

MEMORANDUM

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

Date: April 18, 2007

From: Catherine Miller, Consumer Safety Officer (b) (6)
Advertising and Promotional Labeling Branch (APLB), HFM-602
Division of Case Management (DCM)

Through: Ele Ibarra-Pratt, RN, MPH, Branch Chief, APLB, HFM-602 (b) (6)
Robert A. Sausville, Director, DCM, HFM-610 (b) (6)

To: Lori Tull, CSO, OCTGT/RMS, HFM-705
Keith Wonnacott, PhD, OCTGT/DCGT/CTB, HFM-715
Ke Liu, MD, OCTGT/DCEPT/CEB, HFM-755

Cc: Debbie Cordaro, OBRR/DBA/RPMB, HFM-370

Subject: Re-evaluation of proposed proprietary name **PROVENGE**[®]
BLA STN 125197

Recommendation: Proposed proprietary name **PROVENGE**[®] is Acceptable

Executive Summary:

APLB has performed a re-evaluation of the proposed proprietary name, PROVENGE, to determine if any new products have been approved since our previous review on June 24, 2005 (memo attached). APLB found that no new products have been approved that would change our previous recommendations; however, APLB has identified a proposed proprietary name, PRIVIGEN (BLA STN 125201), which is currently under review by the Agency, that has the potential for confusion with PROVENGE. These names have potential for strong written and phonetic similarities. However, because of differences in containers, storage conditions, preparations, labeling, and indications, APLB believes that the potential for confusion is low. Therefore, we recommend that the proposed proprietary name PROVENGE be found Acceptable.

Proposed Proprietary Name Evaluation:

APLB re-reviewed the proprietary name because substantial time had passed since our last review and to ensure that our review was within 90 days of approval. There were no newly marketed products whose names resembled PROVENGE; however, there is an injectable product that is currently under review in the Office of Blood Research and Review with a similar name, PRIVIGEN.

PROVENGE is an autologous cellular immunotherapy product designed to stimulate an immune response against prostate cancer. PRIVIGEN is a polyvalent human normal immunoglobulin for intravenous injection (IGIV).

	PROVENGE	PRIVIGEN
Dosage form	Injection, autologous cells	Injection, solution
Proposed Indication	treatment of men with asymptomatic metastatic androgen independent prostate cancer	treatment of primary immunodeficiency (PI) and for treatment of immune thrombocytopenia purpura (ITP) to rapidly raise platelet counts to prevent bleeding
Dose & Administration	Autologous mononuclear cells, including APCs loaded with recombinant prostate antigen, suspended in 250 ml of Lactated Ringer's. 3 doses by IV infusion at approximately 2 week intervals. Each dose is preceded by a leukapheresis procedure approximately 2 to 3 days prior to the infusion date.	PI: 200 to 800 mg/kg body weight IV every 3 to 4 weeks; ITP: 1 g/kg body weight IV for 2 days.
Storage	Refrigerate	Room temperature
Administration locations	Administered at the infusion center.	Administered in hospitals, doctors' offices, outpatient clinics and patients' homes.
Identification	Identified with the patient's full name and date of birth, lot number, product name, manufacturer name and address, storage condition, quantity, and expiration date/time	No patient identification information

PROVENGE will be shipped to the designated infusion center with patient-specific labeling on each unit for delivery to the patient. At the infusion center, the product is held, pending disposition by the sponsor's QA. The infusion procedure is not initiated until a final product disposition form documenting the approval of the product has been received. PROVENGE is ordered from Dendreon and leukapheresis is scheduled, so it does not appear that a patient could take a doctor's order for PROVENGE to a pharmacy or outpatient clinic and receive PRIVIGEN in error. However, if PRIVIGEN is stocked at the infusion centers, a patient who is to receive PROVENGE might receive PRIVIGEN in error.

Recommendations:

APLB recommends that the proposed proprietary name PROVENGE be found acceptable. No recently approved products whose names resemble PROVENGE were found. There appears to be a minimal risk for medication errors with the proprietary name for another product (PRIVIGEN) under review, taking into account similarity in spelling, pronunciation, handwriting, dosage form, and administration route. This risk is low since there will be differences in packaging, frequency of infusion, infusion facility, storage location, and patient identification information.

If OCTGT accepts our recommendation that the proposed proprietary name PROVENGE is acceptable, please include the following text in your letter to the manufacturer:

We have considered your proposed proprietary name PROVENCE in consultation with CBER's Advertising and Promotional Labeling Branch (APLB) and conclude that under 21 CFR Part 201 the proposed proprietary name is acceptable at this time.

You should request another proprietary name review of PROVENCE closer to the time of approval since a significant amount of time may pass between now and licensure of the product and to ensure that FDA has not approved a product with a conflicting proprietary name in the interim.

References:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda> (CDER New and Generic Drug Approvals from June 2005 to April 3, 2007)

<http://www.fda.gov/cber/products.htm> (CBER approvals from June 2005 to April 3, 2007)

If you have any questions, please contact Catherine Miller at 301-827-3028.

MEMORANDUM

**Department of Health and Human Services
Public Health Service
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Date: June 24, 2005

From: Beverly Conner, Pharm.D. Consumer Safety Office, (b) (6)
Advertising and Promotional Labeling Branch (HFM-602)
Division of Case Management

Through: Glenn N. Byrd, M.B.A., Branch Chief, APLB (HFM-602) (b) (6)

Through: Robert A. Sausville, Director, Division of Case Management (HFM-610) (b) (6)

To: Daniel Rosenblum, MD, DCEPT/OCTGT (HFM-755)
Keith Wonnacott, Ph.D., DCGT/OCTGT, (HFM-573)
Andrea Wright, Supervisory CSO, RMS/OCTGT, (HFM-705)

Subject: Review of Proposed Proprietary Name **PROVENGE**, BB-IND 6933.

Recommendation: ACCEPTABLE WITH CONCERNS

Executive Summary

APLB recommends that the proposed proprietary name **PROVENGE**[®] be **ACCEPTABLE WITH CONCERNS** at this time. There appears to be a risk for a medication error with proprietary names for other marketed products, taking into account spelling, handwriting, pronunciation, patient population, dosage form, route of administration, storage, and marketing status. However, this risk could be minimized due to differences in dose, dosage interval, strength, indication, labeling, and limited availability of **PROVENGE**.

Background:

On May 30, 2000, Dendreon requested that FDA review their proposed proprietary name **PROVENGE**[®] that was submitted under BB-IND 6933, amendment 62. On March 15, 2001, APLB requested additional information from Dendreon for review of the proposed proprietary name **PROVENGE**[®] for their autologous antigen loaded antigen presenting cells product. On May 8, 2001, the company submitted their original proprietary submission along with the information that was requested. Between the dates of April 23, 2002, and October 23, 2002, the IND was on partial clinical hold. On February 19, 2003, APLB advised Dendreon to resubmit the proprietary name review request after the IND is removed from partial clinical hold.

On February 8, 2005, APLB discussed the proprietary name with Dendreon and on February 14,

2005, Dendreon resubmitted an updated name request for the proposed proprietary name **PROVENGE**. The submission was received in APLB on March 1, 2005.

Dendreon was granted Fast Track Designation for **PROVENGE** and is currently conducting a pivotal Phase 3 clinical trial. This proposed pivotal clinical protocol for this study was reviewed under the Special Protocol Assessment policy. Dendreon anticipates the submission of a BLA in the first quarter of 2006.

Dendreon noted that the United States Adopted Names (USAN) has not developed nomenclature for cellular therapy products. Dendreon submitted a proposal for classifying cellular therapies for USAN to consider at their February 14, 2005, USAN Council Meeting. Dendreon plans to submit a proposal for the USAN established name once a nomenclature scheme for cellular products is established.

Overview of the Proposed Indication, Dose, Dosage Form, Administration, and Storage Information:

Dendreon is proposing the proprietary name **PROVENGE**, for an individualized immunotherapy treatment, consisting of autologous antigen presenting cells (APCs) loaded with recombinant Prostate Antigen PA2024 and a recombinant fusion protein composed of prostatic acid phosphatase (PAP) linked to granulocyte-macrophage colony-stimulating factor (GM-CSF)

The proposed indication for **PROVENGE** is to treat asymptomatic males with Gleason Sum ≤ 7 , metastatic androgen independent prostatic adenocarcinomas. **PROVENGE** will be prescribed, prepared and labeled for a specific patient. The product is prepared by isolating antigen presenting cell precursors and mononuclear cells from the patient's blood via leukapheresis. [REDACTED] b(4)

[REDACTED] and suspended in Lactated Ringer's Injection, USP. Within 18 hours after the manufacturing process has been completed the product is shipped to the outpatient clinic and administered to the specific patient. The cells are stored at [REDACTED] during shipment. The proposed treatment consists of three intravenous infusions given as an outpatient procedure every two weeks for one month. The proposed dose and strength is based on what can be collected from the patient within the range of [REDACTED] antigen-presenting cells. These cells are suspended in a large volume of 250 ml of Lactated Ringer's. Labeling and package information was not provided in the proprietary name review request.

Rationale for use of the proprietary name:

Dendreon stated that rationale for selecting **PROVENGE** as the proprietary name was based upon the product's therapeutic action and intended use. The company stated that a linguistics market research study was conducted and foreign language translation issues were not found.

A Thomson & Thomson trademark database search was done for the exact trademark, similar letterstrings, suffix, prefix and phonetics. Results of the trademark search showed that Dendreon's trademark was available for use. Dendreon has registered the trademark, **PROVENGE** with the U.S. Patent and Trademark Office.

Dendreon considered the potential for prescribing errors for the proprietary name, **PROVENGE** and concluded the likelihood for name confusion is minimal to none since the infusion is labeled for a specific patient.

Proposed Proprietary Name Evaluation:

1) **False or Misleading [21 CFR 201.6 (a)]:**

The proposed proprietary name **PROVENGE** is not regarded to be false or misleading.

2) **Fanciful [21CFR 201.10 (c)(3)]:**

The proposed proprietary name, **PROVENGE** is not regarded to be fanciful. However, the proposed proprietary name, **PROVENGE** appears to imply that the drug or ingredient has some unique effectiveness or duration. The prefix root, “prove” is defined in Webster’s Dictionary as to be known to be valid, effective, or genuine. “Proven” is defined as established truth or validated truth by soundness by presentation of argument or evidence. In addition, the prefix, “Pro” means acting in place of or in support of and the suffix, “Venge” means to avenge. “Vengeance” is defined as “with great force or fury and excessively. It is also possible that the first three letters of the name might have originated from the term “prostate” and the “venge” is used to demonstrate that the product “avenges” the disease from the cancerous prostate gland. At this time we are not able to determine if this will be supported by data.

3) **Similarity in Spelling or Pronunciation [21 CFR 201.10 (c) (5)]:**

PROVENGE may be confused with the proprietary or the established name of a different drug, because of similarity in spelling, pronunciation, and handwriting with proprietary names for other marketed products, especially for the ones as outlined below. Since, drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary and /or established names sound or look alike. Even when proprietary names are only slightly similar, overlapping product characteristics may create a greater potential for confusion. The names are listed in the tables below from the highest to lowest potential for causing a medication error.

APLB also has concerns with similar letters in the first part of a proprietary or established name because the prescriber’s handwriting may become less legible at the end of the name making these names undistinguishable with sound-alike, look-alike name for products that already exist in the U.S. marketplace.

- There are several marketed products of moderate concern that contain the “**Prev**” prefix in their proprietary name. We believe that products beginning with the prefix “**Prev**” could be confused with products beginning with “**Prov**” prefix since an “**e**” could look like an “**o**” if the prescriber handwrites the prescription. In this group **Previd (injection, oral)** and **Prevnar (injection)** are the most concerning, because like the proposed proprietary name **PROVENGE** they are given as an injection. Although the beginning of these two marketed products sound alike and could be confused with “**Prov**,” the endings are not similar to the ending of the proposed

proprietary name **PROVENGE**, thus this lessens the risk of a mix-up.

- There are more than 70 marketed products that begin with the “Pro” prefix in their proprietary or established name. A number of the “Pro” drugs have limitations to their use and availability, thus they have been eliminated from the discussion. **PROVENGE** could be confused with some of the marketed products that begin with the “Pro” pre-fix in their proprietary name. The products that are of moderate or higher concern include: **Provigil (oral)**, **Procrit (injection)**, **Protonix (injection)**, and **Proleukin (injection)**. The established name **Prochlorperazine (injection, oral, rectal)** is of moderate concern because it begins with the prefix “Pro” and could be confused or misread on a written prescription.
- Due to spelling there is moderate concern for potential confusion and mix-ups with the proposed proprietary name **PROVENGE** with those marketed products that have 4 or more consecutive letters in their proprietary names that match **PROVENGE**. The proprietary names that meet these criteria are: **Provigil (oral)**, **Provera (oral)**, **Proventil (oral, aerosol)** and **Proventil HFA (aerosol)**.
- The proprietary name for the combination product **ProVisc (injection)** matches the first four letters of the proposed proprietary name **PROVENGE** and is also of moderate concern of being confused with **PROVENGE** with either a verbal phone order or a written order. Both products have 2 syllables in their names.
- Of high concern for sound-alike and look-alike products with **PROVENGE** is the proprietary name **Provigil**. A handwritten order for **PROVENGE** or **Provigil** could be easily mistaken for the other product because the beginning and ending of both products look very much alike. Although **Provigil** is 3 syllables and **PROVENGE** is two, these two products could sound similar if a prescription was phoned-in for either product.

Brand name	Dosage Form	RX / OTC	Dose & Administration	Indication	Storage	Potential
PROVENGE	Injection	RX	b(4) antigen-presenting cells suspended in a large volume of 250 ml of Lactated Ringer's IV infusion delivered over 60 minutes every 2 weeks, for one month.	Treatment of asymptomatic males with Gleason Sum ≤ 7, metastatic androgen independent prostatic adenocarcinomas	Refrigerate	N/A
Proleukin (aldesleukin)	Lyophilized powder. Each vial contains 22 x 10 ⁶ million International units	RX	600,000 IU/kg every 8 hours. Reconstituted and diluted in 50	Treatment of adults with metastatic renal cell carcinoma	Refrigerate	High

Brand name	Dosage Form	RX / OTC	Dose & Administration	Indication	Storage	Potential
	(IU).		mL of D ₅ W and IV infused over 15 minute to a maximum of 14 doses. Following 9 days of rest, the schedule is repeated for another 14 doses, for a maximum of 28 doses per course as tolerated.	and adults with metastasic carcinoma		
Procrit (Epoetin Alfa, recombinant)	Injection 1mL Single dose vials: 2000 units/mL, 4000u/mL, 10,000units/mL, 20,000units/mL, 40,000units/mL 2 mL Multidose vials: 10,000, 20,000units/mL	RX	Intravenous bolus or subcutaneous Adults: 50-100 units/kg given 3 times/weekly Children: 50 units/kg 3 times/weekly Reduce dose when hemoglobin approaches 12g/dL	Chronic renal failure anemia; Anemia relate to zidovudine therapy in HIV; anemia in cancer patients; and reduction of allogeneic blood transfusion in surgery patients	Refrigerate	High
Provigil (modafinil)	Oral tablet: 100 mg, and 200 mg	RX C-IV	Oral dose: 200 mg /day	Improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work	Room temp. Schedule IV drug	High
ProVisc (Sodium Hyaluronate)	Injectable: 10mg/mL Glass syringes come in following volumes: 0.4 mL, 0.55 mL, and 0.85 mL glass syringed	RX	Slowly and carefully inject a sufficient amount of drug into the anterior chamber during the procedure.	For use as an ophthalmic surgical aid in the anterior segment during cataract extraction and ocular lens implantation	Refrigerate	Moderate
Previcid I.V. (Lansoprazole)	Powder for injection: 30 mg/vial Reconstitute with 5 mL sterile water for injection; then dilute	RX	IV infusion - Alternative for short-term treatment (up to 7 days) of all	Erosive Esophagitis	Room Temp	Moderate

Brand name	Dosage Form	RX / OTC	Dose & Administration	Indication	Storage	Potential
	reconstituted solution with 50 mL compatible IV solution		grades of erosive esophagitis. Then switch to oral formulation for a total of 6-8 weeks			
Pprevnar (Pneumococcal 7-valent Conjugate Vaccine CRM ₁₉₇ Protein)	Injectable	RX	0.5 mL Intramuscularly Doses given in Infants at 2 months, 4 months, 6 months, and 12-15 months	Immunization of infants against invasive disease caused by S. pneumoniae	Refrigerate	Moderate
Established name of prochlorperazine	Injection: 5 mg/ml; 2 mL and 10 mL vials & ampules.. Oral Tablets: 5 mg, 10 mg, 25 mg; Spansule: 10, 15, & 30 mg Syrup: 5mg/5mL Suppositories: 2.5, 5, 10 and 25 mg	RX	Adult Surgery: IM: 5 –10 mg 1-2 hrs before induction of anesthesia (may repeat once in 30 minutes), or to control acute symptoms after surgery; IV injection: 5 to 10 mg 15 to 30 minutes before induction of anesthesia or to control symptoms after surgery, may repeat once. Do not use bolus injection, do not exceed 5mg/ml/min. IV infusion: 20 mg/L of isotonic solution. Add to IV 15 to 30 minutes prior to induction. Adults - control of nausea: Oral: 5-10 mg 3 to 4 times daily, 15 mg (SR) on arising every 12 hours; Rectal: 25 mg bid; IM: 5 to 10 mg. Repeat every 2 to 4 hrs	Control of severe nausea and vomiting	Room temperature	Moderate

Brand name	Dosage Form	RX / OTC	Dose & Administration	Indication	Storage	Potential
			if necessary. Do not exceed 40 mg/day Should not be used in Pediatric patients under 20 lbs in weight or 2 yrs of age. Children oral & rectal dose for nausea: 20-29 lbs: 2.5 mg 1-2 times daily 30-39 lbs: 2.5 mg, 2-3 times daily 40-85 lbs: 2.5 mg 3 times /day or 5 mg twice daily Pediatric IM Injection: 0.06 mg of drug per lb of body weight deep IM.			
Proscar (Finasteride)	Oral Tablet: 5mg	RX	5 mg orally once daily with or without meals	Benign prostatic hyperplasia Investigational use: b(4) b(4)	Room Temperature	Moderate
Provera (medroxyprogesterone)	Tablet: 2.5 mg, 5mg, 10mg	RX	For reduction of endometrial hyperplasia in post-menopausal hyperplasia in postmenopausal women receiving 0.625 mg conjugated estrogen is 5-10 mg daily for 12-14 consecutive days per month; Secondary amenorrhea is 5-10 mg for 5-10 days; Abnormal uterine bleeding due to hormonal	Amenorrhea, abnormal uterine bleeding due to fibroids or uterine cancer; and to reduce incidence of endometrial hyperplasia in women receiving conjugated estrogen	Room temperature	Moderate

Brand name	Dosage Form	RX / OTC	Dose & Administration	Indication	Storage	Potential
			imbalance - on 16 th or 21 st day of menstrual cycle 5-10 mg for 5 to 10 days			
Proventil (albuterol)	Inhalation Solution 0.083%; unit dose vials of 3mL each, 24 vials in each carton	RX	Dose for adults and patients 12 yrs or older is 1 vial administered every 3 to 4 hours by nebulizer PRN	Relief of bronchospasm with reversible obstructive airway disease and acute attacks	Room temperature	Moderate
Proventil HFA (albuterol)	Inhalation Aerosol Each actuation delivers 108mcg albuterol sulfate (equivalent to 90 mcg of albuterol base)	RX	Acute episodes adults and children 4 yrs or older than: 2 inhalations repeated every 4 -6 hours. Exercise induced bronchospasm dose is 2 inhalations 15 to 30 minutes prior to exercise	Adults and children 4 yrs of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm	Room temperature	Moderate
Protonix I.V. (pantoprazole)	Freeze-dried powder for injection: 40 mg. Must reconstitute with 10 mL 0.9% sodium chloride injection	RX	40 mg in 100 mL compatible fluid and infuse IV over a period of 15 minutes once daily	Short term treatment for 7-10 days of gastroesophageal reflux reflux disease and a history of erosive esophagitis and treatment of hypersecretory conditions associated with Zollinger-Ellison syndrome or other neoplastic conditions.	Room temperature	Moderate

The following risk factors should also be considered when evaluating the degree to which **PROVENGE** may be of concern for medication errors.

Strength/ Dose/Dosage Form/Route of Administration:

Two different products with similar or identical strengths and with proprietary names that sound or look alike could be more easily confused than two products with very different strengths. The risk of confusion increases substantially if two products with similar proprietary names have identical strengths and dosing intervals

The risk of a medication error is increased when products with similar proprietary names are dosed or prescribed in an identical manner (i.e., once a day). In addition, there is evidence that medication errors can occur even between different dosage forms and routes of administration (capsule vs. injection) and between products with similar routes of administration when similar proprietary names exist.

PROVENGE is supplied as an injectable solution. This product is individualized and contains a minimum number of cells collected from a single leukapheresis of the donor patient for the final preparation of the **PROVENGE**. The final amount of the **PROVENGE** should contain b(4) b(4) antigen presenting cells suspended in 250 ml of Lactated Ringer's. **PROVENGE** is shipped at b(4) b(4) by courier/plane to an outpatient clinical site. The patient is scheduled to receive his **PROVENGE** infusion intravenously over 60 minutes in an outpatient setting within 18 hours of completing the manufacturing process.

PROVENGE is supplied as injectable solution. Of the injectable products in the table, **Proleukin**, **Previcid IV**, and **Protonix I.V** like **PROVENGE** are administered by IV infusion; **Prevnar** by IM, **prochlorperazine** by IM, IV, oral or rectal routes; **Procrit** by IV or subcutaneous, and **ProVisc** is injected into the anterior chamber of the eye. The route of administration for **Proventil** is oral inhalation and **Provera**, **Proscar** and **Provigil** are all given orally.

PROVENGE has a dose range of b(4) b(4) (antigen presenting cells). The dosages of **PROVENGE** and **Proleukin** could look very similar to each other if stored in the same area. The recommended dose for **Proleukin** is 600,000 IU/kg, so an adult male with a weight of 85 Kg would need a dose of 51,000,000 IU or if expressed exponentially this dose would translate to 5.1×10^7 . The wrong product might be accidentally chosen because of confusion caused by similar looking dosages on the bottle labels. Differences in the route of administration do not prevent similarity in name or poorly handwritten orders errors from occurring.

PROVENGE will not be routinely stocked on the formulary since this is an autologous cell-based therapy that is manufactured for a specific patient. Due to differences in doses, dosage intervals, and strength, the risk for confusion of **PROVENGE** between these products may be minimized; however, the potential risk of confusion due to dosage form and injectable administration exists.

Indications and/or Pharmacological-Therapeutic Categories:

The proposed indication for **PROVENGE** is for the treatment of asymptomatic males with Gleason Sum ≤ 7 , metastatic androgen independent prostatic adenocarcinomas. **PROVENGE** is an individualized, cellular therapy product. While **Prevnar** is a vaccine used in pediatrics to prevent pneumonia. **PROVENGE** will be used to treat men who have prostate cancer. Prescriptions for drugs do not usually indicate the use of the product or if the patient is male or female. Numerous names can be used for both female and males. Additionally the person filling the prescription

would not necessarily know what the product **PROVENGE** is indicated for and that it is a “male only” product. So potentially some of the oral products beginning with “**PROV**” could accidentally be dispensed.

A number of products in the above table could be used in oncology patients. **Proleukin** is indicated for the treatment of adults with metastatic renal cell carcinoma, and with metastatic carcinoma. **Proscar** is approved for the treatment of benign prostatic hyperplasia and it is being investigated for b(4). Two products used to treat the side effects of cancer treatment are **Procrit**, which is used to treat the anemia often seen in cancer patients and **prochlorperazine** is used to treat chemotherapy-induced nausea. **Provera** is indicated for the treatment of women with uterine cancer, but this drug would probably be obtained from a retail pharmacy for home use.

While the other products in the table above do not have similar indications or are not in a similar pharmacological/ therapeutic category as **PROVENGE**, different indications will not decrease the risk of confusion since the intended use or indication is not routinely written on a prescription or medication order, and the patient may have more than one pre-existing illness/disease state. Therefore, the possibility of a medication error exists between products listed in the table and **PROVENGE** if a verbal or written order is received. In addition, because **PROVENGE**, **Proleukin**, **Procrit**, **Proscar**, **Procrit**, and **Prochlorperazine** could be used in cancer patients, there is a moderate risk of confusion with these products.

Storage Location:

The use of a different storage location (i.e., refrigerator vs. room temperature, oral dosage form location vs. intravenous dosage form location) for two different products with similar names does not significantly decrease the risk of wrong product selection by the health care professional. Therefore, the use of different storage locations for drugs with names that look or sound alike may not mitigate the potential risk of medication errors.

PROVENGE will be shipped refrigerated to the clinical site via courier or plane. **PROVENGE** has a very short shelf life, and will be refrigerated until administered in an oncology or outpatient setting. **Proleukin** and **Procrit** would be found in the refrigerator in an oncology clinic or hospital pharmacy.

In addition, **ProVisc** would likely be refrigerated in a surgery suite, and could be stored in a hospital pharmacy. **Plevnar** is also refrigerated, but its use is restricted to infants and toddlers and would not be routinely stored in an oncology clinic. **Prochlorperazine**, **Proscar**, and **Provera** are stored at room temperature and could be used in an oncology or outpatient setting.

Previdid IV, **Proventil**, and **Protonix IV** are stored at room temperature and would not be found in an oncology setting, but in a hospital pharmacy. **Provigil** is a C-IV controlled substance that is stored at room temperature under lock up and signed out on a narcotic log. **PROVENGE** is refrigerated for a short time and the probability of these products coming within close proximity is very low. However, there is a moderate potential for confusion with **PROVENGE** and accidental use of refrigerated products and products used in an oncology setting due to storage location.

Marketing Status:

Two products with similar proprietary names that are in the same marketing arena (e.g., prescription drug products) could more easily be confused than two products with similar names in different markets (one Rx and the other OTC).

Like **PROVENGE**, all the products listed in the above table are available on prescription. Because a number of these products are also injectable products, the potential for confusion with these products due to marketing status exists. However, the sponsor proposes that **PROVENGE** use will be limited to prostate cancer patients treated at oncology sites that administer the product, thus minimizing the risks for error.

Packaging and Labeling:

When the container labels, carton labeling, and/or packaging is similar for two different drug products with similar proprietary names, the risk for confusion with similar proprietary names is increased. The packaging/labeling of the **PROVENGE** and marketed products was not available; therefore, the risk of confusion due to packaging/labeling could not be evaluated.

A significant risk for medication errors or confusion with this novel cellular therapy exists. Safety considerations should be addressed when designing and reviewing the labels for **PROVENGE** to prevent dispensing errors.

Safety Concerns:

The sponsor for **PROVENGE** has not conducted drug interaction studies. In addition, it is difficult to predict if **PROVENGE** could be safely administered in other cancers, transplant, cardiac, or non-cancer patients or conversely, if another product was administered instead of **PROVENGE**.

Therefore, due to the serious life-threatening nature of the potential adverse events that might occur from incorrect product administration, the sponsor should ensure that steps be taken to educate caregivers to prevent incorrect dispensing of sound alike name products.

Because this is a patient specific treatment, the chance of medication mix-up errors should be less than with the more traditional mainstream type prescription drugs. This is not foolproof since tissue based treatments could be accidentally given to the wrong patient. Each year more than 850 patients in the United States receive transfusions intended for someone else, and according to projections from a New York study, at least 20 of these 850 patients die from complications of receiving the incorrect blood type.¹ If more than one patient is waiting to be treated at the same clinic, the drug could be administered to the wrong patient and this mix-up could cause severe injury or death to the patient. It will be important for the company to be proactive and take special labeling measures to ensure that mix-ups do not occur. This could include NDC barcodes or armbands with special identifiers that match the infusion bottle label for the specific patient.

Recommendations for proposed name:

APLB recommends that the proposed proprietary name **PROVENGE** be found **acceptable with concerns**. There appears to be a risk for a medication error with proprietary names for other marketed products, taking into account spelling, handwriting, pronunciation, patient population, dosage form, route of administration, storage, and marketing status. However, this risk could be minimized due to differences in dose, dosage interval, strength, indication, labeling, and limited availability of **PROVENGE**.

To mitigate the potential medication errors that might occur from incorrect product administration,

¹The Boston Globe, Scott Allen, "System Targets Blood-Type Mix-Ups," 2/24/05.

the sponsor should develop creative ways to restrict the product by unique procedures taken to educate caregivers and/or alter planned distribution schemes to prevent incorrect dispensing of sound alike name products and designing labels for the **PROVENGE** product to ensure that the correct product is administered to the correct patient.

If OCTGT accepts our recommendation that the proposed proprietary name **PROVENGE** be found **acceptable with concerns**, please include the following text in your letter to the manufacturer:

We have considered your proposed proprietary name **PROVENGE** in consultation with CBER's Advertising and Promotional Labeling Branch (APLB) and conclude that under 21 CFR Part 201, the proposed proprietary name **PROVENGE** is acceptable.

You should request another proprietary name review for **PROVENGE** closer to the time of approval since a significant amount of time will pass between now and the licensure of the product to ensure that FDA has not approved a product with a conflicting proprietary name in the interim.

*The following references were used:

1. The Boston Globe, Scott Allen, "System Targets Blood-Type Mix-Ups," 2/24/05.
2. 2002 American Drug Index
3. 2005 Physicians' Desk Reference.
4. Martindale's (through Micromedex Integrated)
5. Electronic Orange Book through June 6, 2005
6. <http://www.rxlist.com>.(RxList)
7. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda> (CDER New and Generic Drug Approvals: 1998 to June 15, 2005). Also, looked at CBER New BLA, NDA and ANDA approvals lists ending June 15, 2005
8. <https://www.factsandcomparisons.com/efacts.asp> (Drug Facts and Comparisons)
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