# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**22-210**

# PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services**

**Public Health Service**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Surveillance and Epidemiology**

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| Date: | July 30, 2009 |
| To: | Donna Griebel, MD, Director<br>Division of Gastroenterology Products |
| Through: | Todd Bridges, RPh, Team Leader<br>Denise P. Toyer, PharmD, Deputy Director<br>Carol Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Deveonne Hamilton-Stokes, RN, BSN, Safety Evaluator<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Zenpep (Pancreliapase) Delayed-Release Capsules, USP<br>5000 USP units, 10,000 USP units, 15,000 USP units,<br>20,000 USP units |
| Application Type/Number: | NDA 22-210 |
| Applicant: | Eurand |
| OSE RCM #: | 2009-1186 |

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## EXECUTIVE SUMMARY

This re-assessment of the proprietary name is written in response to a notification that NDA 22-210 may be approved within 90 days. DMEPA found the proposed proprietary name, Zenpep, acceptable in OSE Review #2009-179, dated March 4, 2009. Since that review, none of Zenpep's product characteristics have changed. During this re-review we identified one new name (Zipsor) for its similarity to Zenpep. The results of the Failure Mode Effects Analysis (FMEA) found that the proposed name, Zenpep, is not vulnerable to name confusion that could lead to medication errors with Zipsor. Thus, the Division of Medication Error Prevention and Analysis does not object to the use of the proprietary name, Zenpep, for this product. Additionally, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on February 12, 2009.

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 Gastroenterology products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

## 1 METHODS AND MATERIALS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We use the same search criteria that were used in OSE Review# 2009-179 for the proposed proprietary name, Zenpep. DMEPA bases the overall risk assessment on the findings of a Failure Mode Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

## 2 RESULTS

### 2.1 DATABASES

The searches of the databases referenced in Section 4 yielded one new name (Zipsor) which was thought to have some look-alike similarity to the name, Zenpep.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 21, 2009.

### 2.2 SAFETY EVALUATOR RISK ASSESSMENT

The name Zipsor was evaluated for its potential similarity to Zenpep. The FMEA indicates that the proposed name, Zenpep, is not likely to result in name confusion with Zipsor that could lead to medication errors (see Appendix A).

Additionally, 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 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Zenpep, 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, Zenpep, for this product at this time.

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 Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

## 4 REFERENCES


1. OSE review # 2009-179 Proprietary Name Review of Zenpep; Hamilton-Stokes, Deveonne

***2. 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.

***3. 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.

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

USAN Stems List contains all the recognized USAN stems.


**Appendix A:** Product with no numerical overlap in strength or dose

| Product name with potential for confusion | Similarity to Proposed Proprietary Name | Strength | Usual Dose (if applicable) |
|---|---|---|---|
| **Zenpep (Pancreliapse) Delayed-Release Capsules** | **N/A** | **5,000 USP units, 10,000 USP units, 15,000 USP units, 20,000 USP units** | **Individualized dosing based on weight; 1,000 lipase units/kg/meal** |
| Zipsor (Diclofenac potassium) Capsules | Look | 25 mg | 25 mg four times daily |

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/s/

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