CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-992

PROPRIETARY NAME REVIEW(S)

MEMORANDUM	Division of Medication Errors and Technical Support Office of Surveillance and Epidemiology HFD-420; WO22, Mail Stop 4447 Center for Drug Evaluation and Research

To: Thomas Laughren, MD
Director, Division of Psychiatry Products

Through: Todd Bridges, RPh, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Carol A. Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

From: Diane C. Smith, PharmD, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

Date: January 15, 2008

Subject: DMETS Proprietary Name Review
Drug: Pristiq (Desvenlafaxine Succinate) Extended-Release Tablets
NDA#: 21-992
Applicant: Wyeth Pharmaceuticals

Review #: 2007-2197

*****NOTE: This review contains proprietary and confidential information that should not be released to the public.*****

This memorandum is written in response to a request from the Division of Psychiatry Products (HFD-130), for a reassessment of the proposed proprietary name, Pristiq. Additionally, DMETS provided Pristiq label and labeling recommendations to minimize medication errors and in the interest of patient safety. In response to these recommendations, the applicant has submitted revised container labels, carton and insert labeling for review and comment at this time.

In OSE review# 06-0097 (dated October 6, 2006), DMETS identified one proposed name [redacted], with similar appearance and sound to Pristiq, in addition to similar product characteristics. Therefore, we recommended that only one name be approved. The applicant of [redacted] has withdrawn the name [redacted] from consideration. Therefore, confusion between Pristiq and [redacted] is no longer of concern. However, DMETS has identified five additional names [redacted] since our previous review (OSE Review #06-0097) as having potential look-alike and/or sound-alike similarities to Pristiq. After evaluation of these five names, we determined that all of the names exhibited minimal potential for confusion and will not be considered further for the following reasons:

- [redacted] are proprietary names that are owned by Wyeth Pharmaceuticals and Novartis Pharmaceuticals, respectively. These proprietary names were identified in both the U.S. Patent and Trademark Office's Text and Image Database [1] and the Saegis[2] Pharma-In-Use database. However, no product information was found regarding these names in commonly used drug

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[1] WWW location http://www.uspto.gov/tmdb/index.html.
[2] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

references such as the Orange Book, Clinical Pharmacology, Facts and Comparisons and the Red Book. Additionally, to our knowledge [redacted] have never been submitted to the Agency as proposed names for any application nor do they appear to be attached to any specific drug product.

- [redacted] is a proprietary name under review at the Agency. However, this name pair lacks convincing look-alike properties as well as having differentiating product characteristics, such as dose ([redacted] 50 mg), route of administration [redacted] oral), dosage form [redacted] tablet), strength [redacted] 50 mg 100 mg and 200 mg) and duration of treatment [redacted] chronic).
- Prostec is an herbal, over-the-counter product. Prostec and Pristiq do not share product commonalities such as frequency of administration (twice daily vs. daily) and prescription status (OTC vs. prescription). Additionally, the product was not found in commonly used drug references such as the Orange Book, Facts and Comparisons, Clinical Pharmacology, or the Red Book. Finally, we were unable to locate Prostec at websites that would generally sell such a product (e.g., Drugstore.com, Walgreens.com, or gnc.com).
- [redacted] was a proprietary name submitted for [redacted] but has subsequently been withdrawn and replaced with the proprietary name [redacted].

In the review of the container labels, carton and insert labeling of Pristiq, DMETS has conducted a FMEA (Failure Mode and Effects Analysis) and applied principles of human factors. Our analysis identified the following areas of needed improvement.

A. CONTAINER LABEL (14, 30 and 90 count)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]

B. BLISTER LABEL

[redacted]

C. CARTON LABELING (Unit Dose 10 x 10)

See Comments A1 and A2.

We would be willing to meet with the Division for further discussion, if needed. DMETS would appreciate feedback of the final outcome of this consult. Please copy DMETS on any correspondence to the sponsor pertaining to this review. If you have questions or need clarification, please contact Daniel Brounstein, OSE Project Manager, at 301-796-0674.

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/s/

Diane Smith
1/15/2008 10:37:05 AM
CSO

Todd Bridges
1/15/2008 11:04:15 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
1/15/2008 02:45:26 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
1/15/2008 04:07:02 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

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

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**OSE REVIEW #:** 06-0097
March 13, 2006 (IND#: 64,816) June 21, 2006 (NDA#: 21-992)	April 25, 2006 (IND#: 64,816) September 1, 2006 (NDA#: 21-992)	
DOCUMENT DATE: February 14, 2006 (IND#: 64,816) June 7, 2006 (NDA#: 21-992)	**PDUFA DATE:** October 22, 2006 (NDA#: 21-992)	

TO: Scott Monroe, MD
Director, Division of Reproductive and Urologic Products, HFD-580

Thomas Laughren, MD
Director, Division of Psychiatry Products, HFD-130

THROUGH: Alina R. Mahmud, RPh, MS, Team Leader
Denise Toyer, PharmD, 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:	**SPONSOR:** Wyeth Pharmaceuticals
Pristiq™ (Desvenlafaxine Succinate) Extended-release Tablets 50 mg, 100 mg, [redacted] 200 mg **IND#:** 64,816 **NDA#:** 21-992	

RECOMMENDATIONS:

1. DMETS identified one proposed proprietary name [redacted] that has similar appearance and sound to Pristiq. Because these names have orthographic, phonetic, and product similarities, we recommend that only one name is approved. DMETS recommends your division contact the Division of Anesthesia, Analgesic, and Rheumatology Products to determine the status of [redacted] If this application will be approved first, then the sponsor for [redacted] will need to be notified. If this application is going to be approved after [redacted] then request the sponsor submit an alternate name. If the approval of this application is delayed beyond 90 days from the signature date of this document, the name Pristiq must be re-evaluated. (See Section IIC).

2. DMETS recommends implementation of the label and 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, Pristiq™, 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 301-827-3242.

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: April 14, 2006

IND#: 64,816
NDA#: 21-992

NAME OF DRUG: **Pristiq™**
(Desvenlafaxine Succinate) Extended-release Tablets
50 mg, 100 mg, [redacted] 200 mg

IND/NDA HOLDER: Wyeth Pharmaceuticals

NOTE: This review contains proprietary and confidential information that should not be released to the public.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Reproductive and Urologic Products (HFD-580) and the Division of Psychiatry Products (HFD-130) for a review of the proprietary name, "Pristiq", regarding potential name confusion with other proprietary and/or established drug names. Container labels, carton, and insert labeling were not submitted at this time. The sponsor submitted an independent market research analysis conducted by [redacted] for DMETS to review and comment.

[redacted] The sponsor wishes to use the proprietary name "Pristiq" [redacted].

PRODUCT INFORMATION
Pristiq (desvenlafaxine succinate) is a selective serotonin norepinephrine reuptake inhibitor under review for the treatment of vasomotor symptoms (VMS) associated with menopause (IND [redacted]. The recommended dosage range of Pristiq for this indication is [redacted] Pristiq is also under review for the treatment of major depressive disorder (MDD) (NDA 21-992) and the recommended dose for this indication is 100 mg – 200 mg once daily. Pristiq will be available in 50 mg, 100 mg, [redacted], and 200 mg extended-release tablets.

II. RISK ASSESSMENT

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3,4] for existing drug names which sound-alike or look-alike to Pristiq 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 conducted[5]. The SAEGIS™ Online service[6] 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.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Pristiq. 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, Pristiq, in regard to promotional claims.

2. The Expert Panel identified three proprietary names that were thought to have the potential for confusion with Pristiq. One additional name, [redacted] was identified through independent analysis. These products are listed in Table 1 (see page 4), along with the dosage forms available and usual dosage.

MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

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

AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.

Phonetic and Orthographic Computer Analysis (POCA).

www location http://www.uspto.gov/tmdb/index.html.

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 Pristiq

Product Name	Dosage Form(s) Established Name Strength(s)	Usual adult dose	Other*
Prostep OTC	Nicotine Extended-release Transdermal Film 11 mg/24 hr, 22 mg/24 hr	Apply 1 patch daily.	LA/SA
Priftin Rx	Rifapentine Capsules 150 mg	Treatment of tuberculosis. 600 mg twice weekly for 2 months, then 600 mg once weekly for 4 months.	LA
Prestim UK, Ireland, Netherlands	Timolol and Bendroflumethiazide Tablets 10 mg/2.5 mg	Antihypertensive agent. One tablet daily.	LA

*Frequently used, not all-inclusive
**LA (look-alike), SA (sound-alike)
*** Proprietary and confidential information that should not be released to the public

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 Pristiq 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 Pristiq (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.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Pristiq 100mg #6 1 QD	Pristiq 100 mg Quantity 60. One tablet daily.
Inpatient RX: Pristiq 100mg 1 tablet daily	

2. Results:

   None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. 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 Pristiq, the primary concerns relating to look-alike and sound-alike confusion are with Prostep, Priftin, and Prestim.

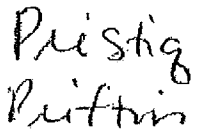
Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that Pristiq could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of the misinterpretations were misspelled/phonetic variations of the proposed name, Pristiq.

1.

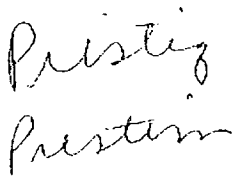
2. Prostep was identified as having look-alike and sound-alike potential with Pristiq. Prostep (nicotine) is an over-the-counter (OTC) smoking cessation drug product. Prostep is available as 11 mg/24 hour, 22 mg/24 hour extended-release transdermal patches and the usual dose is to apply one patch once daily, dependant on the patients smoking habits. Prostep and Pristiq both contain seven letters and have four overlapping letters in the same position (PROSTEP vs. PRISTIQ), which contribute to their orthographic and phonetic similarities. Although the ending letter is different (-P vs. -Q), both letters have a downstroke (see sample below) which can look similar and they can also sound similar when spoken softly or deemphasized. Although the two products have the same frequency of administration (once daily), numerous differing product characteristics such as route of administration (transdermal vs. oral), dosage form (patch vs. tablet), available strength (50 mg, 100 mg, [illegible] 200 mg vs. 11 mg, 22 mg), dosage (100 mg – [illegible] vs. 11 mg – 22 mg), and prescription status (OTC vs. prescription) help distinguish the two products. Due to these product differences, DMETS believes the likelihood for confusion between Prostep and Pristiq is minimal.

Pristiq
Prostep

3. Priftin and Pristiq may look-alike when scripted. Priftin (Rifapentine) is an antimycobacterial agent indicated for the treatment of pulmonary tuberculosis. Priftin is available as 150 mg tablets and the usual dose is 600 mg twice weekly (with an interval of no less than 3 days between doses) for 2 months, followed by 600 mg once weekly for 4 months. Priftin must always be used in conjunction with at least one other antituberculosis drug to which the isolate is susceptible. The two names have the same number of letters (seven), five of which overlap (PRIFTIN vs. PRISTIQ). However, upstroke of the "F" in Priftin and the endings (-N vs. -Q) help differentiate the two products (see writing sample below). Priftin and Pristiq have overlapping product characteristics, such as route of administration (oral), dosage form (tablet). However, they differ in dosing regimen (once or twice weekly vs. once daily) and indication for use (pulmonary tuberculosis vs. vasomotor symptoms, major depressive disorder). Although Priftin and Pristiq share some product characteristics, the lack of convincing look-alike potential minimizes the risk of confusion. Due to the aforementioned reasons, DMETS believes the likelihood for confusion between Priftin and Pristiq is minimal.



4. Prestim and Pristiq may look-alike when scripted. Prestim is a foreign combination product containing timolol and bendroflumethiazide. Prestim is available in the foreign market (UK, Ireland, Netherlands) as a 10 mg/2.5 mg oral tablet and is dosed once daily. Additional information related to this agent is difficult to obtain, since it is not available in the U.S. The drug names are identical aside from the third and last letters ("PRESTIM" vs. "PRISTIQ"). The differing letters "E" vs. "I" can look similar when scripted (see writing sample below). However, the endings "M" vs. "Q" provide a visual distinction between the two names. With the information available, the two products have overlapping characteristics such as route of administration (oral), dosage form (tablet) and frequency of administration (once daily). However, since Pristiq is available in four different strengths (50 mg, 100 mg, 200 mg), a prescription will likely include a strength, which will help prevent name confusion between Prestim and Pristiq. Due to the differing endings, the multiple strengths for Pristiq, and the different areas of marketing, DMETS believes the likelihood for name confusion and error between Prestim and Pristiq is minimal.



D. INDEPENDENT NAME ANALYSIS

The sponsor submitted an independent market research analysis, conducted by [redacted] for the proposed name Pristiq, dated summer 2005. rxmark conducted a name validation study known as the 10/10 Trademark Evaluation Model to evaluate the potential for error between Pristiq and currently marketed brand and generic drug products. [redacted] reported that 630 participants, including 200 pharmacists (140 retail-based and 60 hospital-based), 230 physicians (100 primary care physicians, 80 OB/GYNs, and 50 Psychiatrists), and 200 consumers (60 men aged 35 – 70 and 140 women aged 35 – 70) participated in the primary research intended to identify potential drug similarity conflicts specific to simulated verbal and written prescription interpretation. Eighteen names were assessed in this study and randomization was employed to avoid respondent fatigue; therefore, after randomization, the name Pristiq was evaluated by a total of 305 participants (104 pharmacists, 113 physicians, and 88 consumers). The study consisted of an online survey with three portions; a Pharmacist Study, a Physician Study, and a Consumer Study.

The [redacted] evaluation identified two names (Prestige and Actiq) from the Pharmacist Study and two names (prednisone and Prozac) from the Consumer Study to have potential look-alike and/or sound alike confusion with Pristiq that were not identified by DMETS. [redacted] analyzed the names Actiq, Prestige, prednisone, and Prozac as potential sound or look-alike safety risks. [redacted] did not find the reviewed names to be of concern for look-alike or sound-alike confusion with the proposed trade name, Pristiq. [redacted] concluded that Pristiq is an acceptable proprietary name for desvenlafaxine tablets

Table 1: Potential Sound-Alike/Look-Alike Names Identified by [redacted]

Product Name	Dosage form(s), Established name	Usual adult dose*	Other*
Pristiq [redacted]	Desvenlafaxine Succinate Extended-release Tablets 50 mg, 100 mg, [redacted] 200 mg	VMS, MDD 100 mg – 200 mg once daily.	
Prestige OTC	Blood glucose monitoring system products.	As directed.	LA/SA
Actiq Rx	Fentanyl Transmucosal Lozenges 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg	The dose should be individually titrated to provide adequate analgesia and minimizes side effects.	LA/SA
Prednisone Rx	Prednisone Tablets 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 25 mg, 50 mg Prednisone Oral Solution 5 mg/5 mL	5 – 60 mg daily, in single or divided doses.	LA/SA
Prozac Rx	Fluoxetine Tablets 10 mg Fluoxetine Capsules 10 mg, 20 mg, 40 mg Fluoxetine Oral Solution 20 mg/5 mL	20 – 80 mg daily.	LA/SA

*Frequently used, not all-inclusive.
**LA (look-alike), SA (sound-alike)

DMETS Response:

After reviewing the product profiles of the names identified by ~~~ DMETS believes that the potential for name confusion between Pristiq and Prestige, Actiq, prednisone, and/or Prozac is minimal due to visual and phonetic differences as well as product differences such as dosage form (Pristiq vs. Actiq & Prestige), frequency of administration (Pristiq vs. Actiq, Prestige, & prednisone), and usual dose (Pristiq vs. Actiq, Prestige, prednisone, & Prozac). DMETS concurs with the overall findings of the study that Pristiq is an acceptable proprietary name.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

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

A. GENERAL COMMENT

[redacted]

B. CONTAINER LABEL

1. See General Comment.
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]

[redacted] as the proprietary name.

C. UNIT DOSE LABELS

1. See General Comment.

2. See Container Label Comments B.2 and B.4.

3. Increase the prominence of the product strength (i.e. bolding, highlighting) so that it has the same prominence as the proprietary name and dosage form.

D. CARTON LABELING (UNIT DOSE 10 x 10)

1. See General Comment.

2. See Container Label Comment B.4.

E. PACKAGE INSERT LABELING

No comments at this time.

Appendix A – DMETS Prescription Study Results for Pristiq

Inpatient	Outpatient	Voice
Pristiq	Pristiq	Pristique
Pristig	Pristiq	Pristique
Pristiq	Pristig	Prestique
Pristiq	Pristiq	Prestique
Pristiq	Pristiq	Prestique
Pristq	PRISTIQ	Prestique
PRISTIG	Pristiq	Prestique
Pristinq	Pristiq	Prestiq
Pristiq	Pristiq	Presteke or Presteek
Pristic	Pristiq	Prestic
Pristiq	Pristiq	Prestique
Pristiq	Pristiq	Pristig
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/s/

Tina Tezky
10/6/2006 02:10:53 PM
DRUG SAFETY OFFICE REVIEWER

Alina Mahmud
10/6/2006 03:14:18 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
10/6/2006 03:55:02 PM
DRUG SAFETY OFFICE REVIEWER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Christine M. Rosser
Sr. Manager, Global Regulatory Affairs
Wyeth Research
P.O. Box 8299
Philadelphia, PA 19101-8299
Fax (484) 865-6465

RE: NDA # 21-992
Name of Drug: proposed tradename "Pristiq" (desvenlafaxine succinate)
MACMIS # 14824

Dear Ms. Rosser:

This letter responds to Wyeth's November 29, 2006 request to the Food and Drug Administration's (FDA) Division of Drug Marketing, Advertising, and Communications (DDMAC) for advisory comments on a proposed logo for desvenlafaxine succinate, proposed tradename Pristiq (Pristiq).

DDMAC offers the following comments, which should be applied to this submission and all future promotional materials that contain the same or similar claims for Pristiq.

General

DDMAC's comments are provided prior to the official decision for the pending NDAs for Pristiq. As such, DDMAC's comments are tentative and do not consider the final labeling for Pristiq, or any decision concerning the proposed tradename. DDMAC reminds Wyeth of the regulations governing reminder advertisements *Cf.* 21 CFR 202.1(e)(2)(i).

DDMAC notes Wyeth's acknowledgment that the "generic name is not one half the size of the tradename. In the final executed version of the logo the size of the generic name will be increased." DDMAC reminds Wyeth that it is your responsibility to ensure that your promotional materials for Pristiq comply with each applicable requirement of the Federal Food, Drug, and Cosmetic Act and FDA implementing regulations.

Proposed Logo

DDMAC has reviewed the proposed logo for Pristiq and has no objections at this time.

If you have any questions, please direct them to me at the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communication, 5901-B Ammendale Road, Beltsville, MD 20705, or by facsimile at 301-796-9878. In all future correspondence regarding this matter, please refer to MACMIS ID# 14824 in addition to the NDA number. We remind you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Robert Dean, MBA
Regulatory Review Officer
Corrinne Kulick, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

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/s/

Robert Dean
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