

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**22-363**

**PROPRIETARY NAME REVIEW(S)**

7/2/09



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

Date: July 2, 2009

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Subject: Proprietary Name Review

Drug Name(s): Livalo (Pitavastatin) Tablets  
1 mg, 2 mg, 4 mg

Application Type/Number: NDA# 22-363

Applicant/Applicant: Kowa Research Institute, Inc.

OSE RCM #: 2009-592

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## **EXECUTIVE SUMMARY**

This re-assessment of the proprietary name is written in response to a notification that NDA # 22-363 may be approved within 90 days. DMEPA found the proposed proprietary name, Livalo, acceptable in OSE Review# 2007-1426 dated November 24, 2008. Since that review, none of Livalo's product characteristics have changed.

During this re-review we identified fourteen new names for their similarity to Livalo. The results of the Failure Mode and Effects Analysis found that the proposed name, Livalo, is not vulnerable to name confusion that could lead to medication errors with any of the fourteen names. Thus, the Division of Medication Error Prevention and Analysis does not object to the use of the proprietary name, Livalo, for this product.

DMEPA considers this a final review however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

## **1 PRODUCT INFORMATION**

Livalo (Pitavastatin) is a competitive inhibitor of HMG-CoA reductase. It is an adjunct to diet to reduce total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in adult patients with primary hypercholesterolemia and mixed dyslipidemia. The usual dose is 1 mg orally once daily. This may be titrated up to 4 mg per day. Livalo will be available as 1 mg, 2 mg, and 4 mg oral tablets. This product has been marketed in Japan since September 2003.

## **2 METHODS AND MATERIALS**

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a re-assessment of a proprietary name 90 days prior to approval of an application. Section 2.1 identifies the specific search criteria associated with the proposed proprietary name, Livalo.

### **2.1 SEARCH CRITERIA**

We used the same search criteria used in OSE Review# 2007-1426. Please refer to Section 2.1.1 of that review for the search criteria.

## **3 RESULTS**

### **3.1 DATABASE AND INFORMATION SOURCES**

The searches of the databases listed in Section 6 yielded a total of fourteen names as having some similarity to the name Livalo.

Twelve of the names were thought to look like Livalo. These include (b) (4) Lovaza, Savella, (b) (4) Linalon, Uvilon, Virilon, and Livostin. The remaining names (Levoxyl and Livalo) were thought to look and sound similar to Livalo.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 20, 2009.

### **3.2 EXPERT PANEL DISCUSSION**

The Expert Panel, as described in Appendix A, section 2, reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Livalo. One participant commented that the established name for Livalo, pitavastatin, was orthographically similar to pravastatin and had numerical overlaps in strengths. Pravastatin is the established name for Pravachol and is indicated for hyperlipidemia.

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

### **3.3 SAFETY EVALUATOR RISK ASSESSMENT**

Independent searches by the primary Safety Evaluator resulted in no new additional names which were thought to look or sound similar to Livalo and represent a potential source of drug name confusion.

Twenty-four names (See Appendix B) were identified in the previous Livalo proprietary name review. Since none of Livalo's product characteristics have changed since the previous review, the original assessment is maintained. Please see OSE# 2007-1426 for a detailed analysis of these names.

The proprietary name, Livalo, was also identified but upon further investigation was found to be the same drug product marketed in Japan.

Attempts to identify the drug name, (b) (4) were unsuccessful. However, the name Livaid was identified, thus we determined that the name was misspelled as (b) (4) during the search process. Hence, (b) (4), was not evaluated but, the name, 'Livaid' was assessed for this review.

As such, fourteen names (thirteen proprietary and one established name) were analyzed to determine if the drug names could be confused with Livalo. Seven names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix C).

The remaining seven names were determined to have some orthographic and/or phonetic similarity to Livalo, and thus determined to present some risk for confusion. Failure Mode and Effects Analysis (FMEA) was then applied to determine if the proposed name, Livalo, could potentially be confused with any of the seven (7) names and lead to medication errors. This analysis determined that the name similarity between Livalo and the identified names was unlike to result in a medication error with the five (5) products identified for the reasons presented in Appendices D through H.

## **4 DISCUSSION**

DMEPA identified and evaluated fourteen new names for their potential similarity to the proposed name, Livalo. The results of our proprietary name risk assessment found that the proposed name is not vulnerable to name confusion that could lead to medication errors with any of the fourteen names for the reasons presented in Appendices C through G.

## **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Livalo, is not vulnerable to name confusion that could lead to medication errors. Thus the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Livalo, for this product at this time. Additionally, DDMAC does not object to the proposed name, Livalo, from a promotional perspective.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date. If the Division has further questions or need clarifications, please contact Mildred Wright, OSE project manager, at 301-796-1027.

## 6 REFERENCES

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

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

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

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

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

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

4. *AMF Decision Support System [DSS]*

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

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

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

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

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

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

9. *Clinical Pharmacology Online* ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

10. *Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at* ([www.thomson-thomson.com](http://www.thomson-thomson.com))

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

11. *Natural Medicines Comprehensive Databases* ([www.naturaldatabase.com](http://www.naturaldatabase.com))

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

12. *Stat!Ref* ([www.statref.com](http://www.statref.com))

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

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

USAN Stems List contains all the recognized USAN stems.

14. *Red Book Pharmacy's Fundamental Reference*

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

15. *Lexi-Comp* ([www.lexi.com](http://www.lexi.com))

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

16. *Medical Abbreviations Book*

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

## APPENDICES

### **Appendix A:**

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>1</sup>

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>2</sup> DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate

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<sup>1</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

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

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

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

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

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

### 1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the

proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

## **2. CDER Expert Panel Discussion**

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

## **3. Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>4</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

*“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”*

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

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<sup>4</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

***“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”***

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Applicant. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a

predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. (See Section 4 for limitations of the process).

**Appendix B: Names previously reviewed (in OSE# 2007-1426) and determined not to pose a safety risk.**

Name	Similarity to Livalo
Vivelle	Look
Hivid	Look
Lialda	Look and Sound
Lo Ovril	Look and Sound
Zevalin	Look
Uvadex	Look
(b) (4)	Look
Cerato	Look
Livarole	Look and Sound
Vivacor	Look
Vivalan	Look
Lorelco	Look
Levulan	Look
Levall	Look and Sound
Levlen	Look
(b) (4)	Look and Sound
Levora	Look
Levolet	Look
Livalon	Look
Levatol	Look
Levitra	Look
Elavil	Look
Revatio	Look
Cialis	Look

**Appendix C: Names Lacking Orthographic and/or Phonetic Similarity.**

Name	Similarity to Livalo
(b) (4)	Look
(b) (4)	Look
(b) (4)	Look
Savella	Look
(b) (4)	Look
Livostin	Look
Levoxyl	Sound and Look

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

**Appendix D: Proprietary or Established Names used only in Foreign Countries**

Proprietary Name	Similarity to Livalo	Country	Description
Uvilon	Look	Italy	piperazine

**Appendix E: Drug products no longer under consideration by the Agency**

Proprietary Name	Similarity to Livalo	Status and Date
(b) (4)	(b) (4)	(b) (4) Sponsor September 9, 2008

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**Appendix F: Trade names not associated with an approved application**

Name	Similarity to Livalo	Comments
(b) (4)	Look and Sound	(b) (4)
Linalon	Look	Trademarked name in USA, Japan (Saegis)

**Appendix G:** Potential confusing name with numerical similarity in strength or dose or achievable dose

<b>Failure Mode: Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Rationale why medication error is unlikely to occur in the usual practice setting.</b>
<b>Proprietary Name</b>	<b>Strength</b>	<b>Usual Dose:</b>
<b>Livalo (pitavastatin) Tablets</b>	<b>1 mg, 2 mg, 4 mg</b>	<b>1 mg orally daily</b>
Virilon (methyltestoste-rone) 10 mg capsules	<p>Orthographic similarity stems from the fact that upper case ‘V’ and upper case ‘L’ look alike in some handwriting samples and both Virilon and Livalo have the combination letters ‘-lo-’ in their suffixes</p> <p>Doses of Virilon are achievable using the available strengths of Livalo</p> <p>Both names share the same route and frequency of administration.</p> <p>Virilon is no longer on the market but there are other oral methyltestosterone products in the marketplace.</p>	<p>Orthographically, the third and fourth letters in Livalo (‘-va-’) give the infix an expanded appearance compared to similarly located letters in Virilon (‘-ri-’). Additionally, the last letters in these names are distinctly different (‘o’ vs. ‘n’) further distinguishing this name pair.</p> <p>If Virilon 10 mg were misinterpreted as Livalo 10 mg, this would represent an overdose since the maximum recommended dose for Livalo is 4 mg/day. If Livalo 1 mg were misinterpreted as Virilon 1 mg, this dose is not achievable since the lowest available strength for Virilon is 10 mg.</p>

Failure Mode: Name confusion	Causes (could be multiple)	Rationale why medication error is unlikely to occur in the usual practice setting.
<b>Proprietary Name</b>	<b>Strength</b>	<b>Usual Dose:</b>
<b>Livalo (pitavastatin) Tablets</b>	<b>1 mg, 2 mg, 4 mg</b>	<b>1 mg orally daily</b>
pravastatin 10 mg, 20 mg, 40 mg capsules (established name for Pravachol)	<p>Orthographic and phonetic similarity of established names stems from same first letter ('p') and same suffixes ('-statin')</p> <p>Numerical overlap exists (1 mg, 2 mg, 4 mg vs. 10 mg, 20 mg, 40 mg)</p> <p>Both names have the same route of administration (oral) and same frequency of administration (daily)</p>	<p>The upstroke (represented by lower case 't') in the prefix of pitavastatin differentiates this name from pravastatin. Additionally, the prefix in pravastatin is longer in appearance because of the letter '-r-' vs. the slimmer looking letters '-it-' in pitavastatin. These orthographic differences may distinguish this name pair from each other.</p> <p>If pravastatin 10 mg were misinterpreted as pitavastatin 10 mg, this would represent a 2.5-fold overdose of this product as the maximum recommended daily dose for pitavastatin is 4 mg. If pitavastatin 1 mg were misinterpreted as pravastatin 1 mg, the dose of pravastatin would not be achievable as the lowest available strength pravastatin is 10 mg.</p>

<b>Failure Mode: Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Rationale why medication error is unlikely to occur in the usual practice setting.</b>
<b>Proprietary Name</b>	<b>Strength</b>	<b>Usual Dose:</b>
<b>Livalo (pitavastatin) Tablets</b>	<b>1 mg, 2 mg, 4 mg</b>	<b>1 mg orally daily</b>
<p>Livaid (Glycyrrhiza Uralensis Radix 40mg, Cordyceps Sinensis 50mg, Radix Panax Quinquefolii 50mg, Radix Paeoniae Alba 25mg, Curcuma Aromatica 25mg, Astragalus Membranaceus 40mg, Polygonatum Sibricum Rhizoma 20mg, Scutellaria Baicalensis Radix 25mg, Isatidis Tinctoria Radix 45mg, Polygonum Cuspidatum Rhizoma 20mg, Rehmannia Glutinosa Libosh 25mg, Polyporus Umbellatus 20mg, Salviae Miltiorrhizae radix 45mg, Ganoderma Lucidum (Mycelium) 50mg, Radix Angelicae Sinensis 20mg)</p>	<p>Orthographic similarity stems from the sharing of the same first 4 letters ('Liva-') and an upstroke near or at the end of the name ('l' vs 'd').</p> <p>Numerical overlap in doses (2 capsules vs 2 mg) and 4 capsules vs. 4 mg)</p> <p>Overlap in route of administration (oral)</p>	<p>Livaid is used in the alternative, self-care market and is unlikely to be prescribed in the traditional medical practice setting. Thus, Livaid can be acquired without a formal prescription from a prescriber.</p>

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Denise Baugh  
7/2/2009 01:58:03 PM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
7/2/2009 02:58:07 PM  
DRUG SAFETY OFFICE REVIEWER

11/24/08



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

Date: November 24, 2008

To: Mary Parks, MD  
Director, Division of Metabolism and Endocrinology Product,  
HFD-510

Through: Todd Bridges, RPh., Team Leader  
Denise P. Toyer, Pharm.D., Deputy Director  
Carol Holquist, R.Ph., Director  
Division of Medication Error Prevention and Analysis (DMEPA)

From: Denise V. Baugh, PharmD., BCPS, Safety Evaluator  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Livalo (Pitavastatin) Tablets  
1 mg, 2 mg, 4 mg

Application Type/Number: IND# 60,492

Applicant/sponsor: Kowa Research Institute, Inc.

OSE RCM #: 2007-1426

\*\*This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.\*

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## **EXECUTIVE SUMMARY**

The findings of the Proprietary Name Risk Assessment indicate that the proposed name is not vulnerable to confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis has no objection to the use of the proposed name, Livalo for this product at this time.

This name will be re-evaluated at the time of NDA submission and 90 days prior to approval. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, the Division of Medication Error Prevention and Analysis rescinds this Risk Assessment finding and the name must be resubmitted for review.

The sponsor is encouraged to submit container labels, carton and insert labeling for review and comment when available.

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

This consult was written in response to a request from the Division of Metabolism and Endocrinology Products (HFD-510), for assessment of the proprietary name, "Livalo" regarding potential name confusion with other proprietary and/or established drug names. DDMAC objected to this name, but the division did not concur. Therefore, the Division of Medication Error Prevention and Analysis proceeded with this name review from a safety perspective. Container labels, carton and insert labeling were not submitted for review and comment.

### **1.2 PRODUCT INFORMATION**

Livalo (Pitavastatin) is a competitive inhibitor of HMG-CoA reductase. It is an adjunct to diet to reduce total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in adult patients with primary hypercholesterolemia and mixed dyslipidemia. The usual dose is 1 mg orally once daily. This may be titrated up to 4 mg per day. Livalo will be available as 1 mg, 2 mg, and 4 mg oral tablets. This product has been marketed in Japan since September 2003.

## **2 METHODS AND MATERIALS**

This section describes the methods and materials used by the Division of Medication Error Prevention and Analysis medication error staff to conduct a proprietary name risk assessment. The primary focus of the assessments is to identify and remedy potential sources of medication error prior to drug approval. The Division of Medication Error Prevention and Analysis defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>1</sup>

### **2.1 PROPRIETARY NAME RISK ASSESSMENT**

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

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<sup>1</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

For the proprietary name, Livalo, the medication error staff of the Division of Medication Error Prevention and Analysis search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Section 2.1.1) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see Section 2.1.1.2). The Division of Medication Error Prevention and Analysis also conducts internal FDA prescription analysis studies (see Section 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see Section 2.1.3).

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see Section 2.1.3). The overall risk assessment is based on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>2</sup> FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. The Division of Medication Error Prevention and Analysis defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>3</sup> We use the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed drug name include, but are not limited to established name of the proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, the Division of Medication Error Prevention and Analysis considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>4</sup>

### **2.1.1 Search Criteria**

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

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

<sup>3</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>4</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

For this review, particular consideration was given to drug names beginning with the letter 'L' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>56</sup>

To identify drug names that may look similar to Livalo, the Staff also consider the other orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (6 letters), upstrokes (2, capital letter 'L and lower case 'l'), downstrokes (none), cross-strokes (none), and dotted letters (1, 'i'). Additionally, several letters in Livalo may be vulnerable to ambiguity when scripted, including the upper case 'L' may appear as an 'S', 'V' or an 'F'; lower case 'i' may appear as lower case 'e', 'u' or 'a'; lower case 'v' may appear as a lower case 'u', 'b', 'r' or 'w'; lower case 'l' may appear as 't', 'd', 'e', or 'b'; and lower case 'o' may appear as an 'i', 'a', or 'e'. As such, the Staff also considers these alternate appearances when identifying drug names that may look similar to Livalo.

When searching to identify potential names that may sound similar to Livalo, the Medication Error Staff search for names with similar number of syllables (3), stresses (Li-VA-lo or LI-va-lo or Li-va-LO), and placement of vowel and consonant sounds. In addition, several letters in Livalo may be subject to interpretation when spoken such as Livalo may sound like 'live low' or the letters '-VA-' may sound like '-BA-'. The Sponsor's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the Medication Error Staff were provided with the following information about the proposed product: the proposed proprietary name (Livalo), the established name (pitavastatin), proposed indication (primary hypercholesterolemia and mixed dyslipidemia), strength (1 mg, 2 mg, 4 mg), dose (1 mg titrated up to 4 mg based upon patient's needs), frequency of administration (daily), route (oral) and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics the Medication Error Staff general take into consideration.

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

#### **2.1.1.1 Database and Information Sources**

The proposed proprietary name, Livalo, was provided to the medication error staff of the Division of Medication Error Prevention and Analysis to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to Livalo using the criteria outlined in Section 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the medication error staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex

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<sup>5</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>6</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the Medication Error Staff review the United States Adopted Names (USAN) stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators are then pooled and presented to the Expert Panel.

#### **2.1.1.2 FDA Adverse Event Reporting System (AERS) Database**

Livalo has been marketed in Japan since 2003. Therefore, the FDA's Adverse Event Reporting System (AERS) was searched for all post-marketing reports concerning medication errors associated with Livalo. Search names used were "Livalo", "Pitavastatin" and the verbatim names "Liva%" and "Pitav%". The following High Level Term (HLGT) was used: "Medication errors". The following MedDRA Preferred Term (PT) was used: "Pharmaceutical Product Complaint".

The cases were manually reviewed to determine if a medication error occurred. Those cases that did not describe a medication error or did not describe an error applicable to this review were excluded from further analysis. The cases that did describe a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors, and to ascertain if these risks might apply to the proposed Livalo product.

#### **2.1.1.3 CDER Expert Panel Discussion**

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

The pooled results of the medication error staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

#### **2.1.2 FDA Prescription Analysis Studies**

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

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

**Figure 1. Livalo Prescription Study (conducted on July 13, 2007)**

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Prescription:</u></p> <p><i>Livalo 4mg #.60</i> <i>7 tab po daily</i></p>	<p>"Livalo 4 mg – one tablet by mouth daily"</p>
<p><u>Inpatient Medication Order :</u></p> <p><i>Livalo 4mg + po od</i></p>	

### 2.1.3 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Mode and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>7</sup> When applying FMEA to assess the risk of a proposed proprietary name, the Division of Medication Error Prevention and Analysis seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, expert panel evaluation, and studies, and identifies potential failure modes by asking: "Is the name Livalo convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?" An affirmative answer indicates a failure mode and represents a potential for Livalo to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the

<sup>7</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

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

The Division of Medication Error Prevention and Analysis will object to the use of proposed proprietary name when one or more of the following conditions are identified in the Safety Evaluator’s Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. The Division of Medication Error Prevention and Analysis identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains a USAN stem, particularly in a manner that is contradictory to the USAN Council’s definition.
5. Medication Error Staff identify a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

If none of these conditions are met, then the Division of Medication Error Prevention and Analysis will not object to the use of the proprietary name. If any of these conditions are met, then we will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Sponsor; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission for Healthcare Organizations (JCAHO), and the Institute of Safe Medication Practices (ISMP). These respective organizations have examined medication errors

resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

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

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

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

### **3 RESULTS**

#### **3.1 PROPRIETARY NAME RISK ASSESSMENT**

##### **3.1.1 Database and Information Sources**

In total, twenty-four names were identified as having some similarity to the name Livalo.

Sixteen (n = 16) of the twenty-four names were thought to look like Livalo, which include: Levulan, Uvadex, Vivacor, Vivalan, Lorelco, Levatol, Levlen, Levora, Zevalin, (b) (4) Cerato, Levitra, Revatio, Cialis, Hivid, and Vivelle.

Eight (n = 8) names (Levolet, Livalon, Levall, Livarole, (b) (4) Lo-Ovral, Elavil and Lialda) were thought to look and sound similar to Livalo.

The Division of Medication Error Prevention and Analysis did not identify any USAN stems in the name, Livalo, as of September 25, 2008.

##### **3.1.2 CDER Expert Panel Discussion**

The Expert Panel reviewed the pool of names identified by the Division of Medication Error Prevention and Analysis staff (see Section 3.1.1. above), and noted no additional names thought to have orthographic or phonetic similarity to Livalo and have the potential for confusion.

“DDMAC objected to the proposed trade name “Livalo” for the following reason. Because it overstates the efficacy and minimizes potential risks associated with the drug product. “Livalo” can be broken down

into two parts, “liv” and “lo.” “Liv” easily invokes the word “live” and “lo” easily invokes the word “low.” Given that the proposed indication for this drug product is treatment of hypercholesterolemia, the proposed trade implies that this drug product offers a survival benefit because it lowers cholesterol. We are not aware of substantial evidence to support such a treatment benefit.

In addition, the word “liv” can easily invoke the word “liver.” HMG-CoA reductase inhibitors have been associated with biochemical abnormalities of liver function and other statins currently on the market contain a Warning in their approved product labeling (PI) regarding liver dysfunction. The proposed trade name “Livalo” may imply that this statin, pitavastatin, offers “low” risks to the “liver,” thereby minimizing the potential risks of liver dysfunction associated with this drug product. In the absence of substantial evidence to support that pitavastatin impacts patient mortality or that this product offers a lower risk to the liver compared to other statins on the market, the proposed trade name is misleading.

Please note that the Federal Food Drug and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a trade name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)]. “

However, the Division did not concur with DDMAC’s assessment and requested DMEPA continue with the safety review.

### **3.1.3 FDA Prescription Analysis Studies**

A total of 36 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. One third of the participants (n=12) interpreted the name correctly as “Livalo” with correct interpretation occurring more frequently in the outpatient written studies. The remainder of the responses misinterpreted the drug name. Thirteen (n = 13) of the 36 misinterpretations occurred in the phonetic prescription studies, with the vowels in Livalo reported as ‘e’, ‘i’, ‘ou’ and ‘o’ instead of ‘i’, ‘a’ and ‘o’. In the written (inpatient) prescription studies, the letter ‘L’ was misinterpreted as a ‘U’ by half of the respondents and four of the respondents misinterpreted the ‘o’ for a ‘v’. See Appendix A for the complete listing of interpretations from the verbal and written prescription studies.

### **3.1.4 AERS Selection of Cases**

The search did not identify any medication error cases.

### **3.1.5 Safety Evaluator Risk Assessment**

Independent searches by the primary Safety Evaluator did not identify additional names thought to look similar to Livalo and represent a potential source of drug name confusion. As such, a total of 24 names were analyzed to determine if the drug names could be confused with Livalo and if the drug name confusion would likely result in a medication error.

All of the identified names were determined to have some orthographic and/or phonetic similarity to Livalo, and thus determined to present some risk for confusion. Failure mode and effects analysis was then applied to determine if the proposed name, Livalo, could potentially be confused with any of the twenty-four names and lead to medication error.

FMEA analysis determined that the name similarity between Livalo and the identified names was unlikely to result in medication error for all twenty-four names. See Appendices C through G for details.

## **4 DISCUSSION**

We analyzed a total of twenty-four names for their potential similarity to the proposed name, Livalo. The findings of the FMEA indicate that the proposed name is not vulnerable to name confusion that could lead to medication errors.

The findings of the Proprietary Name Risk Assessment are based upon current understanding of factors that contribute to medication errors involving name confusion. Although we believe the findings of the Risk Assessment to be robust, our findings do have limitations. First, because our assessment involves a limited number of practitioners, it is possible that the analysis did not identify a potentially confusing name. Also, there is some possibility that our Risk Assessment failed to consider a circumstance in which confusion could arise. However, the Division of Medication Error Prevention and Analysis believes that these limitations are sufficiently minimized by the use of an Expert Panel and the CDER Prescription Studies that involved 123 CDER practitioners.

However, our risk assessment also faces limitations beyond the control of the Agency. First, as our risk assessment is based on current health care practices and drug product characteristics, future changes to either could increase the vulnerability of the proposed name to confusion. Since these changes cannot be predicted or accounted for by the current Proprietary Name Risk Assessment process, such changes limit our findings. To help counterbalance this impact, the Division of Medication Error Prevention recommends that the proprietary name be re-submitted for review if approval of the product is delayed beyond 90 days.

## **5 CONCLUSIONS**

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

## **6 RECOMMENDATIONS**

### **6.1 Comments to the Division**

The Division of Medication Error Prevention and Analysis has no objections to the name, Livalo, for this product. However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, the Division of Medication Error Prevention and Analysis rescinds this Risk Assessment finding and the name must be resubmitted for review. Additionally, this name will be re-evaluated at the time of the NDA submission and 90 days prior to product approval.

The Division of Medication Error Prevention and Analysis would appreciate feedback of the final outcome of this consult. Please copy us on any correspondence forwarded to the sponsor pertaining to this review. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarification, please contact Cheryl Campbell, OSE Project Manager, at 301-796-0723.

### **6.2 Comments to the Applicant**

The Division of Medication Error Prevention and Analysis has no objection to the proposed proprietary name, Livalo at this time. If any of the proposed product characteristics are altered as provided in your June 12, 2007 submission, we rescind this Risk Assessment finding. A request for a proprietary name review for Livalo should be submitted once the NDA is submitted.

## 7 REFERENCES

### 1. *Adverse Events Reporting System (AERS)*

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufactures that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential postmarketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

### 2. *Micromedex Integrated Index (<http://weblern/>)*

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

### 3. *Phonetic and Orthographic Computer Analysis (POCA)*

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

### 4. *Drug Facts and Comparisons, online version, St. Louis, MO (<http://weblern/>)*

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

### 5. *AMF Decision Support System [DSS]*

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

### 6. *Division of Medication Error Prevention and Analysis proprietary name consultation requests*

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

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name and generic drugs and therapeutic biological products; prescription and over-the-counter human drugs and therapeutic biologics, discontinued drugs and “Chemical Type 6” approvals.

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

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

**9. U. S. Patent and Trademark Office website** <http://www.uspto.gov>.

Provides information regarding patent and trademarks.

**10. Clinical Pharmacology Online** (<http://weblern/>)

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

**11. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at** [www.thomson-thomson.com](http://www.thomson-thomson.com)

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

**12. Natural Medicines Comprehensive Databases** (<http://weblern/>)

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

**13. Stat!Ref** (<http://weblern/>)

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

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

List contains all the recognized USAN stems.

**15. Red Book Pharmacy's Fundamental Reference**

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

**16. Lexi-Comp** ([www.pharmacist.com](http://www.pharmacist.com))

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

**17. Medical Abbreviations Book**

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

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

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

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

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

**Appendix B:**

**CDER Prescription Study Responses**

<b>Outpatient Prescription</b>	<b>Voice Prescription</b>	<b>Inpatient Medication Order</b>
Livalo	Louvello	Levialr
Livalo	Luvella	Uvolv
Livalo	Bavelo	Livalv
Livalo	Livello	Livalo
Livalo	Levello	Uvalo
Livalo	Luvello	Uvalv
Livalo	Lovello	???
Livalo	Mazalo	Uvalo
Livalo	Leuvello	Levalo
Livalo	Novello	Luvilv
Livalo	Lovello	Uvalo
	Bavello	Uvalo
	Levelo	

**Appendix C.** Drug names lacking convincing look or sound-alike similarities to Livalo.

<b>Proprietary Name</b>	<b>Similarity to Livalo</b>
Vivelle	Look
Hivid	Look
Lialda	Look and Sound
Lo Ovril	Look and Sound
Zevalin	Look
Uvadex	Look

**Appendix D.** Drug names with little or no information available in commonly used databases.

<b>Proprietary Name</b>	<b>Similarity to Livalo</b>
(b) (4)	Look-alike
Cerato	Look-alike

**Appendix E:** Proprietary names used only in Foreign Countries

<b>Proprietary Name</b>	<b>Similarity to Livalo</b>	<b>Country</b>
Livarole	Look and Sound	Russia
Vivacor	Look	United Kingdom
Vivalan	Look	Czechoslovakia, France, Germany, United Kingdom
Lorelco	Look	Canada

**Appendix F:** Products with no numerical overlap in strength and dose.

<b>Livalo (Pitavastatin)</b>		<b>Strength: 1 mg, 2 mg, and 4 mg</b>	<b>Usual dose: 1 mg orally daily titrated up to 4 mg per day</b>
<b>Product name with potential for confusion</b>	<b>Similarity to Proposed Proprietary Name</b>	<b>Strength</b>	<b>Usual Dose (if applicable)</b>
Levulan	Look	20% topical solution	One application per treatment site
Levall	Look and Sound	Carbetapentane 30 mg, guaifenesin 100 mg, phenylephrine 8 mg/5 mL, 10 mg/5 mL, or 15 mg/mL	5 ml to 10 ml every 4 to 6 hours as needed
Levlen	Look	Ethinyl estradiol 0.03 mg and 0.15 mg; levonorgestrel	One tablet once daily
(b) (4)	Look and Sound	(b) (4)	(b) (4)
Levora	Look	Ethinyl estradiol 0.03 mg and 0.15 mg levonorgestrel	One tablet once daily

**Appendix G:** Potential confusing name with numerical overlap or similarity in strength or dose

<b>Livalo® (Pitavastatin)</b>	<b>1 mg, 2 mg, and 4 mg</b>	<b>Usual dose: 1 mg orally daily titrated up to 4 mg per day</b>
<b>Failure Mode: Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Effects</b>
Levolet (levothyroxine)	Orthographic similarity (Both names begin with same first letter and lower case 'i' (in Livalo) and lower case 'e' (in Levolet) are not distinguishable in some writing samples; both names have one upstroke in same position (lower case 'l'); same route of administration (oral) and same frequency of administration (daily).  Numerical similarity in strength (1 mg, 2 mg	Medication error unlikely to occur in the usual practice setting.  <i>Rationale:</i>  Lack of convincing orthographic and phonetic similarity primarily because of ending cross stroke represented by lower case 't' in "Levolet".  There is the potential that the preceding zero could be omitted from the prescription, however, the differentiating orthographic variables outlined above would decrease the potential for confusion leading to medication errors.  Although the strength for Levolet is achievable using ten tablets of Livalo, dispensing and/or administering this number of tablets per dose would alert the healthcare provider of potential problems.

	<p>versus 0.1 mg, 0.2 mg)</p> <p>Possibly prescribed in similar patient populations</p>	
Livalon	<p>Orthographic similarity (All letters are the same except for the last letter of Livalon)</p> <p>Same route of administration (route) and frequency of administration (daily)</p>	<p>The different contexts of use minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the differences in the context of use.</p> <p>Livalon is an over-the-counter, nutritional supplement for liver detoxification and therefore, it is unlikely that a prescription would be written for this product. The context of use will help to distinguish them from each other and decrease the potential for confusion between them.</p> <p>Additionally, Livalo is available in multiple strengths, this information must be stated on a prescription whereas there is no specific strength for Livalon. This further differentiates these two drug products.</p>
Levatol (penbutolol sulfate)	<p>Orthographic similarity (lower case 'e' and lower case 'i' are not distinguishable from each other in some handwriting samples; same infix for both names '-va-'; upstrokes represented by lower case 't' (Levatol) and lower case 'l' (Livalo) are in the same positions giving this name pair slightly similar shapes)</p> <p>Numerical similarity in strength and dosage (20 mg daily versus 2 mg), same route of administration (oral) and frequency of administration (daily); existence of trailing zeros may increase risk for confusion (e.g., 20 mg vs. 2.0 mg)</p> <p>Would be prescribed in same patient populations</p>	<p>Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. The cross stroke in Levatol will distinguish this name from the lower case 'l' in Livalo. Additionally, the presence of the lower case 'l' at the end of 'Levatol' makes this name longer than Livalo minimizing the potential for confusion between this name pair.</p> <p>Although the strength for Levatol is achievable using ten 2 mg tablets or five 4 mg tablets of Livalo, dispensing and/or administering this number of tablets per dose would alert healthcare providers of potential problems.</p> <p>The usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Campaigns by numerous organizations (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce the risk of medication error.</p>

<p>Levitra (vardenafil)</p>	<p>Orthographic similarity (The lower case 'e' (Levitra) looks similar to lower case 'i' in some handwriting samples making Lev-' and Liv-' look alike); both names have the first upstroke in the same position ('t' in Levitra vs. 'l' in Livalo)</p> <p>Numeric similarity in strengths (10 mg, 20 mg vs. 1 mg, 2 mg), same route of administration (oral); existence of trailing zeroes may increase potential for confusion (eg. 10 mg vs. 1.0 mg)</p>	<p>Medication errors unlikely to occur in usual practice setting.</p> <p><i>Rationale:</i></p> <p>The cross stroke in Levitra will distinguish this name from Livalo. Additionally, the last two letters in Levitra ("-ra") do not look like 'o' (in Livalo) which distinguishes this name pair.</p> <p>Although the doses for Levitra are achievable using the strengths supplied for Livalo, the administration of ten tablets (e.g., 10 x 1 mg tablets or 10 x 2 mg tablets) or five tablets (of 4 mg) is not a common standard of practice and, dispensing and/or administering this number of tablets would alert the healthcare provider of potential problems.</p>
<p>Elavil (amitriptyline)</p>	<p>Orthographic similarities stem from shared letters (eg., LIVALO vs. ELAVIL)</p> <p>Numerical similarity in strengths (10 mg, 100 mg vs. 1 mg), same route of administration (oral), same frequency (daily), same dosage form (tablet)</p>	<p>Orthographic differences in the name minimize the likelihood of medication errors in the usual practice settings.</p> <p><i>Rationale:</i></p> <p>Although Elavil has been discontinued in the U.S. market, generic products still exist and, thus the brand name may be written for.</p> <p>Although these names share five of their six letters, they lack convincing orthographic similarity due to the different positions of these letters. Additionally, the ending letter in Elavil is an upstroke versus an 'o' in Livalo further making these names distinct from one another when scripted.</p>
<p>Revatio (sildenafil)</p>	<p>Orthographic similarities stem from shared letters in the names (eg. REVATIO vs. LIVALO). Additionally, both names end with an upstroke and an 'o' giving this name pair similar shapes.</p> <p>Numeric similarities in strength (20 mg vs 2 mg).</p> <p>Revatio and Livalo also share the same route of administration (oral) and dosage form (tablet).</p>	<p>Medication error is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>Despite sharing the letters 'v', 'a' and ending in the letter 'o' (REVATIO vs. LIVALO) and having some overlapping product characteristics such as route of administration (oral) and dosage form (tablet), this name pair is orthographically different and have different frequencies of administration (three times daily vs. once daily).</p>

<p>Cialis (tadalafil)</p>	<p>Orthographic similarities stem from shared letters (CIALIS vs. LIVALO)</p> <p>Numerical similarity (10 mg, 20 mg vs. 1 mg, 2 mg); same route of administration (oral) and dosage form (tablet)</p>	<p>Medication errors are unlikely to occur in the usual practice settings</p> <p><i>Rationale:</i></p> <p>Although this name pair shares many letters, the sequence impedes convincing orthographic similarities. For instance, the third letters ('v' in Livalo versus 'a' in Cialis) and the suffix ('-o' in Livalo versus '-is' in Cialis) distinguish these names from each other. Although there is the potential that Cialis and Livalo could be used in the same patient population and the frequency of administration could overlap, the lack of orthographic similarities will likely prevent confusion in the usual practice setting.</p> <p>Although the doses for Cialis are achievable using the strengths supplied for Livalo, the administration of ten tablets (e.g., 10 x 1 mg tablets or 10 x 2 mg tablets) is not a common standard of practice.</p>
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Linked Applications

Sponsor Name

Drug Name

IND 60492

KOWA RESEARCH  
INSTITUTE INC

PITAVASTATIN TABLETS

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