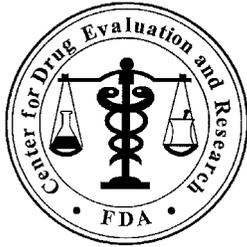


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-311

PROPRIETARY NAME REVIEW(S)



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: October 28, 2008

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Subject: Proprietary Name, Label and Labeling Review

Drug Name(s): Mozobil (Plerixafor) Injection
24 mg/1.2 mL

Application Type/Number: NDA 22-311

Applicant: Genzyme Corporation

OSE RCM #: 2008-1168

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EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name, Mozobil, has some similarity to other proprietary and established drug names, but the findings of the FMEA indicates that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors. Thus, we do not object to the use of the proprietary name, Mozobil, for this product. However, If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, we rescind this Risk Assessment finding, and recommend that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

The results of the Label and Labeling Risk Assessment found that the presentation of information and design of the proposed container label and carton labeling appear to be vulnerable to confusion that could lead to medication error. Specifically, the font colors used to display the proprietary name and the established name on the container labels and carton labeling are too light and difficult to read, and the established name lacks prominence in accordance with 21CFR 201.10(g)(1). The total drug content is not displayed (24 mg/1.2 mL) on the primary display panel of the carton labeling or container label. Additionally, the Dosage and Administration Section 2.1 of the package insert labeling this type of equation presenting the dose to be administered in milliliters, is not typically included in package insert labeling. Finally, there is discordance between the units of measure in container labels and carton labeling presented in milligrams (20 mg/mL) and the package insert labeling 'Dosage and Administration' section expressed in (b) (4). This use of different units is a source of confusion for practitioners when dosing administering Mozobil for administration.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from the Division of Drug Oncology Products submitted to the Division of Medication Error Prevention and Analysis on July 17, 2008, for the assessment of the proprietary name, Mozobil for new drug application (NDA 22-311). Container labels, carton labeling and package insert were also submitted for review and comment.

1.2 REGULATORY HISTORY

The proprietary name, Mozobil, was originally reviewed along with draft package insert labeling, under Investigational New Drug Application (IND 55-851) in OSE Review #2005-0012 on January 10, 2005. The Division of Medication Error Prevention and Analysis had no objection to the proposed proprietary name but did provide recommendations for implementation of package insert labeling revisions. Container labels and carton labeling were not submitted for review or comment at that time.

1.3 PRODUCT INFORMATION

Mozobil (Plerixafor) Injection 20 mg/mL is indicated to enhance mobilization of hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma (MM). The recommended dose of Mozobil is (b) (4) body weight by subcutaneous (SC) injection and should be administered (b) (4) eleven hours prior to initiation of apheresis. Mozobil should be administered by a nurse, physician or other health care professional. Mozobil is commonly used for two to four consecutive days but has been used for up to seven consecutive days in a clinical setting.

The patient's actual body weight will be used to calculate the dose (volume) of Mozobil to be administered. The weight used to calculate the volume of Mozobil should be obtained within one week of the first dose. Each 2 mL vial delivers 1.2 mL of Mozobil 20 mg/mL solution and the volume to be administered to patients will be calculated from the following equation included in the package insert labeling:

$$0.012 \times \text{Patient's Actual Body Weight (in kg)} = \text{Dose to be Administered (in mL)}$$

Mozobil is supplied in a 2 mL single-use vial filled to deliver 1.2 mL of solution (24 mg). The vials are filled to contain a target volume of (b) (4) of the labeled volume (1.2 mL) to account for drug product (b) (4)

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the Division of Medication Error and Prevention's medication error staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment) and label, labeling, and/or packaging risk assessment (see 2.2 Container Labels, Carton Labeling and Insert Labeling Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. The Division defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Mozobil, and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, and ANDA products currently under review by the Agency.

For the proprietary name, Mozobil, the medication error staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). We also conducted internal CDER prescription analysis studies (see 2.1.2). When provided, external prescription analysis studies results are considered and incorporated into the overall assessment, however, there were no external prescription analysis studies provided for this application.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.1.3). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.² FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. We use the clinical expertise of the

¹ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>.

² Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap, or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. As such, the Staff considers the product characteristics associated with the proposed drug throughout the risk assessment, since the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed drug name include, but are not limited to established name of the proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, we consider the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

2.1.1 Search Criteria

The medication error prevention staff considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letters ‘M’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{4,5}

To identify drug names that may look similar to Mozobil, the Staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name, Mozobil (seven letters), upstrokes (one capital letter ‘M’, one ‘b’ and one ‘l’), downstrokes (one ‘z;’) which also can be scripted without a downstroke, cross-strokes (none) and dotted letters (one ‘i’).

Additionally, several letters in Mozobil may be vulnerable to ambiguity when scripted, including the capital letter ‘M’ may appear as capital letter ‘N’ or ‘V’; lower case ‘o’ may appear as ‘a’, ‘e’ or ‘u’; lower case ‘z’ may look like lower case ‘g’, ‘n’ or ‘r’; lower case ‘b’ may look like lower case ‘l’ or ‘t’; lower case letter ‘i’ may appear as lower case ‘e’, ‘r’ or ‘u’; and lower case ‘l’ may appear as lower case ‘t’ or ‘b’. As such, the Staff also considers these alternate appearances when identifying drug names that may look similar to Mozobil.

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

⁴ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

⁵ Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

When searching to identify potential names that may sound similar to Mozobil, the medication error staff search for names with similar number of syllables (3), stresses (MOZ-o-bil, and Moz-0-BIL), and placement of vowel and consonant sounds. Phonetic considerations were also given to the pronunciations of Mozobil that include the ‘Moz’ being pronounced with a soft ‘o’ rather than a hard ‘o’ sound.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the medication error staff were provided with the following information about the proposed product: the proposed proprietary name (Mozobil), the established name (Plerixafor Injection), proposed indication (enhance mobilization of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma), strength (20 mg/mL), dose (0.012 X patient’s weight in kg (b) (4)), frequency of administration (b) (4) eleven hours prior to initiation of apheresis, commonly used two to four consecutive days), route (subcutaneous injection) and dosage form (solution for injection). Appendix A provides a more detailed listing of the product characteristics the medication error staff generally takes into consideration.

Lastly, the medication error staff also considers the potential for the proposed name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

2.1.1.1 Database and information sources

The proposed proprietary name, Mozobil, was provided to the medication error staff to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to Mozobil using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the medication error staff uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the Medication error staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.1.2 CDER Expert Panel Discussion

An Expert Panel Discussion is held by the medication error and prevention staff to gather CDER professional opinions on the safety of the product and the proprietary name, Mozobil. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of medication error prevention staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

The pooled results of the medication error staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to

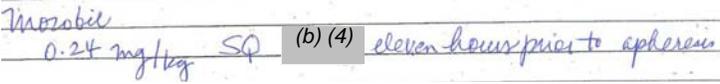
supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name. As part of the Expert Panel Discussion, the group also provides handwriting samples of the proposed proprietary name along with other look-alike names identified by the panel and the Reviewing Safety Officer.

2.1.2 FDA Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Mozobil with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ a total of 123 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Mozobil in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These prescriptions are optically scanned and one prescription is delivered to a random sample of 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to the medication error staff. It is noted that the prescription studies included the frequency of twice daily in error rather than once daily.

Figure 1. Mozobil Study (conducted on September 3, 2008)

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
<u>Outpatient Prescription:</u> N/A	Mozobil
<u>Inpatient Medication Order :</u>  <p>The image shows a handwritten medication order for Mozobil. The text is written in blue ink on a white background. It reads: 'Mozobil 0.24 mg/kg SQ (b) (4) eleven hours prior to apheresis'. The text '(b) (4)' is enclosed in a grey rectangular box, indicating redaction. The word 'apheresis' is written in a cursive script.</p>	0.24 mg/kg under skin (b) 11 hours prior to (4) apheresis

2.1.3 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Modes and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁶ When applying FMEA to assess the risk of a proposed proprietary

⁶ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

name, the Division seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, expert panel evaluation, and studies, and identifies potential failure modes by asking: “Is the name Mozobil convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?” An affirmative answer indicates a failure mode and represents a potential for Mozobil to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking “Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?” The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would ultimately not be a source of medication errors in the usual practice setting, the name is eliminated from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

We will object to the use of proposed proprietary name when one or more of the following conditions are identified in the Safety Evaluator’s Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. We identify that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are

- likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
 5. Medication error staff identifies a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

In the event that we object to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, we will provide a contingency objection based on the date of approval: whichever product is awarded approval first has the right to the use the name, while we will recommend that the second product to reach approval seek an alternative name.

If none of these conditions are met, then we will not object to the use of the proprietary name. If any of these conditions are met, then we will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Applicant; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the Institute of Medicine, World Health Organization, Joint Commission on the Accreditation of Healthcare Organizations and the Institute for Safe Medication Practices, who have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, we contend that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken in the past; but at great financial cost to the Applicant, and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, we believe that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see limitations of the process).

If we object to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used to identify strategies to reduce the risk of medication errors. We are likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for us to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so we may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

2.2 LABEL AND LABELING RISK ASSESSMENT

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The container labels and carton labeling communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The package insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the USP-ISMP Medication Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.⁷

Because the medication error prevention staff analyzes reported misuse of drugs, the staff are able to use this experience to identify potential errors with all medication similarly packaged, labeled or prescribed. We use FMEA and the principles of human factors to identify potential sources of error with the proposed product labels and insert labeling, and provided recommendations that aim at reducing the risk of medication errors.

For this product, the review division forwarded the following label and labeling for our review on July 17, 2008. (See Appendix J and K images):

- Container Labels
- Carton Labeling
- Draft Package Insert labeling (no image)

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and Information Sources

The Division of Medication Error Prevention and Analysis searches yielded a total of 25 names as having some similarity to the name Mozobil. A search of the United States Adopted Name stem list on August 14, 2008 identified no USAN stems within the proposed name, Mozobil.

Sixteen names were thought to look like Mozobil. They include: Marplan, Mazetol, Mazindol, (b) (4) Mobic, Mobidin, Moderil, (b) (4) Moxilin, Mozambin, Mozartan, Muzoral, Nazarin, Nazolin, Nazotral, and Nizoral.

Three names were thought to sound like Mozobil. They include: Moosbeere, Mossberry and Mozzie Patch.

Six names were thought to look and sound like Mozobil. They include: (b) (4), Modafinil, Moexipril, Monopril, Mucosil, and Noxafil.

⁷ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

3.1.2 Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by the staff (see section 3.1.1. above) but did not identify any additional names with similarity to Mozobil.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.1.3 FDA Prescription Analysis Studies

A total of twenty-nine practitioners responded to the FDA Prescription Analysis Studies, but none of the responses overlapped with any existing or proposed drug names. Approximately 66 percent of the participants interpreted the name correctly as Mozobil, with correct interpretations occurring more frequently in the written studies. The remainder of the responses misinterpreted the drug name. The majority of misinterpretations occurred in the phonetic prescription study, with the vowel 'o' being reported as 'e' or 'i', and the letter 'z' being misinterpreted as 's'. Misinterpretations in the written studies occurred mostly in the letter 'z' being misinterpreted as a 'r', and 'b' being misinterpreted as 'f' or 'l'. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 Safety Evaluator Risk Assessment

Independent search by the primary Safety Evaluator identified two additional names thought to both look like Mozobil and represent a potential source of drug name confusion: Macrobid and Mannitol. As such, a total of 27 names were analyzed to determine if the drug names could be confused with Mozobil and if the drug name confusion would likely result in a medication error.

Three of the twenty-seven names identified (Modafinil, Mobic and Monopril) were analyzed in the previous Mozobil review OSE #2005-0012 and were found to be unlikely to result in medication error. No changes in product characteristics were found for these three drug products since the aforementioned review, therefore, it was determined that these three names did not require further evaluation. (See Appendix C).

The remaining 24 names were determined to have some orthographic and/or phonetic similarity to Mozobil, the root name (Mozobil), and thus determined to present some risk of confusion. Failure modes and effects analysis (FMEA) was then applied to determine if the proposed name Mozobil could potentially be confused with any of the 24 names and lead to medication error.

For the remaining 24 names, this analysis determined that the name similarity between Mozobil and the identified names was unlikely to result in medication errors with any of the products identified for the reasons presented in Appendices D through K.

3.2 LABEL AND LABELING RISK ASSESSMENT

We note that the package insert labeling addresses some of our recommendations from previous review (OSE Review 2005-0012). However, review of the container labels, carton labeling and revised package insert labeling identified additional areas of vulnerability that could lead to medication.

3.2.1 Container Labels and Carton Labeling

The font color used to display the proprietary drug name 'Mozobil' and the established name 'Plerixafor Injection) appears too light to visualize clearly and the established name is not prominently displayed proportionally as one half the size of the proprietary name, in accordance with 21CFR201.10(g)(1).

The total drug content (24 mg/1.2 mL) is not displayed on the principle display panel of the carton labeling and is inadequately expressed as “Delivers: 1.2 mL” on the container label.

3.2.2 Package Insert Labeling

There is discordance between the units of measure on container labels/carton labeling expressed in milligrams and the package insert labeling expressed in micrograms.

Section 2.1 of the package insert labeling includes an unconventional equation for calculating the dose to be administered expressed in volume (mL) as follows: $0.012 \times \text{patient's actual body weight (in kg)} = \text{dose to be administered (in mL)}$.

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

Our analysis identified 27 names as having some similarity to the proposed name, Mozobil, but the findings of the FMEA process indicate that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors.

The findings of the Proprietary Name Risk Assessment are based upon current understanding of factors that contribute to medication errors involving name confusion. Although we believe the findings of the Risk Assessment to be robust, our findings do have limitations. First, because our assessment involves a limited number of practitioners, it is possible that the analysis did not identify a potentially confusing name. Also, there is some possibility that our Risk Assessment failed to consider a circumstance in which confusion could arise. However, we believe that these limitations are sufficiently minimized by the use of an Expert Panel and, in this case, the data submitted by the Sponsor from an independent proprietary name risk assessment firm, which included the responses of frontline practitioners.

However, our risk assessment also faces limitations beyond the control of the Agency. First, our risk assessment is based on current health care practices and drug product characteristics, future changes to either could increase the vulnerability of the proposed name to confusion. Since these changes cannot be predicted for or accounted by the current Proprietary Name Risk Assessment process, such changes limit our findings.

4.2 LABELING AND LABELING RISK ASSESSMENT

The Label and Labeling Risk Assessment found that the presentation of information on carton labeling and container labels appear to be vulnerable to confusion that could lead to medication errors.

4.2.1 Readability of the Name

The font color used to display both proprietary name, Mozobil and the established name, Plerixafor Injection, are very light and difficult to visualize on both container labels and carton labeling. The drug name is a critical identifier of a product and as such, should be the most prominently displayed feature in order to assure accurate product selection and minimize medication error that could result from name confusion. Additionally, the presentation of the established name is not prominently displayed in at least half the size as the typed used for the proprietary name, in accordance with 21CFR 201.10(g)(1) .

4.2.2 Expression of Drug Strength

The total drug content (24 mg/1.2 mL) is not displayed on the principle display panel of the carton labeling and is inadequately expressed as “Delivers: 1.2 mL” on the container label. Although the total drug content is described on the back panel of the carton labeling, it should also be adequately displayed on the principle display panel, since the principle display panel will likely be the initial focal point of reference for practitioners selecting and/or administering the product. Additionally, the current presentation of the total drug content on the container label is expressed only in volume (1.2 mL) and it is not presented in conjunction with total drug content (mg). In order to assure accurate dosing of Mozobil, it is imperative that both drug strength and total drug content be adequately displayed on product labeling to calculate the dose to be administered.

4.2.3 Inconsistent Expression of Unit of Measure

We note the discordance between the expressed units of measure on container labels/carton labeling (mg) and package insert labeling (mcg) presents the potential for medication error occurring. Specifically, dosage calculation error may occur due to inaccurate conversion or failure to convert between the microgram and milligram doses, resulting in under-dosing or overdosing of Mozobil. Though we acknowledge that the package insert labeling defines the unit of measure, along with the calculation for dosing administration, discordance between units of measure used on container labels/carton labeling, and the package insert labeling could potentially cause confusion in dose calculation should practitioners fail to cross-reference all labeling sources. In order to provide clear communication of product information in labeling, and avoid the need to convert between different units of measure, labeling should be consistently reflected in the same units of measure for container labels, carton labeling and package insert labeling. We note that our previous review of draft package insert labeling did not identify the discordance in the units of measure due to the fact that container labels and carton labeling were not submitted for review at that time.

4.2.4 Expression of Dosing Equation in Package Insert Labeling

We also note that Section 2.1 of the package insert labeling includes an equation expressing the dose to be administered in milliliters. Since Mozobil is dosed in milligrams according to the patient’s weight in kilograms, the dose will be calculated as such, in conjunction with the drug concentration. Dosing calculations such as these are not typically presented in package insert labeling and we have concerns that the equation presented in the package insert labeling only references the milliliter unit of the dose, not the milligram, and as such, may be a source that could lead practitioners to miscalculate the dose.

5 CONCLUSIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Mozobil, is not vulnerable to name confusion that could lead to medication errors. As such, the Division of Medication Error Prevention and Analysis does not object to the use of the proprietary name, Mozobil, for this product at this time.

The Label and Labeling Risk Assessment findings indicate that the presentation of information and design of the proposed container labels, carton labeling and package insert labeling introduces vulnerability to confusion that could lead to medication errors. We believe the risks identified can be addressed and mitigated prior to drug approval, and provide recommendations in Section 6 that aim at reducing the risk of medication errors.

6 RECOMMENDATIONS

6.1 COMMENTS TO THE DIVISION

The Division of Medication Error Prevention has no objections to the use of the proprietary name Mozobil for this product at this time. If the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

Based upon our assessment of the labels and labeling, Division of Medication Error Prevention and Analysis has identified areas of needed improvement in container labels, carton labeling and draft package insert labeling. We have provided the following recommendations in Section 6.2 and request this information be forwarded to the Applicant.

We would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy us on any communication to the applicant with regard to this review. If you have further questions or need clarifications, please contact Sandra Griffith, Project Manager, at 301-796-2445.

6.2 COMMENTS TO THE APPLICANT

A. The Division of Medication Error Prevention and Analysis (DMEPA) has no objections to the use of the proprietary name, Mozobil, for this product at this time. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding. Furthermore, this name must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approval of other proprietary or established names from the signature date of this document

B. The Division of Medication Error Prevention and Analysis has identified the areas of needed improvement in the container labels, carton labeling and draft package insert labeling and provides the following recommendations:

1. Revise the font color used to display the proprietary name ‘Mozobil’ and the established name, ‘Plerixafor Injection’ on container labels and carton labeling to a more prominent and visible color and increase the size of the established name to at least half that of the proprietary name in accordance with 21CFR 201.10(g)(1). The font color used to display the proprietary name and the established name is very light, does not afford sufficient color contrast and makes it difficult to visualize on both the container labels and carton labeling. The proprietary name is a critical identifier of a drug product and as such, should be the most prominently displayed feature in order to assure accurate product selection and minimize medication error that could result from name confusion.

2. Revise the carton labeling and container labels to include the total drug content along with the product strength. In order to assure accurate dosing of Mozobil, it is imperative that both drug strength and total drug content be adequately displayed on product labeling to accurately calculate the dose to be administered. Revise as follows:

24 mg/1.2 mL
(20 mg/mL)

3. Resolve the discordance between the expression of units of measure on container labels/carton labeling (expressed in milligrams) and the expression of units of measure in the package insert labeling (expressed in micrograms). This inconsistent presentation of the units of measure could lead to dosage calculation error occurring due to inaccurate conversion of microgram to milligrams or vice versa, potentially resulting in under-dosing or overdosing of Mozobil. Though

the package insert labeling defines the unit of measure, along with the calculation for dosing administration, discordance between units of measure used on container labels/carton labeling, and the package insert labeling could potentially cause confusion in dose calculation should practitioners fail to cross-reference all labeling sources. In order to provide clear communication of product information in labeling, and avoid the need to convert between different units of measure, labeling should be consistently reflected in the same units of measure for container labels, carton labeling and package insert labeling. Since the container labels and carton labeling currently provide a clear presentation of the units of measure in milligrams, we recommend that the Applicant consider using milligrams as the unit of measure for all labeling including container labels, carton labeling and package insert labeling.

4. Remove the dosing equation presented in Section 2.1 of the package insert labeling. Since Mozobil is dosed in milligrams according to the patient's weight in kilograms, the dose will be calculated as such, in conjunction with the drug concentration. Dosing calculations such as these are not typically presented in package insert labeling and we have concerns that the equation presented in the package insert labeling only references the volume of dose to be administered. As such, we are concerned that this equation may be a source of confusion to practitioners that could lead to a medication error in miscalculation of the dose.

7 REFERENCES

1. *Micromedex Integrated Index* (<http://csi.micromedex.com>)

Contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

3. *Drug Facts and Comparisons, online version, St. Louis, MO* (<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. *AMF Decision Support System [DSS]*

DSS is a government database used to track individual submissions and assignments in review divisions.

5. *Division of Medication Errors Prevention and Analysis proprietary name consultation requests*

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand](#)

[name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

7. ***Electronic online version of the FDA Orange Book***
(<http://www.fda.gov/cder/ob/default.htm>)

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

Provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

10.. ***Data provided by Thomson & Thomson’s SAEGIS™ Online Service, available at***
(www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)

Contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

12. ***Stat!Ref*** (www.statref.com)

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

13 ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/category/4782.html>)

List contains all the recognized USAN stems.

14. ***Red Book Pharmacy’s Fundamental Reference***

Contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

15. ***Lexi-Comp*** (www.lexi.com)

A web-based searchable version of the Drug Information Handbook.

16. ***Medical Abbreviations Book***

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

The Medication error staff considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. We also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication error staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly *and* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has lead to medication errors. The Medication error staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication error staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, we will consider the Applicant’s intended pronunciation of the proprietary name. However, because the Applicant has little control over how the name will be spoken in practice, we also consider a variety of pronunciations that could occur in the English language.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Downstrokes Cross-strokes	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication

		<p>Dotted letters</p> <p>Ambiguity introduced by scripting letters</p> <p>Overlapping product characteristics</p>	
Sound-alike	Phonetic similarity	<p>Identical prefix</p> <p>Identical infix</p> <p>Identical suffix</p> <p>Number of syllables</p> <p>Stresses</p> <p>Placement of vowel sounds</p> <p>Placement of consonant sounds</p> <p>Overlapping product characteristics</p>	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Appendix B: CDER Prescription Study Responses – Mozobil Study

Voice Prescription	Inpatient Prescription	Outpatient Prescription
Mosivil	Mozobil	Morobil
Mozabil	Mozobil	Mozobil
Mozebil	Mozobil	Mozobil
Mozibil	Mozobil	Mozobil
Mozibill	Mozobil	Mozobil
Mozobil	Mozobil	Mozobil
	Mozobil	
	Mozobiol	
	Mozofil	
	Mozofil	
	Mozolil	

Appendix C: Drug names evaluated in previous Mozobil Review #05-0012

Proprietary Name	Similarity to Mozobil	FMEA Determination
Mobic	Look-Alike	No objection to name
Modanfinil	Look-Alike and Sound-Alike	No objection to name
Monopril	Look-Alike and Sound-Alike	No objection to name

Appendix D: Names that lacking convincing look or sound-alike similarities to Mozobil

Proprietary Name	Similarity to Mozobil
Mozzie Patch	Sound-Alike
Moosbeere	Sound-Alike
Mossberry	Sound-Alike

Appendix E: Drug products marketed or trademarked in other countries

Proprietary Name	Countries
Nazotral (Cromoglicic Acid)	Israel, Netherlands, Columbia, Bangladesh, Brazil, Russia

Appendix F: Drug names that were past proposed proprietary names

Proprietary Name	Similarity to Mozobil	Status
** (b) (4)	Look- and Sound-Alike	Proposed proprietary name not used
** (b) (4)	Look-Alike	Proposed proprietary name not used

Appendix G: Name is not a marketed drug product

Proprietary Name	Similarity to Mozobil	Product Information
(b) (4)	Look-Alike	Herb plant (b) (4)

Appendix H: Name products that have been discontinued and/or no longer marketed drug products

Proprietary Name	Similarity to Mozobil	Date
Moderil (Rescinnamine)	Look-Alike	Prior to 1982
Mozambin (Methaqualone)	Look-Alike	1984

Appendix I: Drug names with no numerical overlap in strength and dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Mozobil (Plerixafor Injection)		20 mg/mL (24 mg) 2 mL Vial Delivers 1.2 mL of Mozobil	0.24 mg/kg body weight given subcutaneously
Macrobid (Nitrofurantoin Monohydrate macrocrystals) Capsules	Look-Alike	100 mg capsule	Take one 100 mg capsule every twelve hours with food for seven days
Marplan (Isocarboxazid)	Look-Alike	10 mg tablets	Start with 10 mg tablet twice daily. Increase by increments of 10 mg; titrate up to maximum dosage of 60 mg/day
Mobidin (Magnesium Salicylate)	Look-alike	600 mg tablets	Take one tablet with a full glass of water
Moexipril Hydrochloride	Look- and Sound-Alike	7.5 mg and 15 mg tablets	For patients not receiving diuretics recommended starting dose is 7.5 mg once daily; dose adjusted according to blood pressure response with recommended dose range of 7.5 mg to 30 mg administered in one or two divided doses.
*Moxilin (Amoxicillin) Capsules *Marketed in Thailand but generics available in U.S.	Look-Alike	500 mg Capsule	Take one 500 mg tablet every eight to twelve hours
*Mosartan (b) (4) *Marketed in Germany but available as (b) (4) in U.S.	Look-Alike	25 mg, 50 mg, 100 mg tablets	Starting dose of 50 mg once daily; 25 mg in patients with depletion of intravascular volume; total daily doses ranging from 25 mg to 100 mg once or twice daily.
*Nazolin (Oxymetazoline) Nasal Spray *Available in Singapore but generic available in U.S.	Look-Alike	0.05 % Nasal spray	Spray once in each nostril; wait three to five minutes and then blow nose.
Noxafil (Posaconazole)	Look- and Sound-Alike	400 mg/mL Oral Liquid Suspension	Fungal Infection: 5 mL three times daily Oropharyngeal Candidiasis: 2.5 mL twice daily on first day; then 2.5 mL once daily for thirteen days Refract. Oropharyngeal Candidiasis: 10 mL twice daily; duration based on severity of disease

Appendix J: Drug names with numerical overlap in strength or dose but differentiating product characteristics

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose	Differentiating Product Characteristics
Mozobil (Plerixafor Injection)		20 mg/mL (24 mg) 2 mL Vial Delivers 1.2 mL of Mozobil	0.24 mg/kg body weight given subcutaneously	Dose form is solution for injection Route of administration is subcutaneous Strength: One strength available Frequency of administration is six to eleven hours prior to initiation of apheresis (commonly used two to four consecutive days) Setting of use is restricted to a supervised clinical setting with drug access and administration limited to the practicing health care provider.
Mazetol (Carbamazepine)	Look-Alike	100 mg, 200 mg, 300 mg Extended Release Capsule 100 mg, 200 mg, 300 mg Oral Tablet 100 mg, 200 mg Chewable Tablet 100 mg/5 mL Oral Suspension	200 mg twice daily for capsules or tablets 400 mg/day for oral suspension	Dosage form is tablet or oral suspension Route of administration is oral Multiple strengths available
Mazindol (Tradenames include Mazanor and Sanorex)	Look-Alike	1 mg, 2 mg tablets	Take one to three times daily before meals with full glass of water	Dosage form is tablet Route of administration is oral
Mucosil (Acetylcysteine)	Look- and Sound-Alike	10 % and 20 % Oral Inhalation Solution	Oral: 140 mg/kg followed by 70 mg/kg orally every four hours for seventeen doses. Intravenous: 140 mg/kg in 200 mL D5W infuse over sixty minutes. Then 50 mg/kg in 500 mL D5W maintenance dose over four hours then 100 mg/kg in 1000 mL D5W over sixteen hours	Dosage form varies: Oral versus intravenous solution Route of administration varies: Oral versus intravenous Multiple strengths available Frequency of administration: Every four hours orally; multiple infusions intravenously
*Muzoral (Ketoconazole) *Available only in Indonesia but generics available in U.S.	Look-Alike	200 mg tablet	Take two 200 mg tablets once daily for five days	Dosage form is tablet Usual dose would be 400 mg daily Route of administration is oral
Nazarin (Guaifenesin and Phenylephrine Hydrochloride)	Look-Alike	200 mg/7.5 mg in 5 mL oral solution	Take 5 to 10 mL orally every four to six hours	Dosage form is Liquid Suspension Usual dose would be 5 mL to 10 mL Route of administration is oral
Nizoral (Ketoconazole)	Look-Alike	2 % Shampoo 2 % Cream 200 mg Tablets	Tablet: One tablet daily; may be increased to two tablets once daily	Dose forms include oral tablet and topical solution/cream Route of administration is oral or

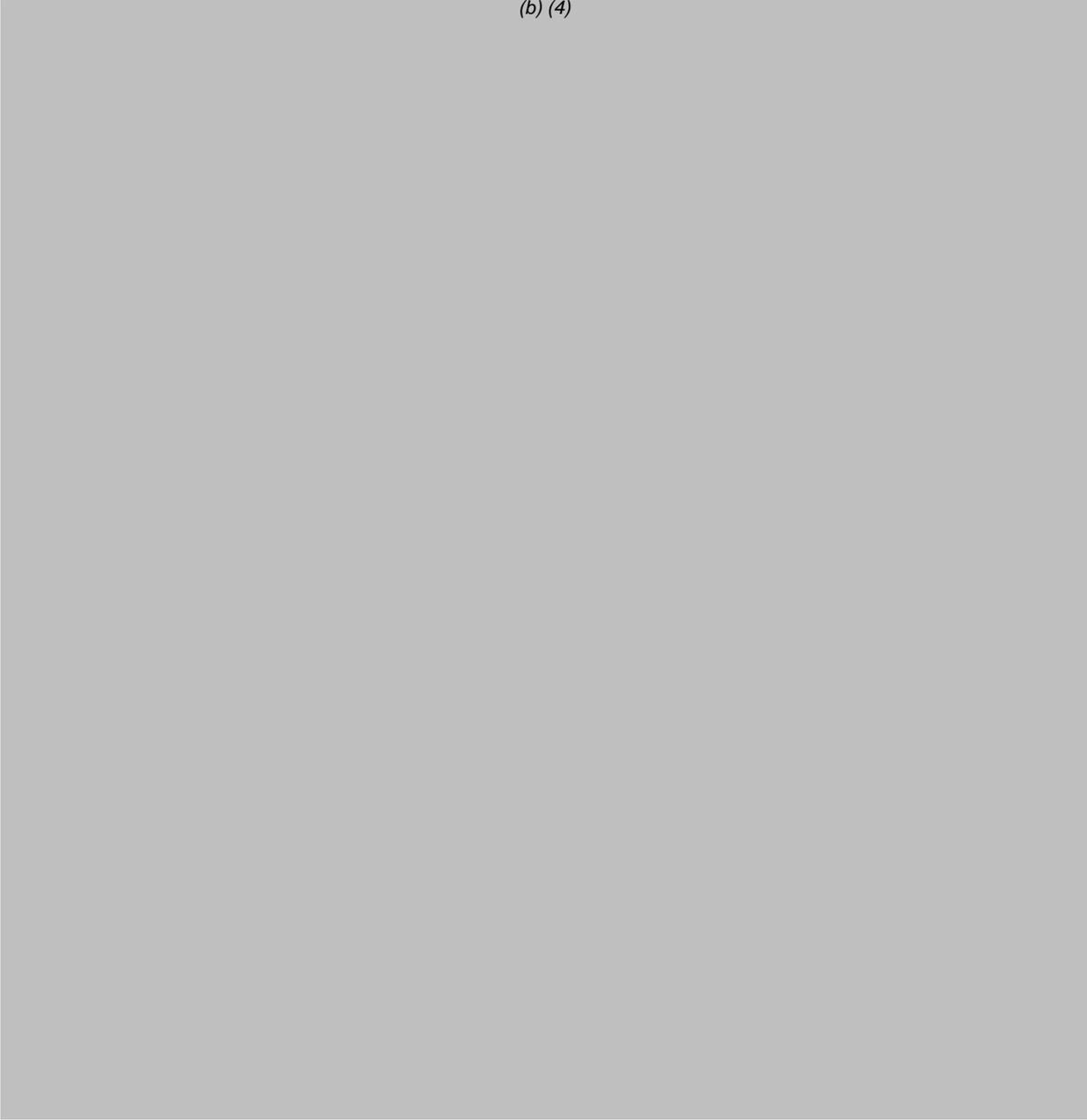
			Shampoo: Shampoo twice weekly Cream: Apply once daily and cover affected area	topical Setting of use is outpatient
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Appendix K: Drug names with potential for confusion due to numeric overlap in drug strength or dose

Failure Mode: Name confusion	Causes (could be multiple)	Effect
Mozobil (Plerixafor Injection)	20 mg/mL (24 mg) 2 mL Vial Delivers 1.2 mL of Mozobil	0.24 mg/kg body weight given subcutaneously
Mannitol I.V. (Mannitol Injection, USP) 5 %, 10 %, 15 %, 20 % , 25 % Usual dose ranges from 50 grams to 200 grams in a twenty-four hour period with achievable dose usually 100 gram/24 hours.	Orthographic similarities: Both names begin with 'M' and end with 'l'. The 'an' can look like 'oz' when 'z' scripted without downstroke. Numerical overlap in strength: 20 % and 20 mg/mL	Orthographic differences in the names, route of administration, available strengths, usual dose and product packaging minimize the likelihood of medication error in the usual practice setting. <i>Rationale:</i> Mannitol contains a cross-stroke 't' in the third from the last letter position that is not present in Mozobil. The 'i' appears in the fifth letter position of name Mannitol but appears in the next to last position of the name Mozobil. The 'nn' lengthens the word 'Mannitol' and looks different than 'zo' when scripted. Mannitol is administered via continuous intravenously while Mozobil is administered via intermittent subcutaneous injection. Mannitol is available in five different strengths (5 %, 10 %, 15 %, 20 % and 25 %) which would be identified on physician orders, while Mozobil is only available in one strength (20 mg/mL). Mannitol dose varies from 50 grams to 200 grams, based on patient diagnosis, while Mozobil dose is weight base (0.24 mg/kg body weight). Mannitol is available in 50 mL to 1000 mL flexible containers while Mozobil is only available in a single-use 2 mL glass vial.

Appendix L: Carton Labeling for Mozobil 20 mg/mL

(b) (4)



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