CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202535Orig1s000

CHEMISTRY REVIEW(S)

MEMORANDUM

Date: July 16, 2012

To: NDA 202-535

From: Terrance Ocheltree, Ph.D., R.Ph.
Director
Division of New Drug Quality Assessment II
ONDQA

Subject: Tertiary review of ONDQA recommendation for NDA 202-535, sodium picosulfate, magnesium oxide and anhydrous anhydrous citric acid (10 mg, 3.5 g, and 12 g, respectively) powder for oral solution, Picoprep™. Sodium picosulfate is a new molecular entity (NME).

I have assessed the ONDQA reviews of NDA 202-535 by Hitesh Shroff, Ph.D. The initial ONDQA CMC review was entered into DARRTS on May 16, 2012, with a recommendation for a Complete Response due to an absence of a recommendation from the Office of Compliance on the manufacturing and testing sites acceptability and pending labeling issues. A second CMC review was entered into DARRTS on July 13, 2012 by updating the status of the recommendation from the Office of Compliance. On July 09, 2012 the Office of Compliance entered an Overall Recommendation of "Acceptable" into EES.

All CMC related label/labeling issues were satisfactorily resolved through amendments dated July 13, 2012.

The ONDQA Biopharmaceutics review was not performed since the product is an oral solution (powder is dissolved prior to consumption) when used and the product acts locally within the gastro intestinal tract. Therefore, bioavailability and biopharmaceutics are not an issue.

Picoprep contains three drug substances: sodium picosulfate, anhydrous citric acid and magnesium oxide. The drug substances were each referenced by appropriate Letter of Authorization (LOA) to a Drug Master File (DMF).

- Anhydrous citric acid, DMF (b) (4), is manufactured and tested by (b) (4)
- Sodium picosulfate DMF (b) (4), is manufactured and tested by (b) (4)
- Magnesium oxide, DMF (b) (4), is manufactured and tested by (b) (4)

All three DMFs were reviewed and found to be adequate to support this NDA. For more information see DMF reviews for DMF (b) (4) completed on May 15, 2012, May 9, 2012 and April 17, 2012, respectively.

Picoprep powder for oral administration is packaged in a sachet (b) (4) . Each sachet contains 16.1 g of powder of white crystalline powder with a faint orange odor.

I concur with the determination that the information as provided in the NDA is adequate to assure the identity, strength, purity, and quality of the drug product and support the recommendation of a drug product shelf life of 24 months for the proposed commercial product when it is stored at controlled room temperature.

Secondary review of the CMC reviews was performed by Moo-Jhong Rhee, Ph.D.

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/s/

TERRANCE W OCHELTREE
07/16/2012

Memorandum DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: **July 12, 2012**

From: **Hitesh Shroff, Ph.D.**

Through: **Moo-Jhong Rhee, Ph.D.**
Chief, Branch IV
New Drug Quality Assessment Division II
ONDQA

To: **CMC Review #1 of NDA 202-535**

Subject: **Final Recommendation**

The CMC review #1 has noted the following two pending issues:

1. The Office of Compliance has issued an overall "Withhold" recommendation.
2. Label/labeling issues were not resolved.

And because of these deficiencies, in the CMC Review #1, this NDA was not recommended for approval from the ONDQA perspective.

On July 9, 2012, the Office of Compliance issued the "Acceptable" recommendation for the facilities involved in the NDA (see the **Attachment -1**).

On July 13, 2012, the label and labeling were submitted and they are revised satisfactorily from the ONDQA perspective (see the **Attachment-2**).

Final Recommendation:

This NDA is **now** recommended for approval from the ONDQA perspective.

Attachments:

Attachment-1

EES report

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application:	NDA 202535/000	**Sponsor:**	FERRING PHARMS AS
Org. Code:	180		4 GATEHALL DR 3RD FL
Priority:	1		PARSIPPANY, NJ 07054
Stamp Date:	16-SEP-2011	**Brand Name:**	Prepopik (sodium picosulfate, magnesium
PDUFA Date:	16-JUL-2012	**Estab. Name:**	
Action Goal:		**Generic Name:**	
District Goal:	17-MAY-2012	**Product Number; Dosage Form; Ingredient; Strengths**	001; POWDER, FOR ORAL SOLUTION; SODIUM PICOSULFATE; 10MG 001; POWDER, FOR ORAL SOLUTION; MAGNESIUM OXIDE; 3.5MG 001; POWDER, FOR ORAL SOLUTION; CITRIC ACID; 12GM

FDA Contacts:	C. TRAN-ZWANETZ	Project Manager	(HFD-800)	3017963877
	H. SHROFF	Review Chemist		3017962116
	M. KOWBLANSKY	Team Leader		3017961390

Overall Recommendation:	ACCEPTABLE	on 09-JUL-2012	by A. INYARD	(HFD-323)	3017965363
	PENDING	on 08-DEC-2011	by EES_PROD		
	PENDING	on 07-DEC-2011	by EES_PROD		
	PENDING	on 31-OCT-2011	by EES_PROD		
	PENDING	on 31-OCT-2011	by EES_PROD		

Establishment:	**CFN:**	(b) (4)	**FEI:**	(b) (4)	
				(b) (4)	
DMF No:				**AADA:**	
Responsibilities:				(b) (4)	
Profile:				**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION				
Milestone Date:	01-NOV-2011				
Decision:	ACCEPTABLE				
Reason:	BASED ON PROFILE				

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)
(b) (4)

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE PACKAGER

Profile: POWDERS (INCLUDES ORAL (b) (4) **OAI Status:** NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 08-DEC-2011

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: **CFN:** **FEI:** 3009226362

FERRING PHARMACEUTICALS (CHINA) CO. LTD
NO 6 HUILING LU (FERRING RD)

NTL HEALTH TECH PK, ZHONGSHAN, GUANGDONG, CHINA

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE MANUFACTURER

FINISHED DOSAGE OTHER TESTER

FINISHED DOSAGE PACKAGER

Profile: POWDERS (INCLUDES ORAL (b) (4) **OAI Status:** NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 03-JUL-2012

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)
(b) (4)

DMF No: **AADA:**

Responsibilities: (b) (4)

Profile: **OAI Status:** NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 01-NOV-2011

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Establishment: **CFN:** **FEI:** (b) (4)

DMF No: **AADA:**

Responsibilities: (b) (4)

Profile: **OAI Status:** NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 09-JUL-2012

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: **CFN:** **FEI:** (b) (4)

(b) (4)

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE STABILITY TESTER

Profile: (b) (4) **OAI Status:** NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 28-DEC-2011

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: **CFN:** **FEI:** (b) (4)

(b) (4)

DMF No: **AADA:**

Responsibilities: (b) (4)

Profile: **OAI Status:** NONE

Last Milestone: OC RECOMMENDATION

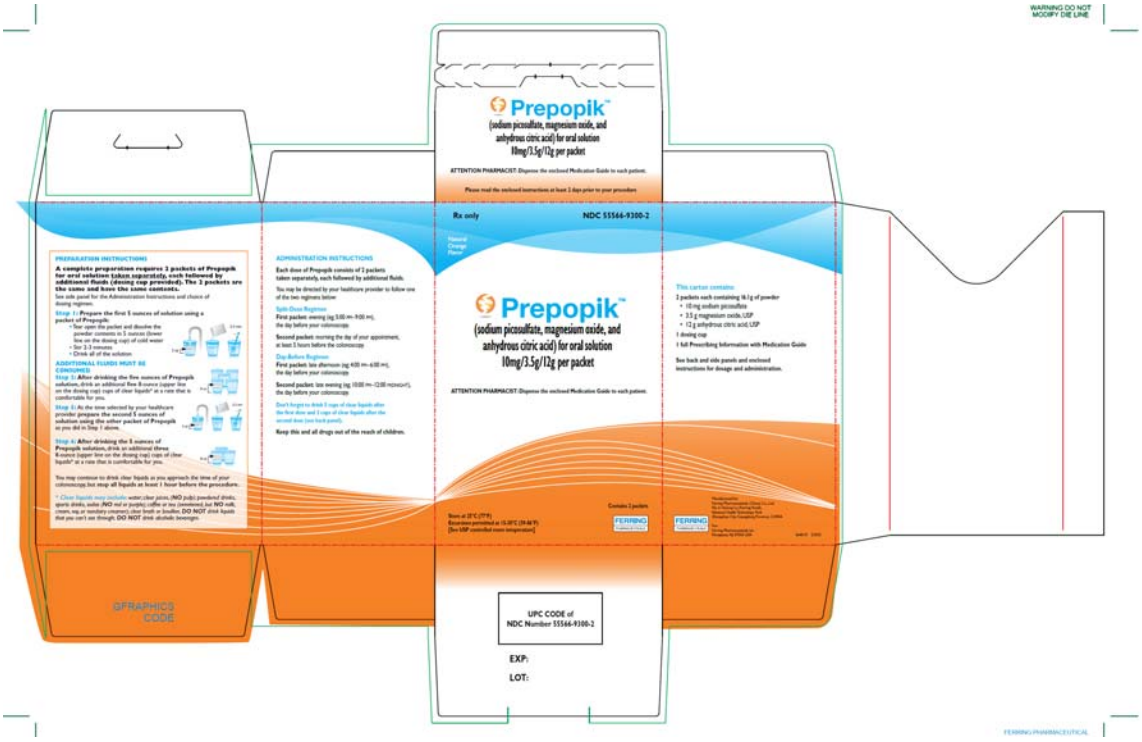
Milestone Date: 04-JAN-2012

Decision: ACCEPTABLE

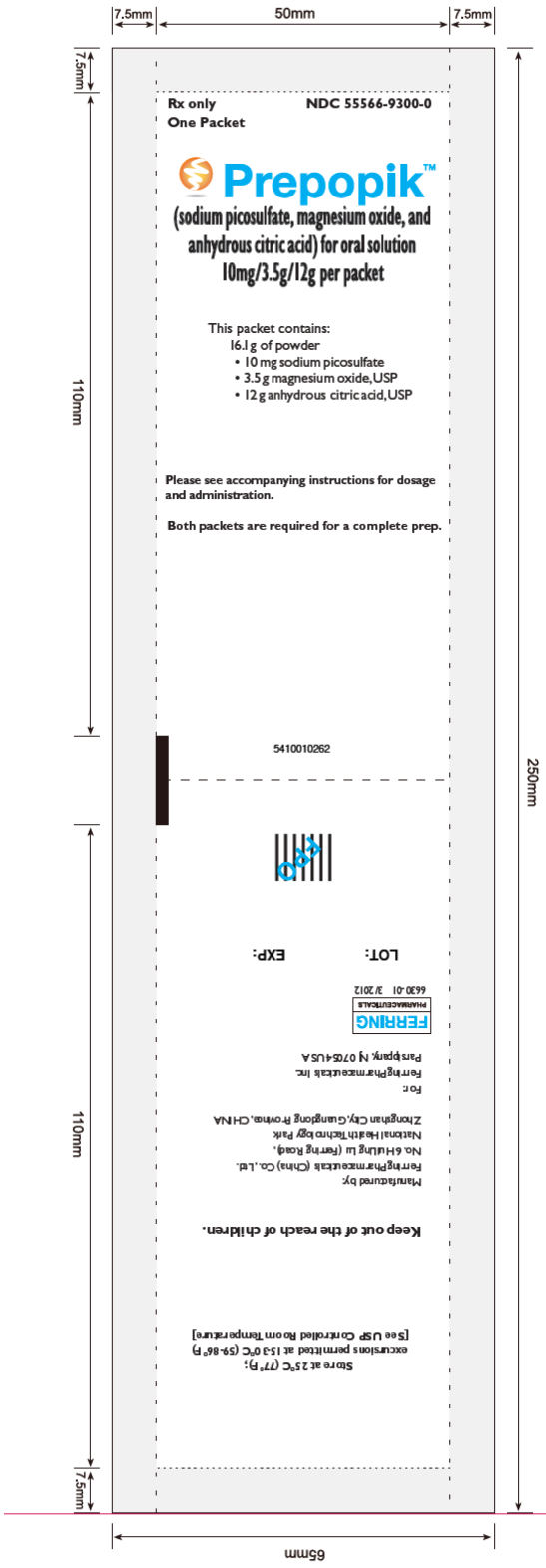
Reason: DISTRICT RECOMMENDATION

Attachment-2.

Carton



Packet


7.5mm
50mm
7.5mm
7.5mm
110mm
250mm
110mm
7.5mm
65mm
Rx only
NDC 55566-9300-0
One Packet
Prepopik™
(sodium picosulfate, magnesium oxide, and anhydrous citric acid) for oral solution
10mg/3.5g/12g per packet
This packet contains:
16.1 g of powder
• 10 mg sodium picosulfate
• 3.5 g magnesium oxide, USP
• 12 g anhydrous citric acid, USP
Please see accompanying instructions for dosage and administration.
Both packets are required for a complete prep.
5410010262
LOT:
EXP:
6630-01 3/2012
FERRING
PHARMACEUTICALS
Store at 25°C (77°F);
excursions permitted at 15-30°C (59-86°F)
[See USP Controlled Room Temperature]
Keep out of the reach of children.
Manufactured by:
FerringPharmaceuticals (China) Co., Ltd.
No. 6 Hulng Ii (Ferring Road),
National Health Technology Park
Zhongshan City, Guangdong Province, CHINA
For:
FerringPharmaceuticals Inc.
Parsippany, NJ 07054 USA

Labeling & Package Insert

1. Package Insert

(a) "Highlights" Section

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PREPOPIK safely and effectively. See full prescribing information for PREPOPIK.

PREPOPIK (sodium picosulfate, magnesium oxide, and anhydrous citric acid) for oral solution
Initial U.S. Approval: 2012

(b) "Full Prescribing Information" Section

#3. Dosage Form and Strength

3 DOSAGE FORMS AND STRENGTHS
For oral solution: each of the two packets contains 10 mg of sodium picosulfate, 3.5 grams of magnesium oxide, and 12.0 grams of anhydrous citric acid in 16.1 grams of powder

#11. Description

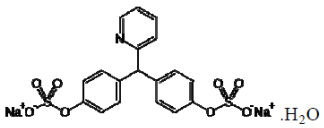
11 DESCRIPTION
PREPOPIK (sodium picosulfate, magnesium oxide and anhydrous citric acid) for oral solution is provided in two packets, the contents of each to be dissolved in 5 ounces of cold water and consumed.

Each packet contains 10 mg sodium picosulfate, 3.5 g magnesium oxide and 12 g anhydrous citric acid. The product also contains the following inactive ingredients, potassium hydrogen carbonate, saccharine sodium, and spray dried orange flavor which contains acacia gum, lactose, ascorbic acid and butylated hydroxyanisole. The following is a description of the three active ingredients:

Sodium picosulfate is a stimulant laxative.

Sodium picosulfate

- Chemical name: 4,4´-(2-pyridylmethylene) diphenyl bis(hydrogen sulfate) disodium salt, monohydrate
- Chemical formula: $C_{18}H_{13}NNa_2O_8S_2.H_2O$
- Molecular weight: 499.4
- Structural formula:



$.H_2O$

- Sodium picosulfate

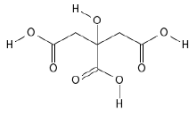
Magnesium citrate, which is formed in solution by the combination of magnesium oxide and anhydrous citric acid, is an osmotic laxative.

Magnesium oxide

- Chemical name: Magnesium oxide
- Chemical formula: Mg O
- Molecular weight: 40.3
- Structural formula: Mg O

Anhydrous citric acid

- Chemical name: 2-hydroxypropane-1,2,3-tricarboxylic acid
- Chemical formula: $C_6H_8O_7$
- Molecular weight: 192.1
- Structural formula:



Anhydrous citric acid

#16. How Supplied/Storage and Handling

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

PREPOPIK is supplied in a carton containing 2 packets, each holding 16.1 grams of powder for oral solution, along with a pre-marked dosing cup. Each packet contains 10 mg sodium picosulfate, 3.5 g magnesium oxide and 12 g anhydrous citric acid. The excipients include potassium hydrogen carbonate, sodium saccharin, spray dried orange flavor which contains acacia gum, lactose, ascorbic acid, and butylated hydroxyanisole.

Storage

Store at 25°C (77°F). Excursions permitted at 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

NDC# 55566-9300-2 Kit, 2 packets and cup

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/s/

HITESH N SHROFF
07/13/2012

MOO JHONG RHEE
07/13/2012
Chief, Branch IV

NDA 202-535

Picoprep (sodium picosulfate, magnesium oxide and anhydrous anhydrous citric acid) powder for oral solution 10 mg, 3.5 g, and 12 g

Ferring Pharmaceuticals Inc.

Hitesh Shroff, Ph.D.
Review Chemist

Office of New Drug Quality Assessment
Division of New Drug Quality Assessment II
Branch IV

CMC Review of NDA 202-535
For the Division Gastrointestinal and Inborn Errors Products (HFD-180)

Table of Contents

Chemistry Review Data Sheet

1. NDA 202-535

2. REVIEW:#1

3. REVIEW DATE: 16-May-2012

4. REVIEWER: Hitesh Shroff, Ph.D.

5. PREVIOUS DOCUMENTS: N/A

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	16-Sep-2011

1. NAME & ADDRESS OF APPLICANT

Name:	Ferring Pharmaceuticals Inc.
Address:	4 Gatehall Drive, Third Floor Parsippany, NJ 07054
Representative:	John B. Berryman Senior Director, Regulatory Affairs
Telephone:	973-796-1746

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Picoprep

b) Non-Proprietary Name (USAN): sodium picosulfate, magnesium oxide and anhydrous citric acid

b) Code Name/# (ONDQA only): None

c) Chem. Type/Submission Priority (ONDQA only):

- Chem. Type: 1 (sodium picosulfate)
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: Irrigation

11. DOSAGE FORM: Powder for oral solution

12. STRENGTH/POTENCY: 10 mg Sodium picosulfate, 3.5 g Magnesium oxide and 12 g Anhydrous citric acid

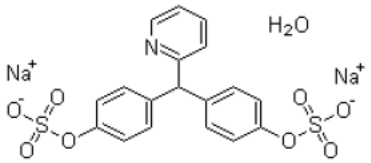
13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: X Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM:
_____SPOTS product – Form Completed

__X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

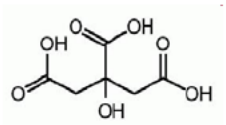


Sodium picosulfate

USAN Name:	Sodium picosulfate
Chemical name:	(pyridine-2-ylmethylene)bisphenyl bis (sodium sulfate), monohydrate Disodium [4-[pyridin-2-yl-(4-sulfonatooxyphenyl) methyl]phenyl] sulfate hydrate 4,4'-(2-Pyridylmethylene)diphenyl bis(hydrogen sulfate) disodium salt, monohydrate
CAS number:	10040-45-6
Molecular Formula:	$C_{18}H_{13}NNa_2O_8S_2.H_20$
Molecular Weight:	499.4

MgO
Magnesium oxide

Compendial /Chemical Name:	Magnesium oxide
CAS number:	1309-48-4
Molecular Formula:	MgO
Molecular Weight:	40.30



Anhydrous citric acid

Compendial Name: Anhydrous citric acid

Chemical Name: 1,2,3-Proanetricarboxylic acid, 2-hydroxy citric acid
CAS Name: 77-92-9
Molecular Formula: $C_6H_8O_7$
Molecular Weight: 192.13

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	II	(b) (4)	sodium picosulfate	1	Adequate	May 9, 2012	Reviewed by Hitesh Shroff, Ph.D.
	II		magnesium oxide	1	Adequate	April 17, 2012	Reviewed by Hitesh Shroff, Ph.D.
	II		anhydrous citric acid	1	Adequate	May 15, 2012	Reviewed by Hitesh Shroff, Ph.D.
	III		(b) (4)	4			Information provided in NDA

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")
[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: N/A

18. STATUS:

ONDQA:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Pending		
Pharm/Tox	N/A		
Biopharm	N/A		
LNC	N/A		

Methods Validation	Acceptable	May 2, 2012	Michael Trehy
DMEPA	N/A		
EA	Claim for categorical exclusion is granted	Mar 8, 2012	Raanan Bloom
Microbiology	N/A		

The Chemistry Review for NDA 202-535

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The NDA has provided sufficient information to assure identity, strength, purity and quality of the drug product.

However, the label/labeling issues are still ***not*** satisfactorily resolved.

Also, a site recommendation from the Office of Compliance has ***not*** been made as of the date of this review.

Therefore, from the ONDQA perspective, this NDA is ***not*** recommended for approval in its present form per 21 CFR 314.125(b)(6) and (13) until these pending issues are resolved.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

No recommendations at this time.

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

(1) Drug Substances

Picoprep contains three active ingredients: sodium picosulfate, anhydrous citric acid and magnesium oxide. Sodium picosulfate is manufactured at (b) (4) The CMC information is provided in DMF (b) (4). It was reviewed on 05-09-12 and found to be adequate. Anhydrous citric acid is manufactured at (b) (4) The CMC information is provided in DMF (b) (4) It was reviewed on 05-15-12 and found to be adequate. Magnesium oxide is manufactured at (b) (4) The CMC information is provided in DMF (b) (4). It was reviewed on 04-17-12 and found to be adequate. The applicant provided LOAs to reference above mentioned DMFs for CMC information.

(2) Drug Product

Picoprep powder for oral administration is a white crystalline powder with a faint orange odor. Picoprep is packaged in a sachet (b) (4) Each sachet contains 16.1 g of powder. Picoprep contains the following inactive

ingredients, potassium hydrogen carbonate, saccharin sodium (b) (4) and orange flavoring, (b) (4) spray dried (b) (4).

The key steps in the manufacturing process of Picoprep are (b) (4) Three production scale batches, each consisting of (b) (4) Picoprep powder (b) (4) were produced.

The release specification of the finished product include appearance, identification, assay of each active ingredient, uniformity of dosage units, impurities, and microbial limits, and they are deemed adequate to assure the identity, strength, purity, and quality of the drug product.

Based on the stability data from three production scale batches of Picoprep at long term (18 months) and accelerated (6 months) conditions, the proposed 24 months expiration dating period, when stored at room temperature, is granted.

B. Description of How the Drug Product is Intended to be Used

Picoprep powder is a stimulant laxative and osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults. One dose of PICOPREP consists of 2 pouches, each dissolved in 5 ounces of cold water and administered at separate times. PICOPREP is supplied in cartons containing 2 pouches and a pre-marked dosing cup.

C. Basis for Not-Approval Recommendation

21 CFR 314.125 (b)(6)

- The label/labeling issues are still pending (see the **List of Deficiencies**, p. 63)

21 CFR 314.125 (b)(13)

- No overall "ACCEPTABLE" site recommendation has been made from the Office of Compliance for this application.

III. Administrative

A. Reviewer's Signature

Hitesh Shroff, Ph.D./ May 16, 2012

B. Endorsement Block

Moo-Jhong Rhee, Ph.D., Branch Chief, Branch IV, Division 2

C. CC Block

Marie Kowblansky, Ph.D.

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/s/

HITESH N SHROFF
05/16/2012

MOO JHONG RHEE
05/16/2012
Chief, Branch IV

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

METHODS VALIDATION REPORT SUMMARY

TO: Hitesh Shroff, CMC Reviewer
Office of New Drug Quality Assessment (ONDQA)
E-mail Address: hitesh.shroff@fda.hhs.gov
Phone: (301)-796-2116
Fax: (301)-796-9877

FROM: FDA
Division of Pharmaceutical Analysis
Michael Trehy, MVP Coordinator
Suite 1002
1114 Market Street
St. Louis, MO 63101
Phone: (314) 539-3815

Through: Benjamin J. Westenberger, Deputy Director
Phone: (314) 539-3869

SUBJECT: Methods Validation Report Summary

Application Number: NDA 202535

Name of Product: PICOPREP (sodium picosulfate, magnesium oxide, and citric acid)

Applicant: Ferring Pharmaceuticals

Applicant's Contact Person: John Berryman, Senior Director of Regulatory Affairs

Address: 4 Gatehall Drive, Third Floor, Parsippany, NJ 07054

Telephone: (973) 796-1746 Fax: (973) 796-1694

Date Methods Validation Consult Request Form Received by DPA: 11/22/2011

Date Samples Received by DPA: 12/27/2011

Date Analytical Completed by DPA: 5/1/2012

Laboratory Classification: **1.** Methods are acceptable for control and regulatory purposes. ☒
2. Methods are acceptable with modifications (as stated in accompanying report). ☐
3. Methods are unacceptable for regulatory purposes. ☐

Comments: Cover memo and summary of results are attached.

Center for Drug Evaluation and Research
Division of Pharmaceutical Analysis
St. Louis, MO 63101
Tel. (314) 539-3815

Date: May 1, 2012

To: Hitesh Shroff, CMC Reviewer (HFD-800)
Marie Kowblansky, CMC Lead (HFD-800)

Through: B. J. Westenberger, Deputy Director, Division of Pharmaceutical Analysis, (HFD-920)

From: Michael Trehy, Chemist (HFD-920)

Subject: Method Validation for NDA 202535
PICOPREP (sodium picosulfate, magnesium oxide, and citric acid)

The method is acceptable for quality control and regulatory purposes.

- Q-3.2.P.5.2 Analytical Procedure-3566; Ver.2.0 PLU-01 Identification, Assay and Content Uniformity of Sodium Picosulfate in PICOPREP

The Division of Pharmaceutical Analysis (DPA) has the following comment pertaining to this method.

The Division of Pharmaceutical Analysis (DPA) strongly suggests the inclusion of system suitability requirements in the procedure. System suitability requirements should be added to the method to assure that the HPLC is performing adequately to obtain quality data. Typical system suitability requirements for an assay by HPLC are reproducibility, peak symmetry and theoretical plates. Reproducibility is an indicator of the performance of the HPLC and peak symmetry and theoretical plates are indicators of the performance of the column and HPLC.

Summary of Results

Method: Q-3.2.P.5.2 Analytical Procedure-3566; Ver.2.0 PLU-01 Identification, Assay and Content Uniformity of Sodium Picosulfate in PICOPREP

Test	Found	Specification
ID	(b) (4)	Passes
Assay		
Avg (2)		Passes
CU n=3		Passes

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/s/

MICHAEL L TREHY
05/01/2012

BENJAMIN J WESTENBERGER
05/02/2012