505(b)(2) application that relies for approval on FDA's finding of safety and/or effectiveness for one or more listed drugs, you must establish that such reliance is scientifically appropriate, and must submit data necessary to support any aspects of the proposed drug product that represent modifications to the listed drug(s). You should establish a "bridge" (e.g., via comparative bioavailability data) between your proposed drug product and each listed drug upon which you propose to rely to demonstrate that such reliance is scientifically justified.

If you intend to rely on literature or other studies for which you have no right of reference but that are necessary for approval, you also must establish that reliance on the studies described in the literature or on the other studies is scientifically appropriate. You should include a copy of such published literature in the 505(b)(2) application and identify any listed drug(s) described in the published literature (e.g. by trade name(s)).

If you intend to rely on the Agency's finding of safety and/or effectiveness for a listed drug(s) or published literature describing a listed drug(s) (which is considered to be reliance on FDA's finding of safety and/or effectiveness for the listed drug(s)), you should identify the listed drug(s) in accordance with the Agency's regulations at 21 CFR 314.54. It should be noted that 21 CFR 314.54 requires identification of the "listed drug for which FDA has made a finding of safety and effectiveness," and thus an applicant may only rely upon a listed drug that was approved in an NDA under section 505(c) of the FD&C Act. The regulatory requirements for a 505(b)(2) application (including, but not limited to, an appropriate patent certification or statement) apply to each listed drug upon which a sponsor relies.

If FDA has approved one or more pharmaceutically equivalent products in one or more NDA(s) before the date of submission of the original 505(b)(2) application, you must identify one such pharmaceutically equivalent product as a listed drug (or an additional listed drug) relied upon (see 21 CFR 314.50(i)(1)(i)(C), 314.54, and 314.125(b)(19); see also 21 CFR 314.101(d)(9)). If you identify a listed drug solely to comply with this regulatory requirement, you must provide an appropriate patent certification or statement for any patents that are listed in the Orange Book for the pharmaceutically equivalent product, but you are not required to establish a "bridge" to justify the scientific appropriateness of reliance on the pharmaceutically equivalent product if it is scientifically unnecessary to support approval.

If you propose to rely on FDA's finding of safety and/or effectiveness for a listed drug

[15] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[16] http://www.regulations.gov

that has been discontinued from marketing, the acceptability of this approach will be contingent on FDA's consideration of whether the drug was discontinued for reasons of safety or effectiveness.

We encourage you to identify each section of your proposed 505(b)(2) application that is supported by reliance on FDA's finding of safety and/or effectiveness for a listed drug(s) or on published literature (see table below). In your 505(b)(2) application, we encourage you to clearly identify (for each section of the application, including the labeling): (1) the information for the proposed drug product that is provided by reliance on FDA's finding of safety and/or effectiveness for the listed drug or by reliance on published literature; (2) the "bridge" that supports the scientific appropriateness of such reliance; and (3) the specific name (e.g., proprietary name) of each listed drug named in any published literature on which your marketing application relies for approval. If you are proposing to rely on published literature, include copies of the article(s) in your submission.

In addition to identifying the source of supporting information in your annotated labeling, we encourage you to include in your marketing application a summary of the information that supports the application in a table similar to the one below.

List the information essential to the approval of the proposed drug that is provided by reliance on the FDA's previous finding of safety and effectiveness for a listed drug or by reliance on published literature	
Source of information (e.g., published literature, name of listed drug)	**Information Provided (e.g., specific sections of the 505(b)(2) application or labeling)**
(1) Example: Published literature	*Nonclinical toxicology*
(2) Example: NDA XXXXXX "TRADENAME"	*Previous finding of effectiveness for indication A*
(3) Example: NDA YYYYYY "TRADENAME"	*Previous finding of safety for Carcinogenicity, labeling section B*
(4)	

Please be advised that circumstances could change that would render a 505(b)(2) application for this product no longer appropriate. For example, if a pharmaceutically equivalent product were approved before your application is submitted, such that your proposed product would be a "duplicate" of a listed drug and eligible for approval under section 505(j) of the FD&C Act, then it is FDA's policy to refuse to file your application as a 505(b)(2) application (21 CFR 314.101(d)(9)). In such a case, the appropriate submission would be an Abbreviated New Drug Application (ANDA) that cites the

duplicate product as the reference listed drug.

4.0 MEETING HANDOUT

See attached.

APPEARS THIS WAY ON ORIGINAL

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/s/

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IND126863

MEETING MINUTES

RxM™ Therapeutics, LLC
c/o B & H Consulting Services, Inc.
Elizabeth N. Dupras, RAC
Senior Director, Regulatory Affairs
50 Division Street, Suite 206
Somerville, New Jersey 08876

Dear Ms. Dupras:

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Omeprazole Powder for Oral Suspension Kit.

We also refer to the meeting between representatives of your firm and the FDA on Wednesday September 4, 2019. The purpose of the meeting was to discuss the Chemistry, Manufacturing and Control data to support a 505(b)(2) NDA for Omeprazole Powder for Oral Suspension Kit.

A copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call LCDR Oumou Barry, Regulatory Business Process Manager at, 240-402-8257.

Sincerely,

{See appended electronic signature page}

Hitesh Shroff, Ph.D.
CMC Lead
Office of New Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

- Meeting Minutes

U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM OF MEETING MINUTES

Meeting Type: B
Meeting Category: Pre-NDA

Meeting Date and Time: Wednesday, September 4, 2019, 3:00 PM to 4:00 PM EST
Meeting Location: FDA White Oak, Building 22, Room 1421

Application Number: 126863
Product Name: Oral Omeprazole Powder for Suspension Kit

Indication: For use in patients for (b) (4) reduction of risk of upper GI bleeding in critically ill patients (b) (4)

Sponsor Name: RxM™ Therapeutics, LLC (A Wholly Owned Subsidiary of CutisPharma, Inc.)

Meeting Chair: Hitesh Shroff, Ph.D
Meeting Recorder: Oumou Barry, MHA, MT, ASCP

FDA ATTENDEES

1. Hitesh Shroff, Ph.D., CMC Lead, Office of New Drug Products (ONDP)/Office of Pharmaceutical Quality (OPQ)/CDER
2. Sam Bain, Ph.D. API Reviewer, ONDP/OPQ/CDER
3. Kejun Cheng Ph.D., Manufacturing Process Reviewer, Office of Process and Facilities (OPF)/OPQ/CDER
4. Yaodong (Tony) Huang, Ph.D., Manufacturing Process Reviewer, OPF/OPQ/CDER
5. Bryan Ericksen, Ph.D., Biopharmaceutics Reviewer, ONDP/OPQ/CDER
6. Oumou Barry, MHA, MT, Regulatory Business Process Manager, Office of Program and Regulatory Operations (OPRO)/OPQ/CDER
7. Jason God, Ph.D. Microbiologist, OPF/OPQ/CDER`

SPONSOR ATTENDEES

1. Neal I. Muni, M.D., MSPH; President and CEO, CutisPharma, Inc.
2. Michael Beckloff, Chief Development Officer, Silvergate Pharmaceuticals Inc.
3. Susan Prather, Director Regulatory Affairs, Silvergate Pharmaceuticals Inc.
4. Zeus Pendon, Ph.D.; Senior Director, Formulation Development, CutisPharma, Inc.

5. Elizabeth N. Dupras, RAC; Senior Director, Regulatory Agent, B&H Consulting Services, Inc.
6. Wei Miao, Regulatory Affairs Project Manager, Regulatory Consultant, B&H Consulting Services, Inc.
7. SehamYennes, Vice President, Corporate Strategy & New Product Planning; CutisPharma, Inc.

1.0 BACKGROUND

The sponsor submitted this pre-NDA meeting request to discuss and obtain the FDA's feedback on CMC data to support a 505 (b)(2) NDA for Omeprazole Powder for Oral Suspension kit. The FDA granted the meeting request as a face-to-face meeting and the meeting was held on September 4, 2019. The product is being developed for use in patients for (b) (4) reduction of risk of upper GI bleeding in critically ill patients (b) (4) The sponsor intends to submit NDA via the 505(b)(2) path.

FDA sent Preliminary Comments to the sponsor on August 23, 2019.

2. DISCUSSION

2.1. Chemistry, Manufacturing and Controls

(b) (4)

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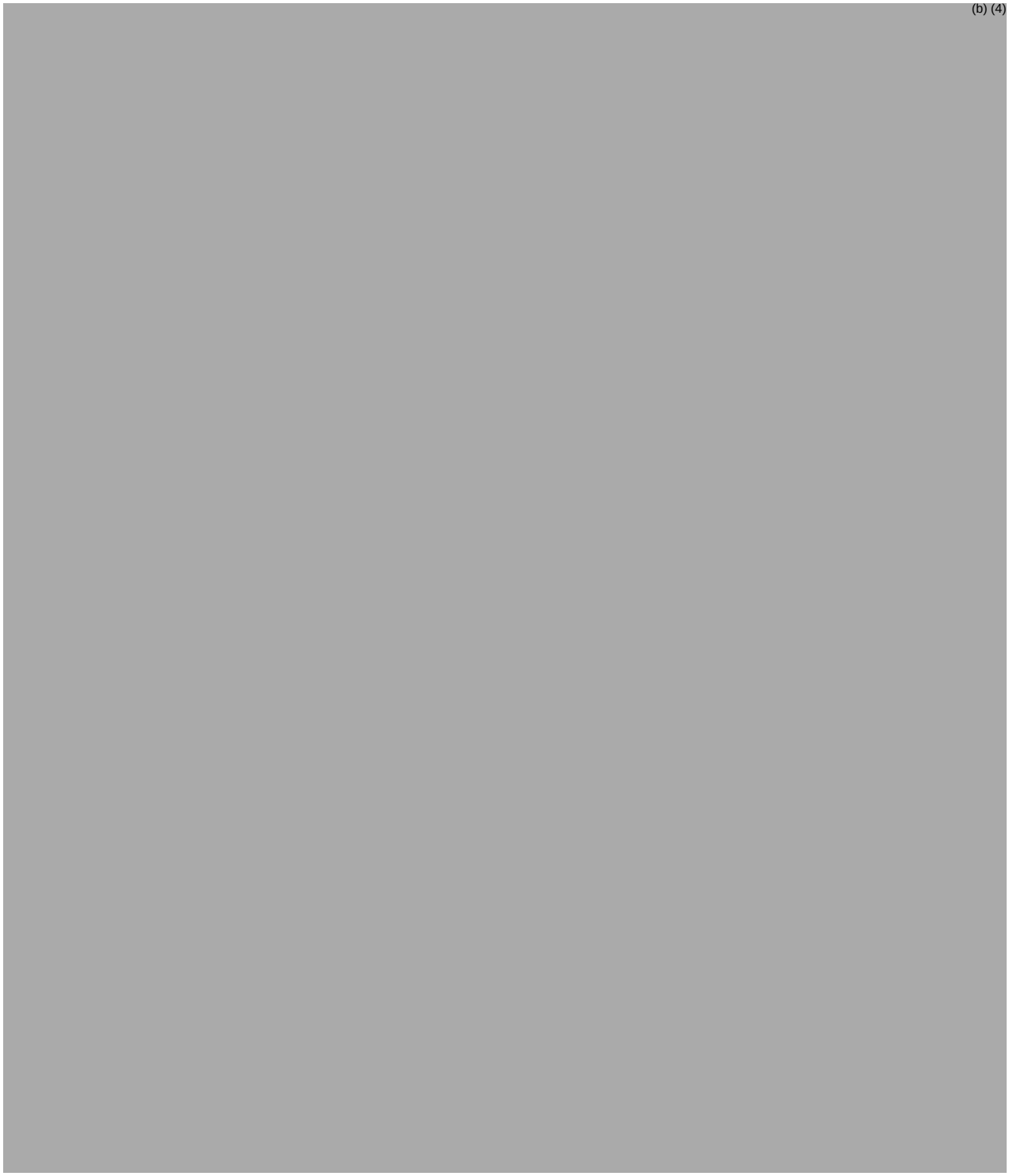

3.0 SUBMISSION FORMAT REQUIREMENTS

The Electronic Common Technical Document (eCTD) is CDER and CBER's standard format for electronic regulatory submissions. The following submission types: **NDA, ANDA, BLA, Master File** (except Type III) and **Commercial INDs** must be submitted in

eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit FDA.gov.[1]

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SECURE EMAIL COMMUNICATIONS

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4.0 ISSUES REQUIRING FURTHER DISCUSSION

There were no issues requiring further discussion.

5.0 ACTION ITEMS

There were no action items.

6.0 ATTACHMENTS AND HANDOUTS

See attached.

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[1] http://www.fda.gov/ectd
[2] http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway

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/s/

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