

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-418**

**PROPRIETARY NAME REVIEW(S)**

5/7/09



**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: May 7, 2009

To: Mary Parks, MD, Director  
Division of Metabolism and Endocrinology Products

Thru: Melina Griffis, RPh, Acting Team Leader  
Denise Toyer, PharmD, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis

From: Robin Duer, RN, MBA, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name: Fibracor (Fenofibric Acid) Tablets, 35 mg and 105 mg

Application Type/Number: NDA 22-418

Applicant: Mutual Pharmaceutical Company, Inc.

OSE RCM #: 2008-1764

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

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## **EXECUTIVE SUMMARY**

The results of the Proprietary Name Risk Assessment found that the proposed name, Fibracor, 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, Fibracor, for this product.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and recommends that the name be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change.

In addition, if approval of this NDA is delayed beyond 90 days of the signature date of this review Fibracor will need to be re-reviewed 90 days prior to the anticipated approval

## **BACKGROUND**

### **1.1 INTRODUCTION**

This review is in response to a request from the Division of Metabolism and Endocrinology Products for an assessment of the proposed proprietary name, Fibracor, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external proprietary name risk assessment from the Drug Safety Institute for Fibracor which was considered in this review. The Applicant also submitted container labels for review, which will be reviewed separately in OSE review # 2009-410.

### **1.2 PRODUCT INFORMATION**

Fibracor (Fenofibric Acid) is indicated for the treatment of hypercholesterolemia and hypertriglyceridemia. Fibracor will be available as oral tablets in two dosage strengths, 35 mg and 105 mg. The recommended usual dose will be 35 mg to 105 mg given once daily. Fibracor will be supplied in bottles of 30, 60, 90, 100, 250, 500 and 1,000 count.

### **1.3 REGULATORY HISTORY**

Fibracor (Fenofibric Acid) is a pending 505(b)(2) NDA application with an anticipated action date of June 15, 2009. The referenced listed drug for Fibracor is Tricor (NDA 21-656).

## **2 METHODS AND MATERIALS**

This section describes the methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment (See 2.1 Proprietary Name Risk Assessment). The primary objective for the assessment is to identify and remedy potential sources of medication error prior to drug approval. 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>

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

## 2.1 PROPRIETARY NAME RISK ASSESSMENT

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.

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources to identify names with orthographic and phonetic similarity (See 2.1.1 for details) and held a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (See 2.1.1.2). DMEPA staff also conducts internal CDER prescription analysis studies. When provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment.

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 2.1.2 for details). 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 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 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>

### 2.1.1 Search Criteria

The DMEPA 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> 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 'F' 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>4,5</sup>

To identify drug names that may look similar to Fibracor, the Staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (8 letters), upstrokes (two, capital letter 'F' and lower case letter 'b'), down strokes (none), cross-strokes (one, upper case letter 'F'), and dotted letters (two, lower case letter 'i').

Additionally, several letters in Fibracor may be vulnerable to ambiguity when scripted, including the capital letter 'F' may appear as 'T', 'L' or 'P'; lower case 'i' may appear as lower case 'a', 'e', 'o' or 'u'; lower case 'b' may resemble a lower case 'l', 'li', 'h' or 't'; lower case 'r' may appear as lower case 'n', 'x', 't', 'v' or 'u'; lower case 'c' may resemble a lower case 'a', 'e', 'i', or 'o', and lower case 'o' may resemble a lower case 'a', 'e', 'i', or 'u'. Further, special consideration was made to searching drug names that end in 'car' and 'cor'. As such, the Staff also considers these alternate appearances when identifying drug names that may look similar to Fibracor.

When searching to identify potential names that may sound similar to Fibracor, the DMEPA staff search for names with similar number of syllables (3), stresses (FI-bri-cor, FIB-ri-cor and Fib-ri-COR) and placement of vowel and consonant sounds. In addition, several letters in Fibracor may be subject to interpretation when spoken; including the letter 'F' may be interpreted as 'V', 'i' may be interpreted as 'ee' or 'ia', 'ri' may be interpreted as 'er', 'b' may be interpreted as 'd', 'or 'cor' may be interpreted as a 'con'. The Applicant's intended pronunciation of the proprietary name was not provided with the proposed name submission and, therefore, could not be taken into consideration. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

The DMEPA 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 DMEPA staff were provided with the following information about the proposed product: the proposed proprietary name (Fibracor), the established name ((Fenofibric Acid), proposed indication (treatment of hypercholesterolemia and hypertriglyceridemia), strength (35 mg and 105 mg), dose (35 mg to 105 mg), frequency of administration (once daily), route of administration (oral) and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics the medication error staff generally takes into consideration.

Lastly, the DMEPA 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. Consequently, these broader safety implications of the name are considered and evaluated throughout this assessment and DMEPA 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 was provided to DMEPA to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed

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<sup>4</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>5</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. *Artificial Intelligence in Medicine* (2005)

drug names that may sound-alike or look-alike to the proposed proprietary name 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, DMEPA staff used 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 medication error staff reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators were then pooled and presented to the CDER Expert Panel.

#### **2.1.1.2 CDER Expert Panel Discussion**

An Expert Panel Discussion is held by DMEPA to gather CDER professional opinions on the safety of the 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). Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed.

The pooled results of the DMEPA 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 the proposed proprietary name 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 (one hundred twenty-three) 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 the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders 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 DMEPA.

**Figure 1. Fibrivor Study (conducted on November 20, 2008)**

HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Medication Order:</u></p> <p><i>Fibrivor 105mg #30 T PO QD</i></p>	<p>Fibrivor 105 mg #30 PO daily</p>
<p><u>Inpatient Medication Order:</u></p> <p><i>Fibrivor 105mg T PO daily</i></p>	

**2.1.3 External Proprietary Name Risk Assessment**

For this product, the Applicant submitted an external evaluation from the Drug Safety Institute for the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA’s database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator’s Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk assessment of the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division’s risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

**2.1.4 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 Modes 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>6</sup> When applying FMEA to assess the risk of a proposed proprietary name, we seek 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

<sup>6</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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 Fibracor 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 Fibracor 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 possesses 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.

DMEPA will object to the use of a 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. 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)].
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 an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. 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.

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 is awarded approval first has the right to the use of 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 DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then DMEPA will object to the use of the proprietary 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 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 on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP), who 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, DMEPA 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 approving the error-prone proprietary name. Moreover, even after a Sponsor 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, 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).

If DMEPA 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 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, and so 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.

### 3 RESULTS

#### 3.1 Database and Information Sources

The searches yielded a total of 24 names as having some similarity to the name Fibracor

Seventeen of the names were thought to look like Fibracor. These include Folacin, Librium, Fibrilan, Dilacor, Tricor, Fibrovein, Fiber Choice, Trecator, Simcor, Fertinex, Fibocil, Fibrinon, Tambocor, Folmor, Furacin, Natrecor, and Fibrocid. One name was thought to sound like Fibracor (Lipitor). The remaining six names were thought to look and sound similar to Fibracor (Fibracor, Fibercon, Fibracol, Fibrocard, Advicor and Primacor).

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 4, 2009.

#### 3.2 Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by DMEPA staff (see Section 3.1.1. above), and noted no additional names thought to have orthographic or phonetic similarity to Fibracor.

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 FDA Prescription Analysis Studies

A total of 29 practitioners responded. One of the outpatient written responses overlapped with the existing product name "Fibercon". Eighteen of the participants interpreted the name correctly as "Fibracor", with correct interpretation occurring more frequently in the written studies (n= 17). The remainder of the responses misinterpreted the drug name. In the verbal studies, all but one response were misspelled phonetic variations of the proposed name, Fibracor. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

#### 3.4 External Name Study

In the submission the Applicant provided a proposed name validation study conducted by the \_\_\_\_\_ which identified 24 names that look or sound similar to the proposed proprietary name, Fibracor. \_\_\_\_\_ utilized an Internal Expert Panel Discussion, Rx Studies and Computerized Orthographic and Phonologic Analysis to identify names that look or sound like Fibracor. The following 24 names were identified by \_\_\_\_\_ Advicor, Baricon, Benicar, Corgard, Dilacor XR, Fenofibrate, Ferocon, Fiberall, Fibercon, Fioricet, Fiorinal, Flexeril, Formoterol, Librium, Lipitor, Mevacor, Primacor, Relacore, Symbicort, Tekturna, Tricon, Tricor, Visicol and Zocor. Six of the 24 names (Advicor, Fibercon, Librium, Lipitor, Primacor and Tricor) were previously identified in the Division of Medication Error Prevention and Analysis staff searches.

b(4)

b(4)

#### 3.4 Safety Evaluator Risk Assessment

Independent searches by the primary Safety Evaluator resulted in no additional names which were thought to look or sound similar to Fibracor and represent a potential source of drug name confusion. However, it should be noted that the name Dilacor was identified by the Expert panel, and the name Dilacor XR was identified in the Applicant's \_\_\_\_\_ report. After a search of commonly used drug information databases it was determined that the name Dilacor is only used with the modifier XR, so those names were considered to be identical. Additionally, one of the names found in SAEGIS was identical to the proposed proprietary name, Fibracor, and was the identical product under review.

b(4)

Thus forty names were analyzed to determine if the drug names could be confused with Fibracor and if the drug name confusion would likely result in a medication error.

Twelve of the 40 names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the potential name, Fibracor could potentially be confused with any of the 28 names and lead to medication errors. This analysis determined that the name similarity between Fibracor and the identified names was unlikely to result in medication errors with any of the remaining 28 products identified for the reasons presented in Appendices D through H.

#### **4 DISCUSSION**

We analyzed a total of 40 names for their potential similarity to the proposed name, Fibracor. The findings of the FMEA indicate that the proposed name is not vulnerable to name confusion that could lead to medication errors. The findings are consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

#### **5 CONCLUSIONS & RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Fibracor, 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, Fibracor, for this product at this time. Additionally, DDMAC does not object to the proposed name, Fibracor from a promotional perspective.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

##### **5.1 COMMENTS TO THE DIVISION**

We are willing to meet with the Division for further discussion, if needed. Please copy DMEPA on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Millie Wright, OSE project manager, at 301-796-1027.

##### **5.2 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name Fibracor and have concluded that it is acceptable. Fibracor will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

#### **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 definition.

## APPENDICES

### Appendix A:

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. 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 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 medication error 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), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the medication error 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.

**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

Pages 14-16 of this review are missing due to a pagination error.

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 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>

**Appendix B:**

CDER Prescription Study Responses

Overheard Medication Order	Impaired Medication Order	Verbal Description
Fibricor	Fibricor	Febricor
Fibricon	Fibricor	Vibricor

Fivuion	Fibricor	Fibrocor
Fibricor	Fibricor	Fibricor
Zimicor	Fibricor	
Fibuin	Fibricor	
Fibuior	Fibricor	
Fibricor	Fibricor	
Fibercon	Fibricor	
	Fibricon	
	Fibrucor	
	Fibricor	

**Appendix C:** Names lacking convincing orthographic and/or phonetic similarities with Fibricor

Drug name	Similarity to Fibricor
Baricon	✓ 7
Benicar	
Corgard	
Fenobibrate	
Fiberall	✓ 7
Fiber Choice	Look Alike
Formoterol	✓ 7
Mevacor	
Symbicort	
Tekturna	
Visicol	
Zocor	✓ 7

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**Appendix D:** Proprietary name used only in Foreign Countries.

Proprietary name	Similarity to Fibrinon	Product Description
Fibrilan	Look Alike	Aciclovir marketed in Europe, found in Micromedex but no trademark found in Saegis.
Fibrinon	Look Alike	Fibrinolytic acid marketed in Japan and the Phillipines.
Fibrocard	Look Alike	Verapamil product marketed in Europe.
Fibrocid	Look Alike	Pentosan polysulfate solution marketed in Spain.
Folacin	Look Alike	Folic acid marketed in Europe, South America, Asia.

**Appendix E:** Products withdrawn from the market.

Proprietary name	Similarity to Fibrinon	Status
Fibocil (Aprindine HCL)	Look Alike	Withdrawn on 7/29/93 per DSS, reason unknown, not found in DFS. Generics not available.

**Appendix F:** Products with no overlap in strength and/or dose

Product name with potential for confusion	Similarity to Fibricor	Strength	Usual Dose
<b>Fibricor</b> ( <i>Fenofibric Acid</i> )	N/A	<b>35 mg and 105 mg tablets</b>	<b>Usual Dose: 105 mg given once daily</b>
Dilacor XR ( <i>Diltiazem Hydrochloride</i> )	Look Alike	120 mg, 180 mg and 240 mg capsules	120 mg to 540 mg given once daily
Ferocon ( <i>Ferrous Fumarate/Vitamin C/Vitamin B12/Folic Acid/ Intrinsic Factor</i> )	DSI	110 mg/75 mg/ 0.015 mg/ 0.5 mg/240 mg capsules	One capsule given once daily
Fertinex ( <i>Urofollitropin</i> )	Look Alike	75 and 150 iu powder for injection	150 iu subcutaneous injection given once daily
Fibro-Vein (Sodium Tetradecyl Sulfate Injection)	Look Alike	1 % (10 mg/mL)	0.5 mL to 2 mL given intravenously; dependent on size and degree of varicosity
Fioricet ( <i>Acetaminophen/Caffeine/Butalbital</i> )	DSI	325 mg/50 mg/40 mg tablets	One to two tablets given every four to six hours (up to six tablets per day)
Fiorinal ( <i>Aspirin/Caffeine/Butalbital</i> )	DSI	325 mg/50 mg/40 mg capsules	One to two tablets given every four to six hours (up to six tablets per day)
Flexeril ( <i>Cyclobenzaprine Hydrochloride</i> )	DSI	5 mg and 10 mg tablets	One tablet given up to twice daily
Folmor ( <i>Folic Acid/Vitamin B6/Vitamin B12/Primorine</i> )	Look Alike	2.5 mg/25 mg/2 mg/875/mg tablets	One to two tablets given twice daily
Furacin ( <i>Introfurazone</i> )	Look Alike	0.2% Topical cream	Apply once daily.

Natreacor (Nesiritide Injection)	Look Alike	1.5 mg single use vials for intravenous injection	2 mg/kg intravenous bolus as needed
Relacore (VitaminC/Calcium/Thia min/ Riboflavin/Vitamin B6/Vitamin B12/Biotin/Pantotenic Acid/Magnesium)	DSI	333 mg/33 mg/5 mg/ 7 mg/17 mg/3.5 mcg/ 150 mcg/7.8 mg/39 mg	Once capsule given once daily
Simcor (Niacin/Simvastatin)	Look Alike	500 mg/20 mg 750 mg/20 mg 1000 mg/20 mg tablets	1000/20 mg to 2000 mg/40 mg given once daily
Tambocor (Flecainide Acetate)	Look Alike	50 mg 100 mg 150 mg tablets	50 mg given twice daily
Trecator (Ethionamide)	Look Alike	250 mg tablets	250 mg given once daily
Tricon (AscorbicAcid/Cyanoco balamin/Ferrous Fumerate/Folic Acid/Intrinsic Factor	DSI	75 mg/0.015 mg/110 mg/0.5 mg/240 mg	One capsule given once daily
Lipitor (Atorvastatin Calcium)	Sound Alike	10 mg, 20 mg, 40 mg, 80 mg tablets	10 to 80 mg given once daily
Advicor (Niacin/Lovastatin)	Look and Sound Alike	500 mg/20 mg 750 mg/ 20 mg 1000 mg/20 mg 1000 mg/40 mg tablets	500 mg to 2000 mg/20 mg to 40 mg given once daily
Fibracol (Collagen Wound Dressing)	Look and Sound Alike	Topical Sponge	Apply once daily to wound.
Primacor (Milrinone Lactate)	Look and Sound Alike	1 mg per mL premixed=200 mcg/mL	50 mcg/kg bolus followed by 0.375 to 0.75 mg/kg/minute continuous infusion

**Appendix G:** Products with orthographic, phonetic and/or product characteristic differences

Failure Mode Name confusion	Causes (could be multiple)	Effects
<p><b>Fibricor</b> (Fenofibric Acid)</p>	<p>N/A</p>	<p><b>35 mg and 105 mg oral tablets</b> <b>Usual Dose: 35 mg to 105 mg given once daily</b></p>
<p>Fibercon Active Ingredients: Calcium Polycarbophil 625 mg tablets</p>	<p>Orthographic and phonetic similarity exists in the presence of the first three letters "Fib". Both names have 8 letters. The last five letters in each name do not have upstrokes or downstrokes and look similar when scripted. Both names have three syllables (FI-BRI-COR and FI-BER-CON).</p> <p>Both products are oral formulations that can be given once daily.</p>	<p>Differences in product characteristics minimize the likelihood of medication errors in the usual practice setting.</p> <p>Fibricor is available in tablets with two strengths (35 mg and 105 mg) and Fibercon is available in tablets with one strength (625 mg). Prescribers would have to specify the strength on a prescription for Fibercon since it is available in multiple strengths, and none of the strengths overlap with Fibercon.</p>
<p>Librium Active Ingredients: Chlordiazepoxide Hydrochloride 5 mg, 10 mg and 25 mg capsules</p>	<p>Orthographic and phonetic similarity exists in the presence of the letters "ibri" in the middle of both names. The last two letters in each name do not have upstrokes or downstrokes and look similar when scripted. Both names have three syllables (FI-BRI-COR) and (LI-BRI-UM).</p> <p>Both products are oral formulations that can be given once daily.</p>	<p>Differences in product characteristics and orthographics and phonetics minimize the likelihood of medication errors in the usual practice setting.</p> <p>Fibricor is available in tablets with two strengths (35 mg and 105 mg) and Librium is available in capsules with three strengths (5 mg, 10 mg and 25 mg). Prescribers would have to specify the strength on a prescription for Fibercon since it is available in multiple strengths, and none of the strengths overlap with Librium. Orthographic differences are introduced since Librium begins with 'L' vs 'F' and ends in 'm' vs 'r'.</p> <p>Phonetic differences in each syllable differentiate Fibricor from Librium. Fibricor is pronounced 'FY-BRI-COR' and Librium is pronounced 'LIB-REE-UM'.</p>
<p>Tricor Active Ingredients: Fenofibrate</p>	<p>Orthographic and phonetic similarity exists in the presence of the last four letters "icor".</p>	<p>Orthographic and phonetic differences in the beginning of the name and differences in product characteristics minimize the likelihood of medication errors in the usual practice setting.</p>

<p>48 mg and 145 mg tablets 67 mg, 134 mg and 200 mg capsules</p>	<p>Both products are oral formulations containing Fenofibric Acid as the single ingredient. Both products given once daily for the same indication.</p>	<p>Fibracor is available in tablets with two strengths (35 mg and 105 mg) and Tricor is available in tablets with two strengths (48 mg and 145 mg) and capsules with three strengths (67 mg, 134 mg and 200 mg). Prescribers would have to specify the strength on a prescription for Fibracor since it is available in multiple strengths, and none of the strengths overlap with Tricor.</p> <p>Orthographic and phonetic differences in the beginning of the name differentiate Fibracor from Tricor. Orthographically, Fibracor has one upstroke in the third letter ('b'), and Tricor does not have upstrokes in the middle of the name. Phonetically, Fibracor has three syllables (FI-BRI-COR), and Tricor has two syllables (TRI-COR).</p>
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Melina Griffis  
5/7/2009 10:17:29 AM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
5/7/2009 11:48:15 AM  
DRUG SAFETY OFFICE REVIEWER