

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-529**

**PROPRIETARY NAME REVIEW(S)**

6/2/06

<b>MEMORANDUM</b>	<b>Division of Medication Errors and Technical Support</b> <b>Office of Surveillance and Epidemiology</b> <b>HFD-420; WO22, Mail Stop 4447</b> <b>Center for Drug Evaluation and Research</b>
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**To:** Daniel Shames, MD  
 Director, Division of Reproductive and Urologic Products  
 HFD-580

**From:** Loretta Holmes, PharmD, Safety Evaluator  
 Division of Medication Errors and Technical Support, HFD-420

**Through:** Linda Y. Kim-Jung, PharmD, Team Leader  
 Denise P. Toyer, PharmD, Deputy Director  
 Carol A. Holquist, RPh, Director  
 Division of Medication Errors and Technical Support, HFD-420

**Date:** May 16, 2006

**Subject:** Proprietary Name Review  
 Drug: Implanon (Etonogestrel Subdermal Implant) 68 mg  
 NDA#: 21-529  
 Sponsor: Organon USA, Inc.

**Project #:** 03-0311-3 and 03-0311-4

This memorandum is in response to an April 10, 2006 request from your Division for a re-review of the proprietary name, Implanon. Additionally, the most recently submitted container label, carton and insert labeling dated April 14, 2006 were submitted to DMETS for review and comment. DMETS did not have objections to the use of the proprietary name, Implanon, in our last three reviews (ODS Consults 03-0311 dated February 2, 2004 , 03-0311-1 dated, August 4, 2004, and 03-0311-2 dated March 20, 2005). Since the completion of the latter review, the Expert Panel identified one proprietary name as having the potential to cause name confusion with Implanon.

“Indiplon”\*\*\* was identified as a name that may look and sound similar to **Implanon**. Indiplon\*

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is a sedative/hypnotic agent indicated for the treatment of insomnia. The recommended dose is 5 mg for elderly patients and 10 mg for adults at bedtime. Both names share similar beginning letters (“In-” vs. “Im-”) and the same last two letters (“-on”). However, the middle portion of the names (“-dipl-” vs. “-plan-”) appear distinguishable when scripted. Additionally, Indiplon contains two upstroke characteristics with the letters “d” and “l”, whereas Implanon only has one upstroke with the letter “l” which helps to differentiate the names (see below).

Both names contain three syllables which contribute to the sound-alike characteristics between the two names. Additionally, the first and third syllables of both names may sound similar [(“IN-” vs. “IM-”) and (“-PLON” vs. “-NON”)] when pronounced which contributes to their phonetic similarity. However, the second syllable of both names are phonetically distinguishable (“DĪ-” vs. “PLĀ-”). Moreover, Indiplon and Implanon differ in route of administration (oral vs. subdermal), strength (5 mg, 10 mg, and 15 mg vs. 68 mg), frequency of administration (daily at bedtime vs. every 3 years), dosage form (tablet vs. subdermal implant), and indication (insomnia vs. contraception). Furthermore, Implanon is an implant that has to be inserted by a healthcare professional and the procedure will likely take place in a physician’s office, clinic, or similar outpatient type setting. Thus, it is unlikely that it would be confused with Indiplon. Therefore, although there are some orthographic and phonetic similarities between the name pair, the different product characteristics such as the context of use may help to minimize the potential for confusion with Implanon and Indiplon.

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

The container label, carton, and insert labeling were reviewed in our previous consult, ODS Consult 03-0311-2 dated March 20, 2005. DMETS acknowledges that the sponsor has addressed some of our recommendations. However, in review of the revised container labels, carton and insert labeling of Implanon, DMETS has the following additional recommendations which might minimize potential user error.

A. GENERAL COMMENT

Increase the font size or thickness of the letters of the established name in order to increase its prominence throughout the container labels, carton and insert labeling.

B. CONTAINER LABELS

1. Trade

Increase the prominence of the strength.

2. Professional Replacement

a. Increase the size of the statement "Professional Replacement – Not for Sale" to improve visibility and awareness of different package types.

b. We recommend substituting the words "Professional Sample" with "Professional Sample", and increasing the prominence of this statement.

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3. Clinic Package

Increase the size of the statement "Clinic Package: Not for Retail Pharmacy Sale" to improve visibility and awareness of different package types.

4. Training and Demonstration

a. The proprietary name is too large and implicates presence of the active ingredient. Since this package is for training and demonstration purposes, the "Training and Demonstration" statement should be the most prominent statement. DMETS recommends the use of boxing or a contrasting color. The sponsor may add "For Training and Demonstration Purposes of Implanon", but Implanon should not be prominent. Postmarketing data has shown instances where training devices were prominently labeled with the drug name and were confused for the actual drug.

b. It is not clear whether the implants for "training and demonstration" contain active drug. Please include a statement on the principle display panel that states whether or not there is active drug in the implant.

C. CARTON LABELING (IMPLANT)

1. Trade

Relocate the statement "1 applicator containing 1 single rod subdermal implant" from the colored section of the principle display panel to the white section of the panel and place above the proprietary name.

2. Professional Replacement and Clinic Package (1 implant)

See Comment B-2(a).

3. Clinic Package (1 implant)

a. See Comment B-3

b. The peach carton color is identical to that of the trade carton which is available for retail sale. Revise the color so that it can be differentiated from the trade carton and to prevent occurrence of selection errors at the wholesale level.

D. CARTON LABELING

1. Clinic Package (10 implants)

- a. See Comments under B-3.
- b. Relocate the statement "10 applicators each containing 1 single rod subdermal implant" from the panel on the back of the carton to the principle display panel and place above the statement "Clinic Package: Not For Retail Pharmacy Sale".

2. Training and Demonstration

- a. See Comment B-4(a and b)
- b. Relocate the statement "10 applicators each containing 1 single rod subdermal implant" from the panel on the back of the carton to the principle display panel and place above the statement "FOR TRAINING AND DEMONSTRATION PURPOSES—NOT INTENDED FOR HUMAN USE, NOT FOR SALE."

E. USER CARD

DMETS has no comments.

F. PATIENT CHART CARD

Include a space for recording the product expiration date.

G. INSERT LABELING

1. General Comment

The abbreviation "µg" is used in the insert labeling. Please change to "mcg" or "micrograms" instead. The abbreviation "µg" may be mistaken for "mg" (milligrams) and is among those abbreviations for possible future inclusion in the *Official "Do Not Use" List* published by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). Furthermore, the FDA will launch a campaign in June 2006, warning health care providers and consumers not to use error-prone abbreviations. Thus we request that the FDA not approve or use abbreviations in their labels and labeling as they can be misinterpreted and contribute to error.

2. Dosage and Administration Section

a.

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- b. The following statement is included in this section: "Implanon™ must be inserted by the expiration date stated on the packaging." It is not clear from this statement whether the implant will provide effective contraception protection for three years beyond the expiration date specified on the package. Please clarify.

3. Instructions for Insertion and Removal

Include instructions that state to check the product expiration date. Additionally, please state whether the product will provide effective contraception protection for three years beyond the expiration date specified on the package.

4. How Supplied Section

Cite all packaging configurations available for sale (i.e., Trade and Clinic package).

in this section.

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G. PATIENT LABELING (Patient Labeling and Implanon™ Patient Information & Consent)

DMETS recommends these two components of the insert labeling be submitted to the Division of Surveillance, Research, and Communication Support (DSRCS) for review and comment.

DMETS considers this a final review. 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 date of this document. 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.

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/s/

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Loretta Holmes  
6/2/2006 03:58:28 PM  
DRUG SAFETY OFFICE REVIEWER

Linda Kim-Jung  
6/2/2006 04:12:07 PM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
6/2/2006 04:17:29 PM  
DRUG SAFETY OFFICE REVIEWER

Carol Holquist  
6/2/2006 04:29:20 PM  
DRUG SAFETY OFFICE REVIEWER

8/05/04

**Office of Drug Safety**

# Memo

**To:** Daniel Shames, M.D.  
Director, Division of Reproductive and Urologic Drugs Products  
HFD-580

**From:** Tia Harper-Velazquez, Pharm.D.  
Safety Evaluator, Division of Medication Errors and Technical Support  
HFD-420

**Through:** Denise Toyer, Pharm.D.  
Deputy Director, Division of Medication Errors and Technical Support  
HFD-420

Carol Holquist, R.Ph.  
Director, Division of Medication Errors and Technical Support  
HFD-420

**CC:** Karen Anderson  
Project Manager  
HFD-580

**Date:** August 4, 2004

**Re:** ODS Consult 03-0311-1; Implanon™ (Etonogestrel Subdermal Implant), 68 mg;  
NDA 21-529

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This memorandum is in response to a July 16, 2004, request from your Division for a re-review of the proprietary name, Implanon. In our last review, dated February 2, 2004, (ODS Consult # 03-0311), DMETS did not have any objections to the use of the proprietary name, Implanon.

Since that review, the Expert Panel identified one established name as having the potential to cause name confusion with Implanon. The Panel identified Imipramine to have look-alike similarities to Implanon (see page 2).

Imipramine is the established name for Tofranil, a tricyclic antidepressant that is also indicated for the treatment of childhood enuresis. The recommended adult dose for the treatment of depression is 75 mg daily, initially, up to a maximum of 200 mg daily. For the treatment of childhood enuresis, the recommended dose is 25 mg daily one hour before bedtime. Imipramine is available as an oral tablet, in strengths of 10 mg, 25 mg, and 50 mg. The look-alike

similarities between the names can be attributed to the letter combination “Im” which appears at the beginning of each name. Both names contain the letter “p”, which provides for a down stroke in a similar position in each name, as well as the letter “n”. In addition, the letter combinations “pra” (in Imipramine) and “pla” (in Implanon), can look similar, depending on how they are scripted. However, the names differ in number of letters (10 vs. 8), which provides for a visible difference in the length of the names when they are written. Imipramine and Implanon also differ in route of administration (oral vs. subdermal), dosage form (tablet vs. subdermal implant), strength (10 mg, 25 mg, and 50 mg vs. 68 mg), and dosing regimen (daily vs. every three years). DMETS believes that the moderate look-alike similarities between the names, in addition to the aforementioned product differences minimize the potential for risk and confusion between Imipramine and Implanon.

**Imipramine**      **Implanon**

*Imipramine Implanon*

The blister foil label, carton, and package insert labeling were previously submitted for review with the initial consult. Revised labels and labeling were not submitted with this consult. Therefore, DMETS refers to ODS Consult # 03-0311, dated February 2, 2004, for DMETS’ label and labeling comments.

DMETS considers this a final review. However, if the approval of the NDA is delayed beyond 90 days from the date of this review, the name must be re-evaluated. A re-review of the name before NDA approval will rule out any objections based upon approvals of other proprietary/established names from this date forward.

If you have any questions or need clarification, please contact the medication errors project manager, Sammie Beam at 301-827-3242.

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/s/

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Tia Harper-Velazquez  
8/5/04 09:29:36 AM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
8/5/04 12:42:55 PM  
DRUG SAFETY OFFICE REVIEWER  
for Carol Holquist

2/18/04

**CONSULTATION RESPONSE**  
**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT**  
**OFFICE OF DRUG SAFETY**  
**(DMETS; HFD-420)**

**DATE RECEIVED:** Dec. 2, 2003  
**DOCUMENT DATE:** Sept. 30, 2003

**DESIRED COMPLETION**  
**DATE:** Feb. 2, 2003

**ODS CONSULT #:** 03-0311

**TO:** Daniel Shames, M.D.  
Director, Division of Reproductive and Urologic Drug Products  
HFD-580

**THROUGH:** Karen Anderson  
Project Manager  
HFD-580

**PRODUCT NAME:**  
**Implanon™**  
(Etonogestrel Subdermal Implant)  
68 mg

**SPONSOR:** Organon USA, Inc.

**NDA #:** 21-529

**SAFETY EVALUATOR:** Tia M. Harper-Velazquez, Pharm.D.

**RECOMMENDATIONS:**

1. DMETS has no objections to the use of the proprietary name, Implanon™. This is considered a tentative decision, and the firm should be notified that this name with its associated labels and labeling 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 approvals of other proprietary or established names from the signature date of this document.
2. DMETS recommends implementation of the labeling revisions as outlined in Section III of this review to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name Implanon acceptable from a promotional perspective.

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Carol Holquist, R.Ph.  
Deputy Director  
Division of Medication Errors and Technical Support  
Office of Drug Safety  
Phone: (301) 827-3242 Fax: (301) 443-9664

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Jerry Phillips, R.Ph.  
Associate Director  
Office of Drug Safety  
Center for Drug Evaluation and Research  
Food and Drug Administration

**Division of Medication Errors and Technical Support**  
**Office of Drug Safety**  
**HFD-420; Parklawn Rm. 6-34**  
**Center for Drug Evaluation and Research**

**PROPRIETARY NAME REVIEW**

**DATE OF REVIEW:** February 2, 2004

**NDA NUMBER:** 21-529

**NAME OF DRUG:** **Implanon™**  
(Etonogestrel Subdermal Implant)  
68 mg

**NDA SPONSOR:** Organon USA, Inc.

**I. INTRODUCTION**

This consult was written in response to a request from the Division of Reproductive and Urologic Drug Products for an assessment of the proprietary name “Implanon” regarding potential name confusion with other proprietary or established drug names. The blister foil label as well as the carton and package insert labeling were submitted for review and comment.

**PRODUCT INFORMATION**

Implanon is the proposed name for etonogestrel subdermal implant. Implanon is a long acting, reversible, progestin-only contraceptive. It is inserted to the inner side of the upper arm, approximately six to eight centimeters above the elbow crease, during an outpatient procedure. It provides up to three years of effective contraceptive protection. Implanon™ will be available in a strength of 68 mg, and supplied as single rods that are contained in the needle of a disposable applicator.

**II. RISK ASSESSMENT**

The medication error staff of DMETS conducted a search of several standard published drug product reference texts<sup>i,ii</sup> as well as several FDA databases<sup>iii</sup> for existing drug names which sound-alike or look-alike to “Implanon” 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<sup>iv</sup> and the data provided by Thomson & Thomson’s SAEGIS™ Online Service<sup>v</sup> were also conducted. 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)

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<sup>i</sup> MICROMEDEX Integrated Index, 2004, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

<sup>ii</sup> Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

<sup>iii</sup> AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support proprietary name consultation requests, New Drug Approvals 1998-2004, and the electronic online version of the FDA Orange Book.

<sup>iv</sup> WWW location <http://www.uspto.gov>.

<sup>v</sup> Data provided by Thomson & Thomson's SAEGIS(tm) Online Service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com).

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

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Implanon. Potential concerns regarding drug marketing and promotion related to the proposed name was 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 any concerns from a promotional perspective regarding the proposed name Implanon.
2. The Expert Panel identified one proprietary name that has potential for confusion with Implanon. This product is listed in Table 1 (see below), along with the dosage forms available and usual FDA-approved dosage.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel

Product Name	Dosage form(s), Established name	Usual adult Dose*	Other**																																																						
<b>Implanon (Rx)</b>	(Etonogestrel Subdermal Implant) 68 mg	Insert to the inner side of the upper arm, approximately six to eight centimeters above the elbow crease.																																																							
Imipenem-Cilastatin <i>Generic for:</i> Primaxin I.V. and Primaxin I.M. (Rx)	Imipenem and Cilastatin Injection <u>I.V.</u> 250 mg/250 mg and 500 mg/500 mg  <u>I.M.</u> 500 mg/500 mg and 750 mg/750 mg	<table border="1"> <thead> <tr> <th colspan="5">Imipenem-Cilastatin IV Dosing Schedule for Adults with Normal Renal Function</th> </tr> <tr> <th rowspan="2">Type or severity of infection</th> <th rowspan="2">Fully susceptible organisms<sup>1</sup></th> <th rowspan="2">Total daily dose</th> <th>Moderately susceptible</th> <th rowspan="2">Total daily dose</th> </tr> <tr> <th>organisms, primarily some strains of <i>P. aeruginosa</i></th> </tr> </thead> <tbody> <tr> <td>Mild</td> <td>250 mg q 8 hr</td> <td>1 g</td> <td>500 mg q 6 hr</td> <td>2 g</td> </tr> <tr> <td>Moderate</td> <td>500 mg q 8 hr or 500 mg q 6 hr</td> <td>1.5 or 2 g</td> <td>500 mg q 8 hr or 1 g q 8 hr</td> <td>2 or 3 g</td> </tr> <tr> <td>Severe, life-threatening</td> <td>500 mg q 6 hr</td> <td>2 g</td> <td>1 g q 8 hr or 1 g q 6 hr</td> <td>3 or 4 g</td> </tr> <tr> <td>Uncomplicated UTI</td> <td>250 mg q 8 hr</td> <td>1 g</td> <td>250 mg q 6 hr</td> <td>1 g</td> </tr> <tr> <td>Complicated UTI</td> <td>500 mg q 6 hr</td> <td>2 g</td> <td>500 mg q 6 hr</td> <td>2 g</td> </tr> </tbody> </table> <p><sup>1</sup>Including gram-positive and -negative aerobes and anaerobes</p> <table border="1"> <thead> <tr> <th colspan="3">Imipenem-Cilastatin IM Dosage Guidelines in Adults</th> </tr> <tr> <th>Type/Location of infection</th> <th>Severity</th> <th>Dosage regimen</th> </tr> </thead> <tbody> <tr> <td>Lower respiratory tract</td> <td>Mild/Moderate</td> <td>500 or 750 mg q 12 hr depending on the severity of infection</td> </tr> <tr> <td>Skin and skin structure</td> <td></td> <td></td> </tr> <tr> <td>Gynecologic</td> <td></td> <td></td> </tr> <tr> <td>Intra-abdominal</td> <td>Mild/Moderate</td> <td>750 mg q 12 hr</td> </tr> </tbody> </table>	Imipenem-Cilastatin IV Dosing Schedule for Adults with Normal Renal Function					Type or severity of infection	Fully susceptible organisms <sup>1</sup>	Total daily dose	Moderately susceptible	Total daily dose	organisms, primarily some strains of <i>P. aeruginosa</i>	Mild	250 mg q 8 hr	1 g	500 mg q 6 hr	2 g	Moderate	500 mg q 8 hr or 500 mg q 6 hr	1.5 or 2 g	500 mg q 8 hr or 1 g q 8 hr	2 or 3 g	Severe, life-threatening	500 mg q 6 hr	2 g	1 g q 8 hr or 1 g q 6 hr	3 or 4 g	Uncomplicated UTI	250 mg q 8 hr	1 g	250 mg q 6 hr	1 g	Complicated UTI	500 mg q 6 hr	2 g	500 mg q 6 hr	2 g	Imipenem-Cilastatin IM Dosage Guidelines in Adults			Type/Location of infection	Severity	Dosage regimen	Lower respiratory tract	Mild/Moderate	500 or 750 mg q 12 hr depending on the severity of infection	Skin and skin structure			Gynecologic			Intra-abdominal	Mild/Moderate	750 mg q 12 hr	**L/A
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<p>*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)</p>																																																									

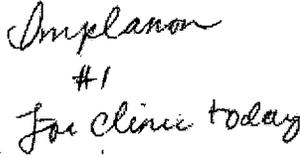
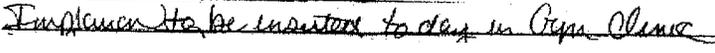
**B. PHONETIC ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)**

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. The phonetic search modules return a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to Implanon were discussed by the Expert Panel (EPD).

**C. PRESCRIPTION ANALYSIS STUDIES**

1. Methodology:

Three separate studies were conducted within FDA for the proposed proprietary name to determine the degree of confusion of Implanon with other U.S. drug names due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 129 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 Implanon (see below). 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
<p><u>Outpatient RX:</u>                        Implanon                      #1                      For clinic today</p>	<p>Implanon, to be inserted to in the clinic, dispense #1.</p>
<p><u>Inpatient RX:</u>    <del>Implanon to be inserted to day in Open Clinic</del></p>	

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.

#### D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name “Implanon”, the primary concerns raised were related to one look-alike and/or sound-alike name currently marketed in the United States. The product considered to have potential for name confusion with Implanon was Imipenem.

We conducted prescription studies to simulate the prescription ordering process. Our study did not confirm confusion between Implanon and Imipenem. However, a negative finding does not discount the potential for name confusion given the limited predictive value of these studies, primarily due to the sample size. The majority of the incorrect interpretations of the written and verbal studies were misspelled/phonetic variations of the proposed name, Implanon.

Imipenem was identified to have look-alike similarities to the proposed name, Implanon (see below). Imipenem in conjunction with Cilastatin constitutes the combination drug Product, Primaxin. It is indicated for the treatment of serious susceptible infections, including bacterial septicemia, lower respiratory tract, urinary tract, skin and skin structure, bone and joint, intra-abdominal, gynecologic, polymicrobial infections, and endocarditis. Imipenem can be administered either intravenously or intramuscularly, and the dosing strength and regimen vary, depending on the condition being treated. Imipenem and Implanon share look alike similarities in that both names contain eight letters, and begin with an identical letter combination (“Im”). The letter combinations of “pe” (in Imipenem) and “pl” (in Implanon) can look similar, particularly if the upstroke of the letter “l” (in Implanon) is not prominent. The ending letter combinations (“nem” vs. “non”) also look similar when scripted. However, there are many differences that help distinguish the two drugs from one another. Imipenem and Implanon each are available in a different dosage form (injection vs. subdermal implant), route of administration (intravenous or intramuscular vs. subdermal), strength (250 mg/250 mg, 500 mg/500 mg, and 750 mg/750 mg vs. 68 mg), and indication for use (infection vs. contraception). Also, because Implanon is a long acting contraceptive that can be used up to three years per implant, its dosing regimen does not overlap with that of Imipenem, which is variable depending on the infection being treated and the route of administration. Lastly, a prescription for Imipenem would need to include a distinguishing strength, whereas a prescription for Implanon will not require a strength since it is only available as a single strength. Based on the above differences in dosage form, route of administration, strength, and indication of use, DMETS believes there is a low risk of error and confusion between Imipenem and Implanon.

Imipenem

Implanon

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### III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In review of the blister foil label and carton and package insert labeling for Implanon, DMETS has focused on safety issues relating to possible medication errors, and has identified areas of possible improvement, which might minimize potential user error.

#### A. USER CARD

Please include a space for recording the drug expiration date of the drug.

#### B. AUXILLARY LABEL (For patient chart)

See comment under "A".

#### C. PACKAGE INSERT LABELING

**b(4)**

2. In the "Dosage and Administration" section, it states that "Implanon must be inserted by the expiration date stated on the packaging". DMETS questions what occurs if the drug expires during the three year period while the drug is still in the arm of the patient. For example, will the drug become ineffective if the expiration reads 6/04, yet the drug is inserted in 6/03 and remains in the patient's arm for three years.
3. In the "Removal Procedure" section, please indicate whether or not the information on the user card is recorded in any other location. This would be a concern, particularly if the user card is lost during the three year time period.

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#### IV. RECOMMENDATIONS

- A. DMETS has no objections to the use of the proprietary name, Implanon. This is considered a tentative decision, and the firm should be notified that this name with its associated labels and labeling 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 approvals of other proprietary or established names from the signature date of this document.
- B. DMETS recommends implementation of the labeling revisions as outlined in Section III of this review to minimize potential errors with the use of this product.
- C. DDMAC finds the proprietary name Implanon acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult (e.g., copy of revised labels/labeling). We are willing to meet with the Division for further discussion as well. If you have any questions concerning this review, please contact Sammie Beam at 301-827-3242.

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Tia M. Harper-Velazquez, Pharm.D.  
Safety Evaluator  
Division of Medication Errors and Technical Support  
Office of Drug Safety

Concur:

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Alina Mahmud, R.Ph.  
Team Leader  
Division of Medication Errors and Technical Support  
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/s/

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