CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204311Orig1s000

CLINICAL REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Division of Antivirals
Food and Drug Administration
Center for Drug Evaluation and Research
Silver Spring, MD 20993

Addendum Regulatory/Administrative and Labeling

Date	**December 19, 2023**
From	**Monica Zeballos, Pharm.D. Senior Program Consultant Division of Antivirals (DAV)**
Through	**Sarita Boyd, Pharm.D., Associate Director for PEPFAR, DAV**
NDA Number	**NDA 204311-ORIG-1-RESUB-39**
Original Regulatory Action and Date	**PEPFAR, Tentative Approval (TA) on 23Oct2014**
Applicant	**Mylan Laboratories Limited, a Viatris Company, India (Mylan)**
U.S. Agent	**Mylan Pharmaceuticals Inc. a Viatris Company POC: Beth Britton, Senior Director, Regulatory Affairs**
Letter Date	**22June2023**
Stamp Date	**22June2023**
PDUFA Resubmission Goal Date	**Friday, 22Dec2023**
Established Name	**Abacavir and Lamivudine Tablets for Oral Suspension**
Proprietary Name	**None**
Dosage Form/Strength	**Tablets for Oral Suspension, 60 mg/30 mg**
Subject	**Class 2 Resubmission after a TA, Requesting Final Approval**
Materials Reviewed and Labeling Consultant Reviews	**1. Electronic Resubmissions [SDN35 dated/received 15July2023, SDN042 dated/received 06Dec2023 (container labels)] in DARRTS and project NDA-204311-ORIG-1-RESUB-39 dated/received 22June2023 in Panorama 2. U.S. labeling for the reference products[a]: a) NDA 20978/S038 ZIAGEN (abacavir) oral solution, 20 mg/mL approved 24Nov2020, b) NDA 20596/S038 EPIVIR (lamivudine) oral solution, 10 mg/mL approved on 10May2019 3. OSE/DMEPA[b] Review of the PI (Prescribing Information) and Carton/Container Labeling dated 15Sep2023, which has no recommendations 4. OMP/OPDP[c] Review of for the PI and Warning Card (WC) in PDF and Container Labeling dated 13Dec2023 5. Collaborative OMP/OPDP and OMP/DMPP[d] Review of the Medication Guide (MG) and Instructions for Use (IFU), both in Word and PDF, dated 11Dec2023**
Recommended	**Approval**

[a]Stacey Min, Pharm.D.,DAV's Associate Director for Labeling (ADL), reviewed the proposed PI utilizing these materials.
[b]Office of Surveillance and Epidemiology/Division of Medication Error Prevention and Analysis
[c]Office of Medical Policy/Office of Prescription Drug Promotion (formerly DDMAC)
[d]Office of Medical Policy/Division of Medical Policy Programs (Patient Labeling Team)

I. Background

This memo serves as an addendum to my 02July2019 clinical labeling/regulatory memo for NDA 204311, which was in response to Mylan's 06Feb2019 request to gain final approval (FA). The original NDA 204311 initially received on 23Dec2013 was granted tentative approval (TA) on 23Oct2014.

Subsequently, the 06Feb20219 FA request was issued two CR (complete response) actions due to deficiencies as follows:

1. On 06Aug2019 due to inspectional issues for a manufacturing facility [[Mylan Laboratories Limited (Unit-8), FEI # 30002785310]. Mylan submitted a complete resubmission (class 2) on 15July2022. This resubmission included updated proposed labeling.
2. On 13Jan2023, a second CR action was issued due inspectional issues for a manufacturing facility [Mylan Laboratories Limited (Unit-8), a Viatris Company, FEI # 30002785310]. Mylan submitted a complete resubmission (class 2) on 22June2023. This resubmission did not include updated proposed labeling.

As a 505(b)(2) NDA, OND's 505(b)(2) Clearance Committee cleared this NDA for approval on 14Nov2023.

Since the 19Feb2019 FA request, Mylan has not submitted additional change amendments. Previously, Mylan submitted 8 manufacturing change amendments that OPQ reviewed and issued PEPFAR Permitted letters for all of them.

II. Labeling Review

Refer to my memorandum dated my 02July2019 clinical labeling/regulatory memo, summarizing the labeling revisions in support of the FA request.

Stacey Min, Pharm. D., DAV's ADL, and the review team reviewed and compared the PI, MG, and IFU for this pediatric fixed-combination product to the latest approved U.S. labeling for ZIAGEN and EPIVIR and the labeling revisions were conveyed to Mylan 07Dec2023. Additional labeling recommendations for the MG, WC, and IFU from our consulting offices (OMP/OPDP and OMP/DMPP) were conveyed to Mylan on 19Dec2023. The annotated PI and MG sent to Mylan on 07Dec2023 and annotated MG, WC, and IFU sent to Mylan on 19Dec2023 are attached at the end of this addendum. Labeling recommendations for the carton and container labels were addressed separately.

Of note, OPQ review team determined to retain the storage language of "Store below 30°C (86°F)." in all proposed labeling.

III. Recommended Regulatory Action

The PI, MG, IFU, and WC were reviewed and should allow for the safe and effective use of this product. Mylan has adequately responded to the Division's labeling revisions conveyed on 07Dec2023, 19Dec2023, and 21Dec2023 via official submission received on 21Dec2023; therefore, an approval action is recommended.

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Monica Zeballos, Pharm.D.

Senior Program Consultant
Division of Antivirals
Office of Infectious Diseases
Office of Antimicrobial Products

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MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Division of Antiviral Products
Food and Drug Administration
Center for Drug Evaluation and Research
Silver Spring, MD 20993

Clinical Labeling and Regulatory Review

Date	**July 2, 2019**
From	**Monica Zeballos, Pharm.D.** **Program Coordinator** **Division of Antiviral Products (DAVP)**
Through	**Sarita Boyd, Pharm.D., Sr. Clinical Analyst, DAVP**
NDA Number	**NDA 204311**
Original Regulatory Action and Date	**PEPFAR, Tentative Approval (TA) on 23Oct2014**
Applicant	**Mylan Laboratories Limited (Mylan), India**
U.S. Agent	**Mylan Pharmaceuticals Inc.; POC: Shane Shupe, Director, Regulatory Affairs**
Letter Date	**06Feb2019**
Stamp Date	**06Feb2019**
Goal Date	**Tuesday, 06Aug2019**
Established Name	**Abacavir and Lamivudine Tablets for Oral Suspension**
Proprietary Name	**None**
Dosage Form/Strength	**Tablets for Oral Suspension, 60 mg/30 mg**
Subject	**Class 2 Resubmission to a TA, Requesting Final Approval**
Materials Reviewed and Labeling Consultant **Reviews**	**1. Electronic Resubmissions [SDN21 dated/received 06Feb2019, SDN023 dated/received 18April2019, and SND08 dated/received 28Oct2014 (container & carton labels)] in DARRTS and project NDA-204311-ORIG-1-RESUB-21 dated/received 06Feb2019 in Panorama** **2. Current U.S. labeling for the reference products: a) NDA 20978/S036 & S037 ZIAGEN (abacavir) oral solution, 20 mg/mL approved 09May2018, b) NDA 20596/S038 EPIVIR (lamivudine) oral solution, 10 mg/mL approved on 10May2019** (b) (4) (b) (4) **3. OSE/DMEPA Review of the PI (Prescribing Information), Medication Guide (MG), Warning Cards (WC), and Container & Carton Labeling dated 12July2019** **4. OPQ[b] Labeling Recommendations for the PI, MG, WC (in PDF), and Container & Carton Labeling dated 01July2019** **5. OMP/OPDP[c] Review of the PI, MG, WC (both in PDF & Word), and Container & Carton Labeling dated 25July2019** **6. Collaborative OMP/OPDP[c] and OMP/DMPP[d] Review of the MG and recommending a new Instructions for Use (IFU) dated 26July2019**
Recommended	**Complete Response**

[a]Office of Surveillance and Epidemiology/Division of Medication Error Prevention and Analysis
[b]Office of Pharmaceutical Quality
[c]Office of Medical Policy/Office of Prescription Drug Promotion (formerly DDMAC)
[d]Office of Medical Policy/Division of Medical Policy Programs (Patient Labeling Team)

I. Background

This complete 505(b)(2) application was originally submitted on 23Dec2013 and was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR) and granted tentative approval (TA) on 23Oct2014.

On 06Feb2019, Mylan submitted a class 2 resubmission after a TA to gain final approval and marketing in the United States with expiration of patent/exclusivity protection for the reference products.

Because NDA 204311 is eligible for final approval, Mylan complied with all the requirements for approval such as participation in the Antiretroviral Pregnancy Registry and labeling that comply with all U.S. regulations (uniqueness of drug product appearance per 21 CFR 206; child-resistant packaging per 16 CFR 1700, etc.). In addition, OND's 505(b)(2) Clearance Committee cleared NDA 204311 for complete response (CR) on 24July2019 or approval on or after 05Aug2019 (the day after the patent extended with pediatric exclusivity expires on ZIAGEN).

As a change in dosage form (from oral solution to scored tablet for oral suspension), this NDA triggered PREA (Pediatric Research Equity Act) and on 17July2019, the Pediatric Review Committee (PeRC) granted a (b) (4) (b) (4) DAVP later determined to also continue using the age limit for this product.

Mylan's proposed indication was for use "in combination with other antiretroviral agents for the treatment of HIV-1 infection." DAVP revised the indication to "in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients aged 3 months and older or weighing at least 5 kg."

To date, Mylan has submitted 8 manufacturing amendments that allowed changes to this NDA after TA and were internally tracked and reviewed as manufacturing supplements. OPQ has reviewed all 8 manufacturing amendments and issued PEPFAR Permitted letters for all of them. No labeling amendments were submitted, and there are no pending or further manufacturing changes submitted for review.

II. Labeling Review

Refer to my memorandum dated 30Sept2014, summarizing the labeling revisions in support of the initial TA.

All sections of the PI, MG, and WC (both in PDF & Word) for this pediatric 2-drug fixed combination product were reviewed, updated, and compared to the latest approved U.S. labeling for (b) (4) EPIVIR, and ZIAGEN. Labeling recommendations for the PI, MG, WC, and a new IFU from consulting offices (OPQ, OSE/DMEPA, OMP/OPDP and OMP/DMPP) are included in the annotated PI/WC and clean versions of the MG and IFU sent to Mylan on 06Aug2019. The content and format of the MG were completely reformatted to be consistent with the PI and current practices. The annotated PI/WC and

clean MG and IFU containing comments to the applicant are attached at the end of this memo. Labeling recommendations for the container and carton labels were addressed separately. All the PI's FPI (Full Prescribing Information) sections (except subsection 7.3 and section 12) were reviewed. However, pending subsection 7.3 and section 12 will be addressed during the next review cycle, and an addendum to this memo will be generated.

The content and format of the proposed PI has been updated and revised. Notable revisions include:

1. Because there is no proprietary name for this product, the Division considers "abacavir and lamivudine tablets for oral suspension" the drug product in singular vs. the plural tablets, thus "is" was used throughout the PI when referring to the drug product. In addition, in this case, the Division prefers adding the word "tablets for oral suspension" as part of the drug product name because omitting it creates ambiguity for some sentences.

2. Revised the proposed INDICATION AND USAGE section as follows:

Abacavir and lamivudine tablets for oral suspension, in combination with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in pediatric patients aged 3 months and older or weighing at least 5 kg.

3. Added the following to DOSAGE AND ADMINISTRATION section:

2.2 Recommended Dosage for Pediatric Patients Aged 3 Months and Older or Weighing at Least 5 kg

The recommended oral dose of abacavir and lamivudine tablets for oral suspension in HIV-1-infected pediatric patients aged 3 months and older or weighing at least 5 kg is abacavir 8 mg/kg/dose orally twice daily or abacavir 16 mg/kg/dose orally once daily (up to a maximum of 600 mg daily) and lamivudine 4 mg/kg/dose orally twice daily or lamivudine 8 mg/kg/dose orally once daily (up to a maximum of 300 mg daily) in combination with other antiretroviral agents. The recommended oral dosage of abacavir and lamivudine tablets for oral suspension for HIV-1-infected pediatric patients is presented in Table 1.

Table 1. Dosing Recommendations for Abacavir and Lamivudine Scored Tablets for Oral Suspension for Pediatric Patients Aged 3 Months and Older or Weighing at Least 5 kg

Weight (kg)	Once-daily Dosing Regimen[a]	Twice-daily Dosing Regimen		
		AM Dose	PM Dose	Total Daily Dose (mg)
5 to less than 6	1 ½ tablets	½ tablet	1 tablet	90 mg ABC/45 mg 3TC
6 to less than 9	2 tablets	1 tablet	1 tablet	120 mg ABC/60 mg 3TC
9 to less than 12	3 tablets	1.5 tablets	1.5 tablets	180 mg ABC/90 mg 3TC
12 to less than 17	4 tablets	2 tablets	2 tablets	240 mg ABC/120 mg 3TC

17 to less than 20	5 tablets	2.5 tablets	2.5 tablets	300 mg ABC/150 mg 3TC
20 to less than 25	6 tablets	3 tablets	3 tablets	360 mg ABC/180 mg 3TC
25 to less than 29	7 tablets	3.5 tablets	3.5 tablets	420 mg ABC/210 mg 3TC
29 to less than 35	8 tablets	4 tablets	4 tablets	480 mg ABC/240 mg 3TC
35 and greater	10 tablets[c]	5 tablets[b]	5 tablets[b]	600 mg ABC/300 mg 3TC

ABC = abacavir; 3TC = lamivudine

[a] Data regarding the efficacy of once-daily dosing is limited to subjects who transitioned from twice-daily dosing to once-daily dosing after 36 weeks of treatment *[see Clinical Studies (14.2)]*.

[b] For recommended doses of abacavir 300 mg twice-daily and lamivudine 150 mg twice-daily (adult maximum daily dose), the adult formulations (abacavir 300 mg tablet and lamivudine 150 mg tablet) can be used.

[c] For recommended dose of abacavir 600 mg once-daily and lamivudine 300 mg once-daily (adult maximun daily dose), the adult fixed-dose combination (abacavir and lamivudine tablets, 600 mg/300 mg) can be used.

2.3 Important Administration and Preparation Instructions

Abacavir and lamivudine tablets for oral suspension can be taken with or without food. Abacavir and lamivudine tablets for oral suspension can be swallowed whole, broken in half along the score, or dispersed in water. Do not chew. Do not mix abacavir and lamivudine tablets for oral suspension with any liquid other than water.

Method of Preparation: For children unable to swallow tablets, dispersion can be prepared by dispersing the required number of tablets in water using the following procedure:

1. Place the tablet(s) for oral suspension in a container and add two teaspoons (10 mL) of drinking water per tablet. One teaspoon (5 mL) of drinking water should be used for ½ tablet.
2. Swirl the container (approximately 2-3 minutes) until the tablet(s) for oral suspension breaks up into pieces small enough for the child to swallow. A spoon can be used to crush the pieces, if needed. Do not chew.
3. Drink the mixture within 1 hour. If not administered immediately upon preparation, swirl the container (approximately 2-3 minutes) before administration. Discard the mixture if not used within 1 hour.
4. Rinse the container with an additional small amount of water (approximately one to two teaspoons (5 mL to 10 mL) per tablet) and drink the contents to ensure that the entire dosage is taken.

For more details on preparation and administration, see **Instructions for Use**.

4. The bioequivalence of abacavir and lamivudine for oral suspension was assessed in a study under fasted and fed conditions; therefore, this fixed combination product may be taken with or without food.

5. Important information from the individual components (ZIAGEN and EPIVIR) relevant to the use of this combination product was added to the HIGHLIGHTS, DOSAGE FORMS AND STRENGTHS (3), HOW SUPPLIED/STORAGE AND HANDLING (16), and PATIENT COUNSELING INFORMATION (17) sections as follows:

   - HL and Sections 3 and 16: Per OPQ's labeling recommendations added "The tables are functionally scored"
   - Section 11: Per OPQ's recommendations based on the USAN on-line https://www.uspusan.com/usan/login, revised the chemical names for both abacavir sulfate and lamivudine
   - Section 16: Section 17: Added language for the new IFU, including information about Important Administration and Preparation Instructions

(b) (4)

[redacted]

III. Recommended Regulatory Action

Based on OPQ's Combined Reviews dated 01July2019 & 30July2019 for this application, a CR action is recommended at this time due to inspectional issues with Mylan Laboratories Limited, Unit 8 (FEI # 3002785310), which is the facility manufacturing abacavir sulfate drug substance. Therefore, a CR action is warranted.

However, the Division conveyed its labeling revisions for the PI, MG, WC (in PDF), and the new IFU to the applicant on August 6, 2019, via email correspondence and requested that the applicant address them prior to resubmitting the labeling.

Monica Zeballos, Pharm.D.
Program Coordinator
Division of Antiviral Products
Office of Antimicrobial Products

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MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Division of Antiviral Products
Food and Drug Administration
Center for Drug Evaluation and Research
Silver Spring, MD 20993

DATE: **September 30, 2014**

TO: **NDA 204-311**
Abacavir and Lamivudine Tablets for Oral Suspension, 60 mg/30 mg

FROM: **Monica Zeballos, Pharm.D.**
Senior Program Consultant
Division of Antiviral Products (DAVP)

THROUGH: **Jeffrey Murray, M.D., M.P.H., Deputy Director, DAVP**

SUBJECT: **Clinical Labeling Review**

I. Background

The purpose of this submission is to gain tentative approval of Mylan Laboratories Limited's (Mylan's) registration application for the following drug product:

- Abacavir and Lamivudine Tablets for Oral Suspension, 60 mg/30 mg

Use of simplified anti-HIV regimens in the form of co-packaged drugs (such as blister packs) or fixed-dose combinations (FDCs) may facilitate distribution and improve patient adherence in the United States and developing countries. To facilitate more rapid development of FDCs or co-packaging of antiretroviral agents, FDA issued a Guidance for Industry on *Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV* (October 2006). This guidance is intended to encourage applicants to submit applications to the FDA for approval of FDCs and co-packaged versions of previously approved antiretroviral therapies.

Mylan's application was submitted in response to this guidance as a 505(b)(2) NDA for a single scored tablet containing abacavir and lamivudine that can be dispersed in water for pediatric patients unable to swallow tablets. The safety and efficacy of the U.S. approved reference listed drugs Ziagen (abacavir sulfate) and Epivir (lamivudine) as part of a highly active antiretroviral therapy (HAART) regimen are supported by previously conducted adequate and well- controlled studies. Because the reference listed drugs for this fixed-dose combination product are under patents, the application cannot be approved but is eligible to receive tentative approval which recognizes that, at the time the tentative approval action is taken, the application meets all the regulatory, scientific, and quality standards requirements for approval, but final approval is blocked by unexpired patents or exclusivities. The President's Emergency Plan for AIDS Relief (PEPFAR) will consider procurement of products reviewed by FDA that have been

granted approval or tentative approval. Such products may be distributed outside the United States, depending on regulatory requirements in other countries.

II. Labeling Review

The revised labeling in PLR (Physician's Labeling Rule) format for this fixed-dose combination product was reviewed and compared to the latest approved U.S. labeling for [redacted] (b) (4). Additionally, the labeling for the individual components: Ziagen (abacavir sulfate), approved on 11Sept2013 and Epivir (lamivudine), approved on 18Nov2011 were also used to support use in the pediatric population.

The content of the proposed labeling for Mylan's fixed-dose combination product is consistent with the U.S. labeling for [redacted] (b) (4) Ziagen, and Epivir. Notable differences include:

1. Revised the recommended pediatric dosage Table 1 to spell out mathematical symbols and to add footnote information as follows:

The recommended oral dosage of scored abacavir and lamivudine in HIV-1-infected pediatric patients 3 months and older is abacavir 8 mg/kg twice daily (up to a maximum of 300 mg twice daily) and lamivudine 4 mg/kg twice daily (up to a maximum of 150 mg twice daily) in combination with other antiretroviral agents is provided in Table 1.

Table 1. Recommended Pediatric Dosage of Scored Abacavir and Lamivudine Tablets for Oral Suspension

Weight (kg)	**Dosage Regimen Using Scored Abacavir and Lamivudine Tablets for Oral Suspension, 60 mg/30 mg**		**Total Daily Dose (mg)**
	AM Dose (mg)	**PM Dose (mg)**	
5 to less than 6	½ tablet (30 mg A/15 mg L)	1 tablet (60 mg A/30 mg L)	90A/45L
6 to less than 9	1 tablet (60 mg A/30 mg L)	1 tablet (60 mg A/30 mg L)	120A/60L
9 to less than 12	1.5 tablets (90 mg A/45 mg L)	1.5 tablets (90 mg A/45 mg L)	180A/90L
12 to less than 17	2 tablets (120 mg A/60 mg L)	2 tablets (120 mg A/60 mg L)	240A/120L
17 to less than 20	2.5 tablets (150 mg A/75 mg L)	2.5 tablets (150 mg A/75 mg L)	300A/150L
20 to less than 25	3 tablets (180 mg A/90 mg L)	3 tablets (180 mg A/90 mg L)	360A/180L
25 to less than 29	3.5 tablets (210 mg A/105 mg L)	3.5 tablets (210 mg A/105 mg L)	420A/210L
29 to less than 35	4 tablets (240 mg A/120 mg L)	4 tablets (240 mg A/120 mg L)	480A/240L
35 and greater	5 tablets (300 mg A/150 mg L)[a]	5 tablets (300 mg A/150 mg L)[a]	600A/300L

A= abacavir; L= lamivudine

a = For recommended doses of abacavir 300 mg twice daily and lamivudine 150 mg twice daily (adult maximum daily dose), the adult formulations (abacavir 300 mg tablet and lamivudine 150 mg tablet) can be used.

2. Because dose reductions are necessary but not possible with abacavir and lamivudine tablets for oral suspension, this fixed-dose combination product is not indicated for use in adult and pediatric patients with impaired renal function (creatinine clearance < (b) (4) mL/min) or patients with impaired hepatic function.

3. Because safety and effectiveness of the individual components abacavir and lamivudine in pediatric patients less than 3 months of age have not been established, abacavir and lamivudine tablets for oral suspension are not recommended in this age group. The pediatric dosing limit is set by both Ziagen and Epivir.

4. The bioequivalence of abacavir sulfate and lamivudine tablets for oral suspension was assessed in a study under fed and fasted conditions; therefore, this fixed-dose combination formulation can be taken with or without food.

5. (b) (4)

All the sections of the package insert (PI), medication guide, and warning card (although there was no current approved warning card for (b) (4) Ziagen at Drugs@FDA or our archival system) were reviewed and the annotated PI and medication guide are attached at the end of this memo.

III. Recommended Regulatory Action

The revised PI, medication guide, and warning card were reviewed and should allow for the safe and effective use of this pediatric fixed-dose combination product. The Applicant has adequately responded to the Division's labeling revisions conveyed on October 16 and October 17, 2014, via email correspondence; therefore, a tentative approval action is warranted.

The labeling for this pediatric two-drug fixed-dose combination product is consistent with the U.S. labeling for (b) (4) Ziagen, and Epivir. Dose reductions or adjustments are not possible with this formulation and safety and efficacy in pediatric patients less than 3 months have not been established for either component. Therefore, abacavir and lamivudine tablets for oral suspension should not be used in the following patient populations:

1. Pediatric patients less than 3 months of age or (b) (4)
2. Contraindicated in patients with previously demonstrated hypersensitivity to abacavir or any other component of the product. NEVER restart abacavir or any other abacavir-containing product following a hypersensitivity reaction to abacavir, regardless of HLA-B*5701 status
3. Contraindicated in patients with hepatic impairment
4. Patients with impaired renal function (creatinine clearance < (b) (4) mL/min)

Additionally, the bioequivalence of abacavir and lamivudine tablets for oral suspension was assessed in a study under fasted and fed conditions; therefore, the recommended administration is “take with or without food.”

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Monica Zeballos, Pharm.D.
Senior Program Consultant
Division of Antiviral Products
Office of Antimicrobial Products

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/s/

MONICA I ZEBALLOS
10/20/2014

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10/20/2014