CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215358Orig1s008

OTHER REVIEW(S)

CLINICAL INSPECTION SUMMARY

Date	October 18, 2024
From	Anthony Orencia, M.D., Ph.D., F.A.C.P., Senior Physician Min Lu, M.D., M.P.H., Team Leader Jenn Sellers, M.D., Ph.D., F.A.A.P., Branch Chief Good Clinical Practice Assessment Branch Division of Clinical Compliance Evaluation Office of Scientific Investigations
To	Gulsum Pamuk, M.D., Clinical Reviewer Lori Ehrlich, M.D., Ph.D. Clinical Team Leader Rachel McMullen, MPH, MHA, Senior Regulatory Health Project Manager Kelly Norsworthy, M.D., Deputy Division Director R. Angelo de Claro, M.D., Division Director Division of Hematologic Malignancy I Office of Oncology Drugs
NDA	NDA 215358 S-08
Applicant	Novartis Pharmaceuticals Corporation
Drug	SCEMBLIX® (asciminib)
NME	No
Classification	Oral tyrosine kinase inhibitor
Proposed Indications	Treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
Review Type	Priority Review
Consultation Request Date	July 3, 2024
Summary Goal Date	October 22, 2024
Action Goal Date	October 31, 2024 (original), October 28, 2024 (updated)
PDUFA Date	November 29, 2024

I. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

Clinical data from Study CABL001J12301were submitted to the Agency in support of a New Drug Application supplement, for asciminib as a first line agent for treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).

Two foreign clinical investigators were inspected for the study: Denis Kim, M.D. (Toronto, Canada), and Jiri Mayer, M.D. (Brno, Czech). The sponsor, Novartis Pharmaceuticals Corporation, was also inspected.

Based on the inspection results, Study CABL001J12301in NDA 215358 S-08 appears to have been conducted adequately and the study data derived from the above clinical investigator sites are considered acceptable. In general, the clinical data submitted to the Agency for assessment are acceptable in support of the proposed indication.

II. BACKGROUND

Asciminib is an oral inhibitor of tyrosine kinase activity of ABL and BCR-ABL1 kinases. Asciminib inhibits the ABL1 kinase activity of the BCR-ABL1 fusion protein, by specifically targeting the ABL myristoyl pocket.

Asciminib (Scemblix) was approved for the treatment of adult patients with: (a) Philadelphia chromosome-positive chronic myeloid leukemia (CML) in chronic phase, previously treated with two or more tyrosine kinase inhibitors. This indication is approved under accelerated approval based on major molecular response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s), and (b) Philadelphia chromosome-positive chronic myeloid leukemia, in chronic phase with the T315I mutation.

In this submission, Novartis submitted Study CABL001J12301 to support asciminib as a first line agent for the treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).

Study CABL001J12301

Study CABL001J12301was a Phase III, multi-center, open-label, randomized study of oral asciminib 80 mg once daily versus investigator selected tyrosine kinase inhibitor, such as imatinib, nilotinib, dasatinib, or bosutinib, in adult participants with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukemia chronic phase. All comparator tyrosine kinase inhibitors were made available, unless not permitted by local regulations or local Health Authority, or not approved for the treatment of CML in the country.

The primary objectives were (a) to compare the efficacy of asciminib versus investigator selected tyrosine kinase inhibitor, with respect to the proportion of participants that are in major molecular response at Week 48, and (b) to compare the efficacy of asciminib versus investigator selected tyrosine kinase inhibitor therapy, within the stratum of participants with imatinib as the pre-randomization selected tyrosine kinase inhibitor, with respect to the proportion of participants that are in major molecular response at Week 48.

The primary study endpoint was major molecular response at Week 48.

The study was conducted at West and Eastern European, Australia, and Southeast Asia in 29 countries. The study initiation date was Oct 6, 2021 (first participant first visit). The data cut-off date was Nov 28, 2023 (primary endpoint analysis at Week 48, study is ongoing). The study enrolled over 400 study subjects: asciminib (201 subjects) and investigator selected tyrosine kinase inhibitor therapy comparators (204 subjects).

III. RESULTS

1. Dennis Kim, M.D. /Site #1002
610 University Avenue, Princess Margaret Cancer Centre
Toronto, Ontario M5G 2M9
Canada

Inspection dates: September 9-13, 2024

There were 19 subjects who were screened, and 17 subjects enrolled in the study. During the treatment period, one subject withdrew consent, and 16 completed the study. All the 16 enrolled subject records were reviewed.

Records reviewed for the study comprised the study subject's medical history, eligibility, adverse events, concomitant medications, molecular response and BCR-ABL1 mutations, as well as treatment with the investigational product. Further, regulatory documentation was reviewed including ethical committee approvals, monitoring, communications with the sponsor, training, staff delegations, and financial disclosure.

The primary efficacy endpoint was verifiable.

No discrepancies were noted after a comprehensive review to all reported adverse events and serious adverse events. There was no evidence of under-reporting of adverse events.

The study data derived from Dr. Kim's site are considered acceptable.

2. Jiri Mayer, M.D. /Site #2080
Jihlavska 20, Fakultni Nemocnice
Brno, Bohunice 625 00
Czech Republic

Inspection dates: September 9-13, 2024

The inspected site had a total of 21 subjects screened and 17 subjects enrolled. During the inspection, one subject withdrew consent after receiving the study drug, three subjects discontinued early from the study. All remaining 13 subjects are still conducting their follow-up visits at the time of the inspection. A total of enrolled 17 subjects' records were inspected.

Study worksheets, electronic case report forms, eligibility records, adverse event reports, and concomitant medications for this study, investigational products records, investigational product storage and shipment, ethical committee and monitor correspondence and training records. FDA reviewed and compared the source data for the endpoints (primary and secondary) with the electronic data capture (EDC) and the Data Line Listings. There was no Electronic Medical Records (EMR) system used in the study. The source data were only on paper and were available.

The primary and secondary efficacy study endpoints were verifiable. No discrepancies were noted. A comprehensive review to all reported adverse events and serious adverse events was conducted. There was no evidence of the under-reporting of serious adverse events.

In general, the data from this clinical study site appeared acceptable.

3. Sponsor

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Inspection dates: August 26 - 29, 2024

The sponsor inspection involved a comprehensive onsite review of selection and monitoring of clinical investigators, selection of monitors, monitoring procedures and activities, quality assurance, reporting to FDA of significant adverse effects/safety oversight, data collection and handling, financial disclosure, and electronic records.

Novartis maintained a quality assurance unit that conducted study site audits as well as vendor audits. FDA inspection reviewed the audit documents for five vendors/CROs when they were last audited during 2022-2024 by Novartis (b) (4)] and no significant issues were identified.

The Sponsor's monitoring files for Site #1002 in Toronto, Canada and Site #2080 in Brno, Czech were reviewed during the FDA inspection. The inspection found that sponsor monitoring for these study sites to be complete, and without discrepancies. Monitoring files and documents, in general, were found to be adequate. Procedure and documents for reviewing and processing of adverse and serious adverse events were evaluated. Compliance documents were reviewed. No discrepancies were observed for adverse event reporting.

In general, the sponsor's oversight and monitoring of this clinical study appear to be acceptable.

{See appended electronic signature page}
Anthony Orencia, M.D., Ph.D., F.A.C.P.
FDA Senior Physician
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
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MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	October 16, 2024
Requesting Office or Division:	Division of Hematologic Malignancies 1 (DHM 1)
Application Type and Number:	NDA 215358/S-008
Product Name, Dosage Form, and Strength:	Scemblix (asciminib) tablets, 20 mg, 40 mg, and 100 mg
Applicant Name:	Novartis Pharmaceuticals Corporation
FDA Received Date:	October 11, 2024
TTT ID #:	2024-9686-1
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS

1 PURPOSE OF MEMORANDUM

Novartis Pharmaceuticals Corporation submitted revised container labels received on October 11, 2024 for Scemblix. We reviewed the revised container labels for Scemblix (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to FDA proposed labeling edits in which the Office of Pharmaceutical Quality (OPQ) recommended the Applicant retain the statement, "Dispense and store in the original container in order to protect from moisture." to avoid potential misinterpretation by a pharmacist that the product can be dispensed to the patient in a container different than the original container.[a]

2 CONCLUSION

The container labels are acceptable from a medication error perspective. We have no recommendations at this time.

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[a] McMullen, R. FDA Communication: NDA 215358/S-008: FDA Proposed Labeling Edits (Response DUE: 10/4/24) for Scemblix. Silver Spring (MD): FDA, CDER, Division of Hematologic Malignancies I (US); 2024 OCT 02. NDA 215358.

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

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

Memorandum

Date: October 1, 2024

To: Rachel McMullen, Regulatory Project Manager
Division of Hematologic Malignancies I (DHM1)

From: Samia Alam, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Jina Kwak, Team Leader, OPDP

Subject: OPDP Labeling Comments for SCEMBLIX® (asciminib) tablets, for oral use

NDA: 215358, S-008

Background:

In response to DHM1's consult request dated May 31, 2024, OPDP has reviewed the proposed Prescribing Information (PI) and Patient Package Insert (PPI) for supplement 008 for SCEMBLIX® (asciminib) tablets, for oral use. This supplement provides labeling updates for a new indication for the treatment of newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) in adult patients.

PI/PPI:

OPDP's review of the proposed PI is based on the draft labeling emailed to OPDP on September 18, 2024, and our comments are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review was completed for the proposed PPI, and comments were sent under separate cover on September 24, 2024.

Thank you for your consult. If you have any questions, please contact Samia Alam at (240) 402-3695 or Samia.Alam@fda.hhs.gov.

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LABEL AND LABELING REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	September 27, 2024
Requesting Office or Division:	Division of Hematologic Malignancies 1 (DHM 1)
Application Type and Number:	NDA 215358/S-008
Product Name, Dosage Form, and Strength:	Scemblix (asciminib) tablets, 20 mg, 40 mg, and 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant Name:	Novartis Pharmaceuticals Corporation
FDA Received Date:	May 29, 2024 and August 14, 2024
TTT ID #:	2024-9686
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS

1 INTRODUCTION

Novartis Pharmaceuticals Corporation submitted an Efficacy Supplement for Scemblix (asciminib) tablets to propose a new indication, for the treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). Additionally, the Applicant proposes to clarify the storage instructions for the product. We reviewed the proposed Scemblix Prescribing Information (PI), Patient Package Insert (PPI), and container labels for areas of vulnerability that may lead to medication errors.

1.1 REGULATORY HISTORY

NDA 215358 was approved on October 29, 2021 as 20 mg and 40 mg tablets for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CMP) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs) and for the treatment of Ph+ CMP in CP with the T315I mutation. Supplement 5 was approved on June 18, 2024, which added the 100 mg tablet presentation.

2 MATERIALS REVIEWED

This section lists the materials considered for our review of NDA 215358/S-008.

Table 1. Materials Considered for this Label and Labeling Review	
Material(s) Reviewed	Appendix Section
Relevant Product Information	A
Labels and Labeling	B
Previous DMEPA Reviews	C

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We performed a risk assessment of the proposed Prescribing Information (PI), Patient Package Insert (PPI), and container labels for Scemblix to identify deficiencies that may lead to medication errors and other areas of improvement.

We noted that the storage conditions listed in Section 16 of the PI and on the container labels changed from "Dispense and store in the original container…" to "(b) (4) (b) (4)". However, the PPI remains unchanged and states for patients to "Store SCEMBLIX in the original container to protect it from moisture." (b) (4) (b) (4) We requested the Office of Pharmaceutical Quality (OPQ) review the proposed change in storage conditions to determine if it is acceptable. OPQ sent an Information Request (IR) to the Applicant requesting clarification (b) (4) (b) (4)

(b) (4) In their response[a], the Applicant stated (b) (4) OPQ and the Division concurred with our evaluation and propose retaining "Dispense and store in the original container in order to protect from moisture." within the PI and on the container labels. OPQ will communicate this recommendation to the Applicant.

4 CONCLUSION

We evaluated the proposed Scemblix container labels and Patient Package Insert (PPI) and determined that they are acceptable from a medication error perspective.

However, the proposed Scemblix Prescribing Information (PI) may be improved to promote the safe use of this product from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error for the Division of Hematologic Malignancies 1 (DHM 1) in Section 5.

5 RECOMMENDATIONS FOR THE DIVISION OF HEMATOLOGIC MALIGNANCIES 1 (DHM 1)

A. Prescribing Information

1. Section 2 Dosage and Administration

   a. Laboratory values are presented with a trailing zero throughout Table 2 in Section 2.4 *Dosage Modifications*, which can lead to tenfold misinterpretations when the decimal point is overlooked (e.g., 1.0 x 10^9/L is read as 10 x 10^9/L). We recommend revising these laboratory values to remove the trailing zeros (e.g., 1 x 10^9/L).

2. Section 16 How Supplied/Storage and Handling

   a. The How Supplied Section is cluttered and contains unnecessary information. For example, the salt equivalency statements are presented in Section 16, however they are required in Section 11 Description of the PI. Therefore, we recommend removal of the salt equivalency statements

[a] Reponses to Questions to Quality Documentation – United States for Scemblix (NDA 215358). East Hanover (NJ): Novartis Pharmaceutical Corporation; 2024 SEP 16. Available from: \\CDSESUB1\EVSPROD\nda215358\0128\m1\us\cmc-response-fda.pdf.

in Section 16 of the PI. For example, revise "SCEMBLIX (asciminib) 20 mg film-coated tablets are supplied as pale yellow, unscored, round, biconvex, with beveled edges, film-coated tablets containing 20 mg of asciminib (equivalent to 108.10 mg of asciminib HCl). Each tablet is debossed with "20" on one side and the "Novartis" logo on the other side." to "SCEMBLIX (asciminib) 20 mg film-coated tablets are supplied as pale yellow, unscored, round, biconvex, with beveled edges, film-coated tablets containing 20 mg of asciminib. Each tablet is debossed with "20" on one side and the "Novartis" logo on the other side.".

APPENDICES: METHODS AND RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. RELEVANT PRODUCT INFORMATION

Table 2 presents relevant product information for Scemblix received on August 14, 2024 from Novartis Pharmaceuticals Corporation.

Table 2. Relevant Product Information for Scemblix	
Initial Approval Date	October 29, 2021
Active Ingredient	asciminib
Indication	For the treatment of adult patients with: • Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). [proposed] • Ph+ CML in CP with the T315I mutation.
Dosage Form	tablets
Strength	20 mg, 40 mg, and 100 mg
Route of Administration	Oral
Dose and Frequency	• Recommended Dosage in Patients with Newly Diagnosed or Previously Treated Ph+ CML-CP: The recommended dose is 80 mg taken orally once daily at approximately the same time each day or 40 mg orally twice daily at approximately 12-hour intervals. The recommended dose is taken orally without food. Avoid food consumption for at least 2 hours before and 1 hour after taking SCEMBLIX. Continue treatment with SCEMBLIX as long as clinical benefit is observed or until unacceptable toxicity occurs. • Recommended Dosage in Patients with Ph+ CML-CP with the T315I Mutation: The recommended dose is 200 mg taken orally twice daily at approximately 12-hour intervals. The recommended dose is taken orally without food. Avoid food consumption for at least 2 hours before and 1 hour after taking SCEMBLIX.

Table 2. Relevant Product Information for Scemblix	
How Supplied	Bottles of 60 tablets: • 20 mg • 40 mg • 100 mg • SCEMBLIX (asciminib) 20 mg film-coated tablets are supplied as pale yellow, unscored, round, biconvex, with beveled edges, film-coated tablets containing 20 mg of asciminib (equivalent to 21.62 mg of asciminib HCl). Each tablet is debossed with “20” on one side and the “Novartis” logo on the other side. • SCEMBLIX (asciminib) 40 mg film-coated tablets are supplied as violet white, unscored, round, biconvex, with beveled edges, film-coated tablets containing 40 mg of asciminib (equivalent to 43.24 mg of asciminib HCl). Each tablet is debossed with “40” on one side and the “Novartis” logo on the other side. • SCEMBLIX (asciminib) 100 mg film-coated tablets are supplied as light red, unscored, round, biconvex, with beveled edges, film-coated tablets containing 100 mg of asciminib (equivalent to 108.10 mg of asciminib HCl). Each tablet is debossed with “100” on one side and the “Novartis” logo on the other side.
Storage	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Store (b) (4) in the original container in order to protect from moisture.
Container Closure	Asciminib 20 mg, 40 mg and 100 mg film-coated tablets are packaged in high density polyethylene (HDPE) bottles with (b) (4) (b) (4) screw cap closures with induction heat seal liner. Asciminib 100 mg film-coated tablets HDPE bottles additionally contains a desiccant (b) (4).

APPENDIX B. LABELS AND LABELING

B.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[b] along with postmarket medication error data, we reviewed the following Scemblix labels and labeling submitted by Novartis Pharmaceuticals Corporation.

- Prescribing Information and Patient Package Insert received on August 14, 2024, available from \\CDSESUB1\EVSPROD\nda215358\0120\m1\us\proposed.pdf
- Container labels received on May 29, 2024
- Professional Sample labels received on May 29, 2024

B.2 Container Labels Images

Container Labels:

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

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APPENDIX C. PREVIOUS DMEPA REVIEWS

On July 29, 2024, we searched for previous DMEPA reviews relevant to this current review using the terms, 'Scemblix', 'asciminib', and '215358'. Our search identified 2 previous reviews[c,d] since the date of our last search on March 22, 2024, and we considered our previous recommendations to see if they are applicable for this current review.

[c] Kundreskas, J. Label and Labeling Review for Scemblix (NDA 215358/S-005). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 APR 05. TTT ID No.: 2024-8773.

[d] Kundreskas, J. Memorandum of Revised Label and Labeling for Scemblix (NDA 215358/S-005). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 APR 16. TTT ID No.: 2024-8773-1.

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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:	September 24, 2024
To:	Rachel McMullen, MPH, MHA Regulatory Project Manager **Division of Hematologic Malignancies I (DHM1)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Barbara Fuller, MSN, BSN, RN Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Helen Young, MSN, MPH, CRRN, PHN, RN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Samia Alam, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	SCEMBLIX (asciminib)
Dosage Form and Route:	tablets, for oral use
Application Type/Number:	NDA 215358
Supplement Number:	S-008
Applicant:	Novartis Pharmaceuticals Corporation

1 INTRODUCTION

On May 29, 2024, Novartis Pharmaceuticals Corporation submitted for the Agency's review a Prior Approval Supplement (PAS) – Efficacy to their approved New Drug Application (NDA) 215358/S-008 for SCEMBLIX (asciminib) tablets. With this supplement, the Applicant is seeking approval for a new indication in the treatment of adults with:

"Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ + CML) in chronic phase (CP)."

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 Hematologic Malignancies I (DHM1) on May 31, 2024, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for SCEMBLIX (asciminib) tablets.

2 MATERIAL REVIEWED

- Draft SCEMBLIX (asciminib) tablets PPI received on May 29, 2024, and received by DMPP and OPDP on September 18, 2024.
- Draft SCEMBLIX (asciminib) tablets Prescribing Information (PI) received on May 29, 2024, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on September 18, 2024.
- Approved SCEMBLIX (asciminib) tablets approved labeling dated October 12, 2022.

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.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the 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)

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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