

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

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**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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Division of Medication Error Prevention and Analysis (DMEPA)  
Subject: Proprietary Name Review  
Drug Name(s): Incivek (Telaprevir) Tablets, 375 mg  
Applicant/sponsor: Vertex Pharmaceuticals  
OSE RCM #: 2011-705

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

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## **EXECUTIVE SUMMARY**

This review summarizes the Division of Medication Error Prevention and Analysis' evaluation for the proposed proprietary name Incivek for Telaprevir Tablets. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Incivek, acceptable for this product. DMEPA will notify the Applicant of these findings via letter.

We consider this a final review of the proposed proprietary name, Incivek. However, if approval of this NDA is delayed 90 days beyond the date of this review, the proposed proprietary name, Incivek, must be re-reviewed. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

This review responds to a request from Vertex Pharmaceuticals dated March 4, 2011, for a promotional and safety assessment of the proposed proprietary name, Incivek.

### **1.2 PRODUCT INFORMATION**

Incivek (Telaprevir) is a Hepatitis C virus (HCV) protease inhibitor proposed, in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment naïve or who have been previously treated, including prior null responder, partial responders, and relapsers. The recommended dose is 750 mg (two 375 mg tablets) taken 3 times a day (7-9 hours apart) with food. Incivek must be administered with peginterferon alfa and ribavirin for all patients for 12 weeks, followed by a response-guided regimen of either 12 or 36 weeks of peginterferon alfa and ribavirin depending on viral response and prior response status. The product will be marketed in 28-day packer containing 4 weekly cartons of 7 blister strips each (6 tablets per blister strip) and in 28-day hospital unit-dose bottles containing 168 tablets.

## **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 proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Incivek.

### **2.1 SEARCH CRITERIA**

For this review, particular consideration was given to drug names beginning with the letter 'I' 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>1,2</sup>

To identify drug names that may look similar to Incivek, the DMEPA safety evaluators also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (two, capital letter ‘I’ and lower case ‘k’), down strokes (none), cross strokes (none), and dotted (one, lower case, ‘i’). Additionally, several letters in Incivek may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA safety evaluator also considers these alternate appearances when identifying drug names that may look similar to Incivek.

When searching to identify potential names that may sound similar to Incivek, the safety evaluators search for names with similar number of syllables (three), stresses (IN-ci-vek, in-CI-vek, and in-ci-VEK), and placement of vowel and consonant sounds (See Appendix B). The Applicant’s intended pronunciation (in-SEE-veck) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## **2.2 PRESCRIPTION ANALYSIS STUDIES**

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies. (See Appendix C for samples and results)

## **3 RESULTS**

The following sections describe the findings from our database searches, expert panel discussion, prescription analysis studies, and safety evaluator risk assessment.

### **3.1 DATA BASE AND INFORMATION SOURCES**

The DMEPA safety evaluators searches yielded a total of 17 names as having some similarity to the name Incivek.

Fifteen of the names were thought to look like Incivek. These include: Kinevac, Endocet, Tenivac, Lavacol, (b) (4), Imovax, Inomax, Iprivask, Mavik, Incendo, Infuvite, Sinarest, Luvox, Imitrex, and Trezix. One of the names, Anzemet, was thought to sound like Incivek. The remaining name, Increlex, was thought to look and sound similar to Incivek.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of March 22, 2011.

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<sup>1</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>2</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

## **3.2 EXPERT PANEL DISCUSSION**

The Expert Panel 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 Incivek.

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 PRESCRIPTION ANALYSIS STUDIES**

A total of 41 practitioners responded to the study with no responses overlapping with an existing name. Nineteen of the participants interpreted the name correctly as “Incivek,” with correct interpretation occurring in all studies. The remainder of the written responses misinterpreted the drug name. In the verbal studies, seven of the responses were correct, while the remaining responses were misspelled phonetic variations of the proposed name, Incivek. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

## **3.4 COMMENTS FROM THE DIVISION OF ANTI-VIRAL PRODUCTS (DAVP)**

### ***3.4.1 Initial Phase of Review***

In response to the OSE March 29, 2011 e-mail, the Division of Anti-Viral Products provided no concerns with the proposed proprietary name, Incivek.

### ***3.4.2 Midpoint of Review***

DMEPA notified the Division of Anti-Viral Products via e-mail on March 31, 2011, that we found the proposed name, Incivek, acceptable. Per e-mail correspondence from DAVP on April 19, 2011, they indicated ‘no objection’ to our assessment.

## **3.5 SAFETY EVALUATOR RISK ASSESSMENT**

Independent searches by the primary Safety Evaluator resulted in one additional name, Oncovin, which was thought to look similar to Incivek.

Thus, we evaluated a total of 18 names: 17 names identified in section 3.1 above and 1 name identified by the primary Safety Evaluator

## **4 DISCUSSION**

This proposed name, Incivek, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

### **4.1 PROMOTIONAL ASSESSMENT**

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Anti-Viral Products concurred with the findings of DDMAC’s promotional assessment of the proposed name.

## **4.2 SAFETY ASSESSMENT**

DMEPA evaluated 18 names for their potential similarity to the proposed name, Incivek. We did not identify any other aspects of the name that would be considered as a potential source for error.

Four of the 18 potentially similar names did not undergo failure mode and effect analysis (FMEA) for the following reasons: names lacking significant orthographic similarity and products not commercially marketed (see Appendices D and E).

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the 14 remaining names and lead to medication errors. This analysis determined that the name similarity between Incivek and all of the identified names was unlikely to result in medication error for the reasons presented in Appendix F.

## **5 CONCLUSIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Incivek, is not vulnerable to name confusion that could lead to medication errors, nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Incivek, for this product at this time. DMEPA will notify the Applicant of this determination via letter.

We consider this a final review of the proposed proprietary name, Incivek. However, if the action on this NDA is delayed 90 days beyond the date of this review, the proposed proprietary name, Incivek, must be re-reviewed.

If you have further questions or need clarifications, please contact Brantley Dorch, project manager, at 301-796-0150.

### **5.1 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name, Incivek, and have concluded that the name is acceptable.

The proposed proprietary name, Incivek, 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.

If any of the proposed product characteristics as stated in your March 4, 2011 submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

## 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. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the 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/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)**

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>3</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. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate 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. 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>4</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 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>5</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

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

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

<sup>5</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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 Sponsor’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor 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.

<b>Type of similarity</b>	<b>Considerations when searching the databases</b>		
	<i>Potential causes of drug name similarity</i>	<i>Attributes examined to identify similar drug names</i>	<i>Potential Effects</i>
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. 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 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify 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/or outpatient prescriptions are 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 the 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.

#### **4. Comments from the OND review Division or Generic drugs**

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

#### **5. 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>6</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

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

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:

***“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 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. In that instance, DMEPA may be able to provide the Sponsor 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 Sponsor. 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), the Joint Commission, 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 Sponsor 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. Sponsors have undertaken higher-leverage strategies, such as drug name changes, 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 Sponsors' 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).

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 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. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

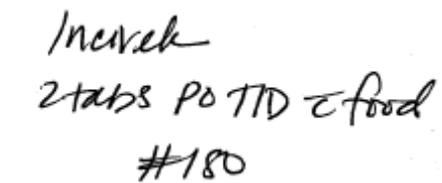
In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has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

**Appendix B:** Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Incivek	Scripted may appear as	Spoken may be interpreted as
Capital 'I'	'l', 'e',	any vowel
lower case 'n'	'm', 'r', 'ri', 'v'	m
lower case 'c'	'a', 'e', 'o',	'k', 's'
lower case 'i'	'l', 'e', 'u'	any vowel
lower case 'v'	'n', 'r', 'u', 'w', 'x'	'b'
lower case 'e'	any vowel, 'l'	any vowel
lower case 'k'	'r', 'x'	'c', or 'x'

**Appendix C:** Prescription study samples and results

**Figure 1. Incivek Study (conducted on 03/04/2011)**

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p>Medication Order:</p> 	<p>Incivek 375 mg Take 2 tablets by mouth three times a day with food</p>
<p>Outpatient prescription:</p> 	

**FDA Prescription Study Responses.**

86 People Received Study

41 People Responded

Study Name: Incivek

<b>INPATIENT</b>	<b>VOICE</b>	<b>OUTPATIENT</b>
Incirek (2)	Ensevex (1)	Incivek (7)
Incivek (11)	Ensivec (1)	Inciveb (10)
	Inceasac (1)	
	ensevec (1)	
	Incevect (1)	
	Incevec (2)	
	Encivex (1)	
	Inceetac (1)	
	incivek (1)	
	Encivec (1)	

**Appendix D:** Proprietary names lacking significant orthographic and/or phonetic similarity to Incivek

<b>Proprietary Name</b>	<b>Similarity To Incivek</b>
Anzemet (dolasetron)	Sound
Sinarest (acetaminophen, chlorpheniramine, pseudoephedrine)	Look

**Appendix E:** Proprietary names with orthographic similarities to Incivek which will not lead to medication errors for reasons stated below

Proprietary Name	Similarity to Incivek	Marketing Status
(b) (4)	Look	(b) (4)
Incendo (Eucalyptol, benzocaine, picric acid, tannic acid, zinc oxide)	Look	Name found in Micromedex but no additional information found in any other drug reference, including Red Book. No information available about manufacturer.

**Appendix F:** Risk of name confusion minimized by preventions listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
<b>Incivek (telaprevir)</b>		<b>375 mg tablets</b>	<b>Take 2 tablets by mouth three times a day with food</b>	
Kinevac (Sincalide) <i>Orthographic similarities: Both names contain 7 letters with the overlapping letters, 'n', 'c', 'i', 'k', 'v', and 'e', and appear similar in length when scripted.</i>	Look	5 mcg/vial powder for injection	0.02 mcg/kg intravenously over 30 to 60 seconds x1, if repeat, use 0.04 mcg/kg	<b>Orthographic differences:</b> Incivek contains two upstroke letters, 'I' and 'k', compared to only one upstroke letter, 'k' in Kinevac. In addition, the letters shared by the two names appear in a different sequence and may help differentiate the names when scripted. <b>Dosage Form:</b> Tablet vs powder for injection <b>Route of Administration:</b> Oral vs intravenous <b>Frequency of Administration:</b> Three times a day vs one time <b>Dose:</b> 2 tablets vs X mcg
Iprivask (desirudin) <i>Orthographic similarities: Both names begin with the letter, 'I' and end in the letter 'k' with both also containing the letters 'i' and, 'v'.</i>	Look	15 mg injection	Inject 15 mg subcutaneously every 12 hours up to 15 days	<b>Orthographic differences:</b> Iprivask contains the downstroke letter 'p' which give it a different shape than Incivek and may help differentiate the names when scripted. <b>Dosage Form:</b> Tablet vs injectable <b>Route of Administration:</b> Oral vs subcutaneous

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
<b>Incivek (telaprevir)</b>		<b>375 mg tablets</b>	<b>Take 2 tablets by mouth three times a day with food</b>	
				<b>Frequency of Administration:</b> Three times a day vs every 12 hours for up to 15 days
Endocet (Oxycodone and Acetaminophen)  <u>Orthographic similarities:</u>  <i>Both names contain 7 letters and appear similar in length when scripted. The beginning letter, 'I' in Incivek may look like the beginning letter, 'E' in Endocet, and both names end in an upstroke letter ('k' vs 't'). They also share the letters 'e', 'c', and 'n'.</i>	Look	5 mg/325 mg; 7.5 mg/325 mg; 10 mg/ 325 mg tablets	Take one to two tablets by mouth every 4 to 6 hours as needed for pain.	<b>Orthographic Differences:</b> Incivek contains two upstroke letters, 'I' and 'k', compared to three upstroke letters in Endocet, 'E', 'd', and 't'. In addition, the ending portion, 'ivek' in Incivek, looks different from the ending letters, 'ocet' in Endocet when scripted.  <b>Strength:</b> Single (375 mg) vs Multiple (5 mg/325 mg; 7.5 mg/325 mg; and 10 mg/325 mg)  <b>Frequency of Administration:</b> Three times a day vs every 4 to 6 hours as needed
Tenivac (tetanus/diphtheria toxoid adsorbed)  <u>Orthographic similarities:</u>  <i>Both names contain seven letters and appear similar in length when scripted. They share the letters, 'n', 'c', 'e', 'v', and 'i', with the letters, 'iv' in similar positions in both names.</i>	Look	NA	Inject 0.5 mL intramuscularly now, repeat in 2 months, then repeat 6 to 8 months after second dose. Single 0.5 mL booster injections every 10 years.	<b>Orthographic differences:</b> Incivek has two upstroke letters, 'I' and 'k', compared to one upstroke letter, 'T' in Tenivac.  <b>Dosage Form:</b> Tablet vs injection  <b>Route of Administration:</b> Oral vs intramuscular  <b>Frequency of Administration:</b> Three times a day vs one dose followed by a second dose in 2 months which is followed by a third dose 6 to 8 months later.
Lavacol (Ethyl Alcohol)  <u>Orthographic similarities:</u>  <i>Both names contain seven letters and appear similar in length when scripted. The beginning letter, 'I' in Incivek may look similar to the beginning letter, 'L' in Lavacol when scripted</i>	Look	70% solution	Apply topically as needed	<b>Orthographic differences:</b> The letter string, 'nci' in Incivek look different than the corresponding letter string, 'ava' in Lavacol.  <b>Dosage Form:</b> Tablet vs solution  <b>Route of Administration:</b> Oral vs topical  <b>Frequency of Administration:</b> Three times a day vs as needed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
<b>Incivek (telaprevir)</b>		<b>375 mg tablets</b>	<b>Take 2 tablets by mouth three times a day with food</b>	
<i>and both names end in upstroke letters, (k vs l). They also share the letters, 'c' and 'v'.</i>				<b>Unit of measure:</b> mg vs % <b>Dose:</b> 2 tablets or 750 mg vs X mL or small amount
Imovax (Rabies Virus Vaccine)  <u>Orthographic similarities:</u> <i>Both names begin with the letter 'I' and share the letter 'v'. They are also similar in length when scripted.</i>	Look	2.5 units/mL	<u>Booster:</u> Inject 1 mL intramuscularly into the deltoid muscle  <u>Post Exposure:</u>  Inject 1 mL intramuscularly on days 0, 3, 7, 14, 30, and 90.	<b>Orthographic differences:</b> Incivek ends in the upstroke letter, 'k' and the letter string, 'civ' in Incivek looks different than the corresponding letter string, 'ova' in Imovax, which may help differentiate the names when scripted.  <b>Dosage Form:</b> Tablet vs injectable  <b>Route of Administration:</b> Oral vs intramuscular  <b>Frequency of Administration:</b> Three times a day vs once on scheduled days over a 3 month period.  <b>Units of measure:</b> mg vs units/mL
Inomax (Nitric Oxide)  <u>Orthographic similarities:</u> <i>Both names begin with the letters, 'In' and share the letter 'v'. They are also similar in length when scripted.</i>	Look	100 ppm inhalation solution	Administered using equipment that provides operator-determined concentrations of nitric oxide in breathing gas continuously for anesthesia during medical procedures.	<b>Orthographic differences:</b> Incivek contains two upstroke letters which may help differentiate it from Inomax which only has one upstroke letter when scripted. Additionally, the ending letter string, 'vek' in Incivek looks different from the ending letter string, 'max' in Inomax when scripted.  <b>Dosage form:</b> Tablet vs inhalation solution  <b>Frequency of Administration:</b> Three times a day vs one time during procedure  <b>Units of measure:</b> mg vs ppm
Mavik (trandolapril)  <u>Orthographic similarities:</u> <i>The beginning letters, 'In' in Incivek may look like</i>	Look	1 mg, 2 mg, and 4 mg tablets	Take 2 mg or 4 mg by mouth once a day	<b>Orthographic differences:</b> Incivek contains 7 letters and appears longer when scripted compared to the 5 letters in Mavik.  <b>Strength:</b> Single (375 mg ) vs

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
<b>Incivek (telaprevir)</b>		<b>375 mg tablets</b>	<b>Take 2 tablets by mouth three times a day with food</b>	
<i>the beginning letter, 'M' in Mavik when scripted. Both names end in the letter, 'k' and the ending letters, 'vek' in Incivek look similar to the ending letters, 'vik' in Mavik.</i>				Multiple (1 mg, 2 mg, and 4 mg) <b>Frequency of Administration:</b> Three times a day vs once a day
Infuvite (ascorbic acid, vitamin A, Vitamin D3, Thiamine, riboflavin, pyridoxine, niacinamide, dextranthenol, vitamin E, vitamin K)  <u>Orthographic similarities:</u> <i>Both names begin with the letters, 'In' and appear similar in length when scripted (7 letters vs 8 letters). They also have the overlapping letters, 'i', 'v', and 'e'. Additionally, the ending letter 'k' in Incivek may look similar to the ending letters, 'te' in Infuvite when scripted.</i>	Look	200 mg/ 3,300 IU,/200 IU/ 6 mg/ 3.6 mg/6 mg/ 40 mg/15 mg/ 10 IU/150 mcg injection	Used as an admixture for intravenous infusion for once a day administration	<b>Orthographic differences:</b> Incivek contains two upstroke letters, 'I' and 'k', compared to three upstroke letters, 'I' 'f', and 't', in Infuvite. The letter 'f' in Infuvite may also provide a downstroke letter depending on how it is scripted which may also help differentiate the names.  <b>Dosage form:</b> Tablet vs injection <b>Route of Administration:</b> Oral vs intravenous <b>Frequency of Administration:</b> Three times a day vs once a day <b>Dose:</b> 750 mg or 2 tablets vs X mL
Luvox (fluvoxamine)  <u>Orthographic similarities:</u> <i>Both names contain the letter, 'v' and the beginning letter, 'I' in Incivek may look similar to the beginning letter, 'L' in Luvox.</i>	Look	25 mg, 50 mg, 100 mg tablets	<u>Daily doses greater than 100 mg:</u> Take one tablet by mouth twice a day	<b>Orthographic differences:</b> Incivek contains seven letters and appears longer when scripted compared to the five letters in Luvox. Incivek has two upstroke letters compared to one upstroke letter for Luvox.  <b>Strength:</b> Single (375 mg) vs multiple (25 mg, 50 mg and 100 mg) <b>Frequency of Administration:</b> Three times a day vs twice a day
Imitrex (sumatriptan)  <u>Orthographic similarities:</u> <i>Both names begin with the letter, 'I' and contain</i>	Look	25 mg, 50 mg, 100 mg tablets;  4 mg/0.5 mL and 6 mg/0.5mL	<u>Oral Tablets:</u> One tablet by mouth. May repeat dose in 2 hours if no relief	<b>Orthographic differences:</b> Incivek ends in an upstroke letter, 'k', which Imitrex does not have and Imitrex has the cross-stroke letter, 't' in the middle of the name which is not present in

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
<b>Incivek (telaprevir)</b>		<b>375 mg tablets</b>	<b>Take 2 tablets by mouth three times a day with food</b>	
<i>seven letters making them appear similar in length when scripted. They also share the letters, 'i' and 'e' in a similar sequence.</i>		injection; 5 mg/0.1 mL, 20 mg/0.1 mL nasal solution	is obtained. <u>Intranasal:</u> A single dose of 5 mg, 10 mg or 20 mg administered in one nostril. Dose may be repeated in 2 hours if no relief.	Incivek. These differences may help to distinguish these names when scripted. <b>Strength:</b> Single strength (375 mg) vs multiple strengths (25 mg, 50 mg, 100 mg) <b>Frequency of Administration:</b> Three times a day vs one dose (may repeat in 2 hours if no relief)
Trezix (acetaminophen, caffeine, dihydrocodeine) <u>Orthographic similarities:</u> <i>The beginning letter, 'I' in Incivek may appear similar to the beginning letter, 'T' in Trezix when scripted.</i>	Look	356.4 mg/30 mg/ 16 mg capsule  712.8 mg/60 mg/ 32 mg tablet	<u>Capsules:</u> Take 2 capsules by mouth every 4 hours as needed.  <u>Tablets:</u> Take one tablet by mouth every 4 hours as needed.	<b>Orthographic differences:</b> Incivek has an upstroke letter, 'k' at the end which Trezix does not have and the letters, 'nci' in Incivek look different from the corresponding letters, 'rez' in Trezix. <b>Strength:</b> Single (375 mg) vs multiple (356.4 mg/30 mg/16 mg and 712.8 mg/60 mg/32 mg) <b>Frequency of Administration:</b> Three times a day vs every 4 hours as needed.
Increlex (mecasermin) <u>Orthographic similarities:</u> <i>Both names begin with the letters, 'Inc' and appear similar in length when scripted (7 letters vs 8 letters).</i>	Look and Sound	40 mg/4 mL (10 mg/mL) injection	40 mcg to 80 mcg/kg subcutaneously twice a day	<b>Orthographic differences:</b> Incivek ends in the upstroke letter, 'k', compared to Increlex which has its second upstroke letter, 'l' in the middle of the name. <b>Dosage form:</b> Tablet vs injection <b>Route of Administration:</b> Oral vs subcutaneous <b>Frequency of Administration:</b> Three times a day vs twice a day
Oncovin (vincristine) <u>Orthographic similarities:</u> <i>Both names contain seven letters and appear similar in length when scripted. They share the letters, 'n', 'c', 'v' and 'i'.</i>	Look	1 mg/mL and 2 mg/2 mL injection	<u>Acute lymphocytic leukemia:</u> 1.4 mg/m <sup>2</sup> intravenously once a week for 4 weeks  <u>Malignant</u>	<b>Orthographic differences:</b> Incivek contains two upstroke letters, 'I' and 'k' compared to one upstroke letter, 'O' in Oncovin. <b>Dosage Form:</b> Tablet vs injection <b>Route of Administration:</b> Oral vs intravenously <b>Frequency of Administration:</b> Three

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
Incivek (telaprevir)		375 mg tablets	Take 2 tablets by mouth three times a day with food	
			<p><b><u>glioma:</u></b> 1.4 mg/m<sup>2</sup> intravenously on days 1 and 8 every 28 days in combination with mechlorethamine and procarbazine.</p> <p><b><u>Neuroblastoma:</u></b> 1 mg/m<sup>2</sup>/day intravenously as a continuous infusion for 72 hours</p> <p><b><u>Breast cancer:</u></b> 1 mg/m<sup>2</sup> intravenously every 28 days or 0.625 mg/m<sup>2</sup> in combination with cyclophosphamide, methotrexate, fluorouracil and prednisone.</p> <p><b><u>Colorectal cancer:</u></b> 1 mg/m<sup>2</sup> every 35 days in combination with fluorouracil and methyl CCNU.</p> <p><b><u>Gestational trophoblastic disease:</u></b> 1 mg/m<sup>2</sup> on day 8 in combination with etoposide, methotrexate, leucovorin, actinomycin D, and cyclophosphamide repeated every 2 to 3</p>	<p>times a day vs infusion on specified days (depending on indication).</p> <p><b>Marketing Status:</b> Oncovin is a discontinued product with generic therapeutic equivalents available</p>

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
Incivek (telaprevir)		375 mg tablets	Take 2 tablets by mouth three times a day with food	
			<p>weeks.</p> <p><b><u>Hodgkin's disease:</u></b></p> <p>1.4 mg/m<sup>2</sup> intravenously on days 1 and 8 every 28 days combined with mechlorethamine, prednisone, and procarbazine.</p> <p><b><u>Idiopathic thrombocytopenic purpura:</u></b></p> <p>2 mg intravenously once a month.</p> <p><b><u>Small cell lung cancer:</u></b></p> <p>2 mg intravenously every 21 days in combination with cyclophosphamide, doxorubicin, or etoposide.</p> <p><b><u>Multiple myeloma:</u></b></p> <p>0.4 mg/day intravenously for 4 days with dexamethasone and doxorubicin.</p> <p><b><u>non-Hodgkin's lymphoma:</u></b> 1 mg to 1.4 mg/m<sup>2</sup> every 21 to 28 days.</p>	

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
Incivek (telaprevir)		375 mg tablets	Take 2 tablets by mouth three times a day with food	
			<p><b><u>Osteogenic sarcoma:</u></b> 1.4 mg/m<sup>2</sup> intravenously once a week for 6 weeks, then once every 21 to 28 days in combination with cyclophosphamide, dacarbazine and doxorubicin.</p> <p><b><u>Metastatic osteogenic sarcoma:</u></b> 0.75 mg to 2 mg/m<sup>2</sup> intravenously every 1 to 2 weeks.</p> <p><b><u>Rhabdomyosarcoma:</u></b> 1.4 mg/m<sup>2</sup> intravenously on days 1 and 5 every 21 to 28 days in combination with cyclophosphamide, dacarbazine and doxorubicin; or 1.5 mg/m<sup>2</sup> every 21 to 28 days in combination with doxorubicin and cyclophosphamide.</p>	

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of product characteristics as well as orthographic and/or phonetic differences as described.
Incivek (telaprevir)		375 mg tablets	Take 2 tablets by mouth three times a day with food	
			<p><b><u>Head and Neck:</u></b> 1 mg intravenously on days 2 and 5 every 21 days in combination with cisplatin and bleomycin.</p> <p><b><u>Wilm's tumor:</u></b> 1.5 mg/m<sup>2</sup> intravenously once a week on weeks 2 through 11, 14 through 19, 23 through 28, 32 through 37, 41 through 46, 50 through 55, and 59 through 64.</p> <p><b><u>Thymic carcinoma:</u></b> 0.6 mg/m<sup>2</sup> intravenously on day 3 with doxorubicin, cisplatin, and cyclophosphamide.</p>	

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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04/29/2011

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