

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-051

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; White Oak 22, Mail Stop 4447)**

DATE RECEIVED: 01/27/06	DESIRED COMPLETION DATE: 05/26/06	OSE REVIEW #'s:
DATE OF DOCUMENT: 12/05/05	PDUFA DATE: 04/29/07	06-0027 & 06-0027-1

TO: Badrul Chowdhury, M.D.
Director, Division of Pulmonary and Allergy Products
HFD-570

THROUGH: Alina R. Mahmud, R.Ph., MS, Team Leader
Denise P. Toyer, Pharm.D., Deputy Director
Carol A. Holquist, R.Ph., Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Jinhee L. Jahng, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: <u> </u> (Fluticasone Furoate) Nasal Spray 27.5 mcg per actuation	SPONSOR: GlaxoSmithKline
NDA #: 22-051 (IND 48,647)	

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name,
2. DMETS recommends implementation of the label and labeling recommendations outlined in Section III of this review in order to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, , acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

15 Page(s) Withheld

 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jinhee Jahng
11/8/2006 03:21:34 PM
DRUG SAFETY OFFICE REVIEWER

Alina Mahmud
11/9/2006 08:53:26 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
11/9/2006 10:44:14 AM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO22, Rm. 4447)**

DATE RECEIVED: January 18, 2007	DESIRED COMPLETION DATE: February 9, 2007	OSE REVIEW #: 2007-165
DOCUMENT DATE: January 16, 2007	PDUFA DATE: April 29, 2007	

TO: Badrul Chowdhury, MD
Director, Division of Pulmonary and Allergy Products
HFD-570

THROUGH: Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Tina M. Tezky, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: Veramyst™ (Fluticasone Furoate) Nasal Spray .75 mcg per actuation	NDA SPONSOR: GlaxoSmithKline
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NDA#: 22-051

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Veramyst™. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature of this document.
2. DMETS recommends implementation of the container label, carton, and insert labeling revisions outlined in Section III of this review in order to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, Veramyst™, acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Nancy Clark, Project Manager, at 301-796-1187.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
HFD-420; WO22, Rm. 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: January 24, 2007
NDA#: 22-051
NAME OF DRUG: Veramyst™
(Fluticasone Furoate) Nasal Spray
27.5 mcg per actuation
NDA HOLDER: GlaxoSmithKline

I. INTRODUCTION:

This consult was written in response to a request from the Division of Pulmonary and Allergy Products (HFD-570) for a review of the proprietary name, "Veramyst", regarding potential name confusion with other proprietary and/or established drug names. This NDA was reviewed by DMETS for the tradename '_____'. DMETS did not recommend the use of the proprietary name, '_____'. Due to potential look-alike and/or sound-alike confusion with Allermed, AllerMax, Alamast, Allerest, Allerhist-1, and Altamist. The sponsor has submitted the proposed proprietary name "Veramyst" for review and comment. Revised container labels, carton and insert labeling were submitted for review and comment.

PRODUCT INFORMATION

Veramyst (fluticasone furoate) is a synthetic fluorinated corticosteroid with potent anti-inflammatory activity. Veramyst is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in patients 2 years of age and older.

Adults and Adolescents 12 years of age and older: The recommended starting adult dosage is 110 mcg once daily administered as 2 sprays in each nostril. Once the maximum benefit has been achieved and symptoms have been controlled, reducing the dosage to 55 mcg (1 spray in each nostril) once daily may be effective in maintaining control of allergic rhinitis symptoms.

Children 2 to 11 years of Age: Children should be started with 55 mcg once daily administered as 1 spray in each nostril. Children not adequately responding to 55 mcg may use 110 mcg (2 sprays in each nostril) once daily. Once adequate control is achieved, the dosage should be decreased to 55 mcg once daily.

Veramyst will be supplied in an amber glass bottle enclosed in a nasal device with a small nozzle and a mist-release button to actuate the spray. Each bottle will contain a net fill weight of 10 g and will provide 120 metered sprays. Each spray delivers a fine mist containing 27.5 mcg of fluticasone furoate in 50 mL of formulation through the nozzle.

II. RISK ASSESSMENT

The medication error staff of DMETS conducted a search of the internet, several standard published drug product reference texts^{1,2} as well as several FDA databases^{3,4} for existing drug name which sound-alike or look-alike to Kuvan to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted⁵. The SAEGIS™ Online service⁶ Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a product must be considered in the overall safety evaluator risk assessment.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Veramyst. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC did not have concerns with the name, Veramyst, in regard to promotional claims.
2. The Expert Panel identified five proprietary names that were thought to have the potential for confusion with Veramyst. One additional name, Viramune, was identified through the prescription studies. These products are listed in Table 1, along with the dosage forms available and usual dosage (see page 4).

¹ MICROMEDEX Integrated Index, 2007, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, Missouri.

³ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-07, and the electronic online version of the FDA Orange Book.

⁴ Phonetic and Orthographic Computer Analysis (POCA).

⁵ www location <http://www.uspto.gov/tmdb/index.html>.

⁶ Data provided by Thomson & Thomson's SAEGIS™ Online service, available at www.thomson-thomson.com

Table 1: Potential Sound-Alike/Look-Alike Names Identified for Veramyst

Product Name	Dosage form(s), Established name	Usual adult dose	Other
Veramyst	Fluticasone Nasal Spray 27.5 mcg/actuation	One – two sprays in each nostril once daily.	
Viracept Rx	Nelfinavir Tablets 250 mg, 625 mg Nelfinavir Oral Powder for Suspension 50 mg base per scoopful	1250 mg twice daily or 750 mg three times daily.	LA
Viramune Rx	Nevirapine Tablets 200 mg Nevirapine Oral Suspension 50 mg/5 mL	200 mg twice daily.	LA
(Zolinza) Vorinostat Rx	Vorinostat Capsules 100 mg	400 mg once daily with food.	LA
Mucomyst Rx	Acetylcysteine Oral Solution for Inhalation 10%, 20%	Acetaminophen overdose: 140 mg/kg initially, then 70 mg/kg every 4 hrs for 17 additional doses. Mucolysis: 1 – 10 mL (20%) or 2 – 20 mL (10%) via nebulization or tracheostomy every 2 – 6 hrs as needed.	LA
Verapamil Rx	Verapamil Tablets 40 mg, 80 mg, 120 mg Verapamil Extended-release Tablets 120 mg, 180 mg, 240 mg Verapamil Extended-release Capsules 120 mg, 180 mg, 240 mg Verapamil Injection 2.5 mg/mL	80 mg – 120 mg three times daily. 180 mg – 480 mg once daily. Max: 540 mg daily. 5 mg – 10 mg IV bolus over 2 min, may repeat after 30 min if necessary.	LA
VitaMist OTC	Multivitamin Oral Spray Product Line Numerous Formulations	4 - 8 sprays (0.4 mL) per day.	LA/SA
*Frequently used, not all-inclusive. **LA (look-alike), SA (sound-alike) *** Name pending approval. Not FOI releasable.			

B. PRESCRIPTION STUDY ANALYSIS

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Veramyst 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. These studies employed a total of 122 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Veramyst (see page 5). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were 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 sent their interpretations of the orders via e-mail to the medication error staff.

Veramyst

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p>Outpatient RX:</p> <p style="text-align: center;"><i>Veramyst</i> <i>#1</i> <i>2 sprays into nostrils</i> <i>QD</i></p>	<p>Veramyst #1 2 sprays into the nostrils once daily.</p>
<p>Inpatient RX:</p> <p><i>Veramyst 2 sp into nostrils QD</i></p>	

3. Results:

One respondent in the inpatient prescription study interpreted the proposed name as Viramune, a currently marketed U.S. drug product. The remaining misinterpretations were misspelled/phonetic variations of the proposed name, Veramyst. See Appendix A for the complete listing of interpretations from the verbal and written studies.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Veramyst, the primary concerns relating to look-alike and sound-alike confusion with Veramyst are Viracept, Viramune, Vorinostat, Mucomyst, Verapamil, and VitaMist.

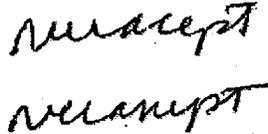
Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case there was confirmation that Veramyst could be confused with Viramune. One respondent from the inpatient prescription study misinterpreted the name for an already existing marketed drug product, Viramune. Although there are limitations to the predictive value of these studies, primarily due to sample size, we have acquired safety concerns due to the positive interpretation with this drug product. A positive finding in a study with a small sample size may indicate a high risk and potential for medication errors when extrapolated to the general U.S. population.

1. Viracept was identified as a name with look-alike similarities with Veramyst.

Viracept (nelfinavir) is a human immunodeficiency virus (HIV) protease inhibitor indicated for the treatment of HIV infection in combination with other antiretroviral agents. Viracept is available as 250 mg and 625 mg tablets and a 50 mg base per

scoopful powder for oral suspension. The recommended dose is 1250 mg twice daily or 750 mg three times daily.

The two names begin (V-) and end (-T) with the same letters and share two additional overlapping letters (VIRACEPT vs. VERAMYST). Additionally, the second and third to last letters (-EP- vs. -YS-) bear a strong resemblance when scripted (see sample below). This can be attributed to the downstroke of the "P" and "Y" and the close proximity of the letter "S" to the "Y" in Veramyst, which gives it the likeness of the letter "P".



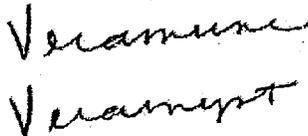
The image shows two lines of handwritten text. The top line is 'Viracept' and the bottom line is 'Veramyst'. The letters 'P' in 'Viracept' and 'Y' in 'Veramyst' are written in a way that their downstrokes are very similar, making them look alike when written quickly.

However, Viracept and Veramyst have numerous differentiating product characteristics such as dosage form (tablet, powder for oral suspension vs. nasal spray), route of administration (oral vs. nasal), frequency of administration (2 – 3 times daily vs. once daily), and available strength (250 mg, 625 mg, 50 mg/scoopful vs. 27.5 mcg/actuation). Although the names are orthographically similar, DMETS believes the differing product characteristics will help avert name confusion and error between Viracept and Veramyst.

2. Viramune was found to have look-alike similarities with Veramyst.

Viramune (nevirapine) is a human immunodeficiency virus (HIV) non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated for the treatment of HIV infection in combination with other antiretroviral agents. Viramune is available as 200 mg tablets and a 50 mg/5 mL oral suspension. The recommended dose is 200 mg once daily for the first 14 days, followed by 200 mg twice daily.

The two names begin (V-) with the same letters and share three additional overlapping letters (VIRAMUNE vs. VERAMYST), which give the names some orthographic similarity (see sample below). Additionally, one respondent in the inpatient written prescription study interpreted the proposed name as Viramune. However, the downstroke of the "Y" and the upstroke of the "T" in Veramyst provide visual distinctions between the two names.

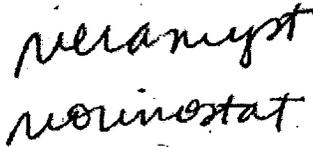


The image shows two lines of handwritten text. The top line is 'Viramune' and the bottom line is 'Veramyst'. The 'Y' in 'Veramyst' has a distinct downstroke, and the 'T' has a distinct upstroke, which helps distinguish it from 'Viramune'.

Viramune and Veramyst have an overlapping frequency of administration (once daily). However, they have numerous differentiating product characteristics such as dosage form (tablet, oral suspension vs. nasal spray), route of administration (oral vs. nasal), and available strength (200 mg, 50 mg/5 mL vs. 27.5 mcg/actuation). DMETS believes the visual distinctions and the differing product characteristics will help avert name confusion and error between Viramune and Veramyst.

3. Vorinostat was found to have look-alike similarities with Veramyst. Vorinostat is the established name for Zolinza and is a histone deacetylase (HDAC) inhibitor indicated for the treatment of cutaneous manifestations in patients with T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies. Vorinostat is available as 100 mg tablets and the recommended dose is 400 mg once daily with food.

Vorinostat and Veramyst begin (V-) and end (-T) with the same letters and share one additional overlapping letter (VORINOSTAT vs. VERAMYST), which contributes to their orthographic similarities (see sample below). However, the names differ in length (ten letters vs. eight letters) and the downstroke of the "Y" in Veramyst gives the names an orthographic distinction.



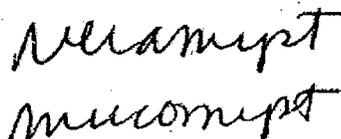
The image shows two lines of handwritten text. The top line is 'veramyst' and the bottom line is 'vorinostat'. Both are written in a cursive, lowercase font. The 'y' in 'veramyst' has a distinct downward stroke that is not present in the 'y' of 'vorinostat', which is a key orthographic difference mentioned in the text.

The products share an overlapping frequency of administration (once daily). However, they have several differing characteristics that helps distinguish the products such as dosage form (capsule vs. nasal spray), route of administration (oral vs. nasal), available strengths (100 mg vs. 27.5 mcg/actuation), and usual dose (400 mg vs. 1 – 2 sprays in each nostril). Because vorinostat is a chemotherapeutic agent, a prescription for vorinostat will most likely include a patient specific dose with specific directions for administration. Although both products are available in one strength, the expression of a patient specific dose will help differentiate the two products.

Due to the visual distinction and product differences, DMETS believes the potential for confusion between Vorinostat and Veramyst is minimal.

4. Mucomyst and Veramyst were found to have orthographic similarities. Mucomyst (acetylcysteine) is a mucolytic agent indicated for the treatment of atelectasis, adjuvant therapy in bronchopulmonary conditions. Mucomyst is also indicated as an antidote for the treatment of acetaminophen toxicity. The dosage range for mucolysis is 1 – 10 mL (20%) or 2 – 20 mL (10%) given via nebulization or tracheostomy every 2 – 6 hours as needed. The dose for acetaminophen toxicity is 140 mg/kg initially, followed by 70 mg/kg every 4 hours for an additional 17 doses.

Mucomyst and Veramyst have the same four trailing letters (-MYST), which contributes to their orthographic similarities. Additionally, the initial letters (M- vs. V-) can look similar when scripted in lower case (see sample below).



The image shows two lines of handwritten text. The top line is 'mucomyst' and the bottom line is 'veramyst'. Both are written in a cursive, lowercase font. The initial letters 'm' and 'v' are written in a way that makes them look very similar, illustrating the orthographic similarity mentioned in the text.

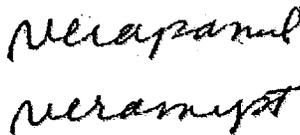
However, Mucomyst and Veramyst have numerous differentiating product characteristics such as dosage form (oral solution for inhalation vs. nasal spray), route of administration (oral inhalation vs. nasal), frequency of administration (every

4 hours for 18 doses or every 2 – 6 hours as needed vs. once daily), and available strength (10%, 20% vs. 27.5 mcg/actuation). Additionally, Mucomyst is primarily used in the inpatient setting, whereas Veramyst will likely be used primarily in the outpatient setting.

Although the names are orthographically similar, DMETS believes the differing product characteristics will help avert name confusion and error between Mucomyst and Veramyst.

5. Verapamil was identified as a name that looks similar to Veramyst. Verapamil is a calcium channel blocker indicated for the treatment of hypertension, angina, and arrhythmias. Verapamil is available as 40 mg, 80 mg, and 120 mg tablets; 120 mg, 180 mg, 240 mg, and 360 mg extended-release capsules; 120 mg, 180 mg, and 240 mg extended-release tablets; and a 2.5 mg/mL injection. The usual dose of the immediate-release tablets is 80 mg – 120 mg three times daily; the extended-release tablets and capsules is 180 mg – 480 mg once daily; and the injection is 5 mg – 10 mg intravenous bolus of 2 minutes, may repeat after 30 minutes if no response.

Verapamil and Veramyst have the same four initial letters (VERA-), which contributes to their orthographic similarities. Both names have an upstroke at the end of the name (-L vs. -T) and contain a downstroke (-P- vs. -Y-) in the middle. However, the downstrokes are located in different positions within each and may help differentiate the names (see sample below).



Verapamil and Veramyst can have an overlapping frequency of administration (once daily). However, they have several differentiating product characteristics such as dosage form (tablet, extended-release capsule, extended-release tablet, injection vs. nasal spray), route of administration (oral, injection vs. nasal), and available strength (2.5 mg/mL, 40 mg, 80 mg, 120 mg, 180 mg, 240 mg vs. 27.5 mcg/actuation). DMETS believes the visual distinctions and differing product characteristics will help avert name confusion and error between Verapamil and Veramyst

6. VitaMist was identified as a name that looks and sounds similar to Veramyst. VitaMist is an over-the-counter (OTC) multivitamin product line used as nutritional supplements. VitaMist comes in many different formulations (e.g. VitaMist Advance Performance, VitaMist Anti-Oxidant, VitaMist Arthriflex, VitaMist B12, VitaMist CardioCare, VitaMist Melatonin, VitaMist Men's Formula, VitaMist PMS, VitaMist Pre-Natal, VitaMist Smoke-Less, VitaMist St. John's Wort, VitaMist VitaCanine, VitaMist VitaFeline, VitaMist VitaSight, VitaMist Women's Health).

VitaMist and Veramyst have the same initial letter (V-), two trailing four letters (-ST), and two additional overlapping letters (VITAMIST vs. VERAMYST), which contribute to their orthographic and phonetic similarities (see sample, page 9). The downstroke

of the "Y" in Veramyst provides a visual distinction; however, it does not offer audible differentiation.

The two products have an overlapping potential frequency of administration (once daily) and dosage form (oral spray vs. nasal spray); however, they differ with respect to, route of administration (oral vs. nasal), and prescription status (OTC nutritional supplement vs. prescription). Additionally, VitaMist is available in numerous different variations and modifiers. The expression and/or clarification of these modifiers will help avert confusion, should the names be confused.

DMETS believes the product differences and multiple variations of the VitaMist product line will help avert confusion and error between VitaMist and Veramyst.

Veramyst
Vitamist

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In review of the container label, carton and insert labeling of Veramyst, DMETS has focused on safety issues relating to possible medication errors. DMETS has identified the following areas of improvement that will minimize potential user error.

A. GENERAL COMMENTS

The labels and labeling provided utilize the word "Tradename" in place of the proposed "Veramyst". It is unclear if the font, color, and style is intended to be the same as the word "Tradename" when replaced with "Veramyst". Therefore the comments presented below may be incomplete. The exact presentation of the labels and labeling will allow DMETS to provide a more comprehensive assessment of the error potential of labels and labeling.

B. CONTAINER LABEL (TRADE & SAMPLE)

1. See General Comment.
2. Ensure the font size of the letters comprising the established name is at least half as large as the letters comprising the proprietary name. We refer you to 21 CFR 201.10(g)(2) for guidance.
3. Relocate the strength (27.5 mcg per spray) to immediately follow the established name. Additionally, increase the prominence of the strength so it is the same size as the proprietary and established names.

4. Ensure the net quantity is located away from the expression of strength. Postmarketing experience has shown that medication errors have occurred due to confusion of the net quantity for the product strength.
5. Increase the prominence of the statement "FOR INTRANASAL USE ONLY" and remove the word "Spray" preceding the statement.
6. Relocate the statement "Shake well before each use" to the principle display panel and increase its prominence.
7. Revise the statement "See prescribing information..." to read "Usual Dosage: See prescribing information..."

C. CARTON LABELING (TRADE & SAMPLE)

1. See General Comment.
2. See Container Label Comments B.2 – B.7.
3. Provide a heading for the statement "TRADE NAME™ Nasal Spray should be primed...". A heading will draw attention to this statement and stress its importance.

D. PACKAGE INSERT LABELING

1. See General Comment.
2. DMETS notes the use of the abbreviation "µL" in the Dosage Forms and Strengths and How Supplied/Storage and Handling portions of the package insert. We do not recommend the use of the abbreviation "µ" for the prefix "micro". Post marketing experience has shown that the abbreviation "µ" has been misinterpreted as an "m", resulting in 1000-fold dosing errors. Furthermore, the abbreviation "µ" appears on the JCAHO's list of dangerous abbreviations. Please revise all incidents of "µL" by spelling out the word "microliter".

E. PATIENT PACKAGE INSERT LABELING

See General Comment.

Appendix A – DMETS Prescription Study Results for Veramyst

Inpatient

Veramyso
Viramist,
Veramyso
Veramyso
Verayso
Veramyst
Veramyso
Viramune
Veramyso
veramyso,

Outpatient

Veranyst
Veramyst
Veramyst
Veianyst
VERAMYST
Veramyst
Veramyst
Veranyst
Veramyst
Veranyst
Veranyst
Veranest
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Veranyst

Voice

Veramist
Veramist
Veramist
Viramist
Viramist
Veramist
Vermis

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/s/

Tina Tezky
3/7/2007 12:46:10 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
3/7/2007 01:45:51 PM
DRUG SAFETY OFFICE REVIEWER